MONSANTO

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November 17, 2006

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ATTN: 8(d) Health and Safety Reporting Rule (Notification/Reporting)

Re: Docket ID number EPA-HQ-OPPT-2005-0055

Dear Sir:

Monsanto Company submits the enclosed health and safety data and unpublished study reports to respond to the final rule issued pertaining to four (4) pesticide intermediates listed as voluntary HPV Challenge Program orphan (unsponsored) chemicals.

Each of the four chemicals is, or previously had been, used solely on-site as a reactant to prepare a pesticide product, which is a FIFRA-regulated activity and for which extensive testing and reporting of health and safety data has been completed in order to maintain the pesticide registration.

Study summaries are included with most of the study reports. In total, 23 study reports are being submitted. The study numbers and study titles pertaining to each chemical used as a test substance are listed below.

The CAS Numbers of the four (4) intermediates listed by this rule and for which Monsanto is submitting study information are as follows:

142-73-4 – Glycine, N-(carboxymethyl)-
Common Name: Iminodiacetic Acid (IDA)
This intermediate is no longer a part of the process, is no longer produced, is not being reported for the current TSCA IUR (2006), and was not reported for the past two cycles of TSCA IUR reporting (2002 and 1998). IDA is essentially the same chemical as CAS Number 928-72-3, only in the form as the free acid. Therefore, studies for both of these CAS Numbers are being considered and listed together.

300276

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928-72-3 – Glycine, N-(carboxymethyl)-, disodium salt
Common Name: Disodium Iminodiacetic Acid (DSIDA)
This intermediate is used solely and entirely on-site for a non-TSCA use. DSIDA is essentially the same chemical as CAS Number 142-73-4, only in the form of the disodium salt. Therefore, studies for both of these CAS Numbers are being considered and listed together.

35203-06-6 – Benzenamine, 2-ethyl-6-methyl-N-methylene-
Common Name: 2-Ethyl-6-Methylphenyl Azomethine (EMAZO)
This intermediate is used solely and entirely on-site for a non-TSCA use. EMAZO is essentially the same chemical as CAS Number 35203-08-8, except that a methyl group replaces an ethyl group on the substituted benzene ring structure. Therefore, studies for both of these CAS Numbers are being considered and listed together.

35203-08-8 – Benzenamine, 2,6-diethyl-N-methylene-
Common Name: 2,6-Diethylphenyl Azomethine (AZO)
This intermediate is used solely and entirely on-site for a non-TSCA use. AZO is essentially the same chemical as CAS Number 35203-06-6, except that an ethyl group replaces a methyl group on the substituted benzene ring structure. Therefore, studies for both of these CAS Numbers are being considered and listed together.

If there are questions about this report, I can be readily contacted by phone [(314) 694-1538] or by Email (clyde.l.livingston@monsanto.com).

Sincerely,

Clyde L. Livingston

Clyde L. Livingston, Ph.D.
Chemical Regulatory Compliance

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List of 10 studies included for CAS Numbers 142-73-4 and 928-72-3.

Study Number	**Study Title or Description**
YO-83-012	Acute Oral Toxicity (Albino Rats), Acute Dermal Toxicity (Albino Rabbits), Acute Eye Irritation (Albino Rabbits), Primary Skin Irritation (Albino Rabbits) with Azomethine (AZO)
ML-83-180	Thirteen-Week Inhalation Toxicity Study of Azomethine (AZO) in Sprague-Dawley Rats
IR-84-040	2,6-Diethylphenylazomethine (AZO): Teratology Study in Rats
AB-84-386	Acute Toxicity of Azomethine (AZO) to Daphnia magna
AB-84-387	Acute Toxicity of Azomethine (2,6-diethylphenyl) (AZO) to Bluegill Sunfish
AB-84-388	Acute Toxicity of Azomethine (2,6-diethylphenyl) (AZO) to Rainbow Trout (Salmo gairdneri)
BD-85-119	Closed-Patch Repeated Insult Dermal Sensitization Study in Guinea Pigs with Diethylphenyl Azomethine (AZO)
SR-85-150	Evaluation of the Potential of Diethylphenyl Azomethine (AZO) to Induce Unscheduled DNA Synthesis in Primary Rat Hepatocyte Cultures
ML-86-360	Fertility and Reproduction Inhalation Studies with 2,6-Diethylphenyl Azomethine (AZO) in Sprague-Dawley Rats
ML-87-104	Acute Inhalation Study of Ethylmethyl Azomethine (EMAZO)

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List of 13 studies included for CAS Numbers 142-73-4 and 928-72-3.

Study Number	Study Title or Description
YO-72-053	Acute Oral (Rats), Acute Dermal (Rabbits), Skin Irritation (Rabbits), Eye Irritation (Rabbits) with Iminodiacetic Acid (IDA)
DA-79-186	Salmonella Mutagenicity Assay of CP#45474-3 (Note: The test material is a code number for Iminodiacetic Acid (IDA)
IR-82-194	Thirteen Week Subchronic Inhalation Toxicity Study on Iminodiacetic Acid (IDA) in Rats
ML-82-286	A Range Finding Study of Iminodiacetic Acid (IDA) Administered by Gavage to Pregnant Rats
IR-83-296	Iminodiacetic Acid (IDA): Teratology Study in Rats
AB-84-392	Acute Toxicity of Iminodiacetic Acid (IDA) to Daphnia magna
AB-84-393	Acute Toxicity of Iminodiacetic Acid (IDA) to Bluegill Sunfish (Lepomis macrochirus)
AB-84-394	Acute Toxicity of Iminodiacetic Acid (IDA) to Rainbow Trout (Salmo gairdneri)
ML-85-012	One Generation Reproduction Study of Iminodiacetic Acid (IDA) in the Diet of Albino Rats
BD-85-013	Iminodiacetic Acid (IDA): A Closed-Patch Repeated Insult Dermal Sensitization Study in Guinea Pigs (Buehler Method)
YO-85-073	Disodium Iminodiacetic Acid (DSIDA): Acute Oral Toxicity (Albino Rats), Acute Dermal Toxicity (Albino Rabbits), Primary Eye Irritation (Albino Rabbits), Primary Skin Irritation (Albino Rabbits)
SR-85-158	Evaluation of the Potential of Iminodiacetic Acid (IDA) to Induce Unscheduled DNA Synthesis in Primary Rat Hepatocyte Cultures
ML-85-253	One Month Dermal Study of Iminodiacetic Acid (IDA) in Albino Rats

YOUNGER LABORATORIES
INCORPORATED

123 CLIFF CAVE ROAD
SAINT LOUIS, MO., 63129

PHONE: (314) 487-6661

Retype Date:
September 12th, 1983

NONCLINICAL LABORATORY STUDY
FINAL REPORT — AMENDED *

TEST MATERIAL: AZOMETHINE
Lot: 5/11/83

PROJECT NUMBER/DATE: YO-83-012 (5/11/83)

STUDY CONDUCTED FOR: MONSANTO COMPANY
800 North Lindbergh Boulevard
St. Louis, Missouri 63167

TOXICITY DATA –

Study Phase	Protocol Number
1) Acute Oral Toxicity (Albino Rats)	A.1.1 (1/28/80)
2) Acute Dermal Toxicity (Albino Rabbits)	B.1.5 (2/08/83)
3) Acute Eye Irritation (Albino Rabbits)	C.1.2 (2/08/83)
4) Primary Skin Irritation (Albino Rabbits)	D.1.3 (2/08/83)

* Request of Sponsor 7/1/83: Primary Irritation Score not reported.

DATE STUDY INITIATED: May 12th, 1983

DATE STUDY COMPLETED: June 28th, 1983

SUBMITTED BY: YOUNGER LABORATORIES, INC.

Michael J. Evans, Study Director

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ACUTE ORAL TOXICITY

Species: Sprague-Dawley Albino Rats

SEX	LD_{50} (Mg / Kg)	95% Confidence Limits (Mg / Kg)	Slope
Males/Females	1,470	1,320 - 1,650	8.4
Males	1,340	1,130 - 1,580	8.1
Females	1,660	1,440 - 1,910	8.4

DOSAGE CONDITIONS: Single Oral Dose -- Undiluted

DATA FOR MALES

Level	Dosage (Mg / Kg)	Average Weight (Gm) Initial (Fasted)	Survivors (Day 7)	Sacrifice (Day 14)	Mortalities / Dosed	Time of Mortality
1	794	210	290	365	0/5	
2	1,000	210	295	370	1/5	1 Day
3	1,260	205	265	335	0/5	
4	1,580	200	---	---	5/5	4 Hrs. - 2 Days
5	2,000	200	295	380	4/5	4 Hrs. - 2 Days
6	2,510	205	---	---	5/5	4 Hrs. - 2 Days

OBSERVATIONS –

Toxic Signs: Lethargy (lasting up to two days), increasing weakness, ocular discharge, collapse, and death.

Gross Necropsy:

Decedents: Hemorrhagic lungs, hemorrhagic liver (discolored in most instances), kidney discoloration (in one instance), spleen blackened (in one instance), and acute gastrointestinal inflammation.

Survivors (14 Days): Viscera appeared normal.

DATA FOR FEMALES

Level	Dosage (Mg / Kg)	Average Weight (Gm) Initial (Fasted)	Survivors (Day 7)	Sacrifice (Day 14)	Mortalities / Dosed	Time of Mortality
1	794	200	260	295	0/5	
2	1,000	205	255	300	1/5	3 Days
3	1,260	205	250	295	0/5	
4	1,580	195	240	280	2/5	5 Hrs. - 1 Day
5	2,000	190	250	290	4/5	4 Hrs. - 2 Days
6	2,510	195	---	---	5/5	5 Hrs. - 3 Days

OBSERVATIONS –

Toxic Signs: Lethargy (lasting up to four days), increasing weakness, ocular discharge, collapse, and death.

Gross Necropsy:

Decedents: Hemorrhagic lungs, hemorrhagic liver (discolored in most instances), kidney discoloration (in some instances), spleen blackened (in one instance), and acute gastrointestinal inflammation.

Survivors (14 Days): Viscera appeared normal.

ACUTE DERMAL TOXICITY

Species: **New Zealand Albino Rabbits**

SEX	LD_{50} (Mg / Kg)	95% Confidence Limits (Mg / Kg)	Slope
Males/Females.....	1,400	1,120 - 1,760	5.8
Males	1,410	1,130 - 1,760	8.4
Females	1,410	1,130 - 1,760	8.4

Exposure: **24-Hours**

DOSAGE CONDITIONS: **Single Dermal Application -- Undiluted**

DATA FOR MALES

Level	Dosage (Mg / Kg)	Average Weight (Kg) Initial	Survivors (Day 7)	Sacrifice (Day 14)	Mortalities / Dosed Intact Skin	Abraded Skin	Time Of Mortality
1	794	2.0	2.1	2.3	0/2		
2	1,000	2.1	2.1	2.5	0/2		
3	1,260	2.2	2.0	2.1	1/2		2 Days
4	1,580	2.2	2.1	2.5	1/2		2 Days
5	2,000	2.2	---	---	2/2		2 Days
6							

OBSERVATIONS --

Toxic Signs: **Lethargy (lasting up to three days), increasing weakness, collapse, and death.**

Gross Necropsy:

Decedents: **Hemorrhagic areas of the lungs, discoloration of liver, kidneys, and spleen, enlarged gall bladder, and gastrointestinal inflammation.**

Survivors (**14** Days): **Viscera appeared normal.**

DATA FOR FEMALES

Level	Dosage (Mg / Kg)	Average Weight (Kg) Initial	Survivors (Day 7)	Sacrifice (Day 14)	Mortalities / Dosed Intact Skin	Abraded Skin	Time Of Mortality
1	794	2.1	2.2	2.4	0/2		
2	1,000	2.2	2.2	2.5	1/2		2 Days
3	1,260	2.2	2.1	2.4	0/2		
4	1,580	2.2	2.2	2.4	1/2		2 Days
5	2,000	2.1	---	---	2/2		2 Days
6							

OBSERVATIONS --

Toxic Signs: **Lethargy (lasting up to two days), increasing weakness, collapse, and death.**

Gross Necropsy:

Decedents. **Hemorrhagic areas of the lungs, discoloration of liver, kidneys, and spleen, enlarged gall bladder, and gastrointestinal inflammation.**

Survivors (**14** Days): **Viscera appeared normal.**

ACUTE EYE IRRITATION

IRRITATION SCORE: 56.8 *
(Ave: 24, 48, 72 Hr. Ave. Mean)
Maximum Score (Cornea + Iris + Conjunctivae) = 110

Species: New Zealand Albino Rabbits (Mixed Sex)

Exposure. 24-Hours

DOSE AND CONDITIONS: 0.1 Milliliter Instilled Undiluted

Time Following Instillation	Ocular Reactions	Readings / Scoring — Animal Number 1	2	3	4	5	6	Average Mean Score
1 Hour	CORNEA - Opacity . . .	0	0	0	0	0	0	
	- Area	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	
	IRIS	0	0	0	0	0	0	
	CONJUNCTIVAE - Redness . . .	3	3	3	3	3	3	
	- Chemosis . .	3	2	3	3	3	3	
	- Discharge . .	3	3	3	3	3	3	
	TOTAL SCORE	18	16	18	18	18	18	17.6
24 Hours	CORNEA - Opacity . . .	3	3	3	3	2	3	
	- Area	4(2)	3(1)	3(1)	3(1)	4(3)	4(1)	
	IRIS	2	2	2	2	2	2	
	CONJUNCTIVAE - Redness . . .	3	3	3	3	3	3	
	- Chemosis . .	4	3	4	4	4	3	
	- Discharge . .	3	3	3	3	3	3	
	TOTAL SCORE	90	73	75	75	70	88	78.5
48 Hours	CORNEA - Opacity . . .	2	2	2	2	2	2	
	- Area	3(1)	3(2)	2(1)	2(1)	3(1)	2(1)	
	IRIS	2	1	2	1	1	1	
	CONJUNCTIVAE - Redness . . .	3	3	3	3	3	3	
	- Chemosis . .	2	2	3	3	2	2	
	- Discharge . .	3	3	3	3	3	3	
	TOTAL SCORE	56	51	48	43	51	41	48.3
72 Hours	CORNEA - Opacity . . .	2	2	2	2	2	2	
	- Area	2(1)	3(1)	2(1)	2(1)	3(1)	2(1)	
	IRIS	1	1	1	1	1	1	
	CONJUNCTIVAE - Redness . . .	3	3	3	3	3	3	
	- Chemosis . .	2	1	2	2	2	1	
	- Discharge . .	3	3	3	3	3	3	
	TOTAL SCORE	41	49	41	41	51	39	43.6
168 Hours	CORNEA - Opacity . . .	0	0	0	0	0	0	
	- Area	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	
	IRIS	0	0	0	0	0	0	
	CONJUNCTIVAE - Redness . . .	0	0	0	0	0	0	
	- Chemosis . .	0	0	0	0	0	0	
	- Discharge . .	0	0	0	0	0	0	
	TOTAL SCORE	0	0	0	0	0	0	0.0

OBSERVATIONS / COMMENTS:

Immediate: Discomfort was severe with pawing, thrashing about the stocks, and eyes tightly closed
10 Min.: Moderate erythema, copious discharge
1 Hr.: Severe erythema, slight to moderate edema, copious discharge
24 Hr.: Areas of translucent to opalescent corneal cloudiness, iris showed no reaction to light;
Severe erythema, moderate to severe edema, copious discharge containing whitish exudate
48 - 72 Hr.: Gradual improvement
168 Hr.: All scored zero

* Scores for area of maximum density (recorded in the parentheses) are not included in the calculations.

PRIMARY SKIN IRRITATION

PRIMARY IRRITATION SCORE: NOT REPORTED * Species: New Zealand Albino Rabbits (Mixed Sex)
(Ave., 24, 72 Hour Mean)
Maximum Score (Erythema + Edema) = 8
Test Site: Intact Skin
Exposure: 4 - Hours

DOSE AND CONDITIONS: 0.5 Milliliter Applied Undiluted

Time Following Patch Removal	Skin Reaction	READINGS/SCORINGS Animal Number 1 F/R	2 F/R	3 F/R	4 F/R	5 F/R	6 F/R	Mean Score
		Patch Position						
1 Hour	Erythema . . .	4 4	4 4	4 4	4 4	4 4	4 4	
	Edema	4 4	4 4	4 4	4 4	4 4	4 4	8.0
24 Hours	Erythema . . .	4 4	4 4	4 4	4 4	4 4	4 4	
	Edema	4 4	4 4	4 4	4 4	4 4	4 4	8.0
48 Hours	Erythema . . .	4 4	4 4	4 4	4 4	4 4	4 4	
	Edema	4 4	4 4	4 4	4 4	4 4	4 4	8.0
72 Hours	Erythema . . .	4 4	4 4	4 4	4 4	4 4	4 4	
	Edema	4 4	4 4	4 4	4 4	4 4	4 4	8.0
168 Hours	Erythema . . .	0 0	0 0	0 0	0 0	0 0	0 0	
	Edema	0 0	0 0	0 0	0 0	0 0	0 0	0.0

OBSERVATIONS / COMMENTS:

Severe Defatting Effect -- Skin sloughed off in fourteen to twenty-one days. There was no injury in depth.

* Request of Sponsor 7/1/83

YOUNGER LABORATORIES
INCORPORATED

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SAINT LOUIS, MO., 63129
PHONE: (314) 487-6661

NONCLINICAL LABORATORY STUDY FINAL REPORT —

September 28th, 1983

TEST MATERIAL: AZOMETHINE
Lot: 5/11/83

PROJECT NUMBER/DATE: YO-83-012 (8/22/83)

STUDY CONDUCTED FOR: MONSANTO COMPANY
800 North Lindbergh Boulevard
St. Louis, Missouri 63167

TOXICITY DATA --

Study Phase	Protocol Number
1) Primary Skin Irritation (Albino Rabbits)	D.1.1 (1/28/80) / MODIFIED

DATE STUDY INITIATED: September 7th, 1983

DATE STUDY COMPLETED: September 26th, 1983

SUBMITTED BY: YOUNGER LABORATORIES, INC.

Michael J. Evans, Study Director

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Page 1 of 2 Pages

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PRIMARY SKIN IRRITATION

PRIMARY IRRITATION SCORE: CORROSIVE
(Ave., 24, 72 Hour Mean)
Maximum Score (Erythema + Edema) = 8

Species: New Zealand Albino Rabbits (Mixed Sex)
Test Site: Intact Skin
Exposure: 24 - Hours

DOSE AND CONDITIONS: 0.5 Milliliter Applied Undiluted

Time Following Patch Application	Skin Reaction	READINGS/SCORINGS Animal Number 1 F/R	2 F/R	3 F/R	4 F/R	5 F/R	6 F/R	Mean Score
24 Hours	Erythema	4 4	4 4	4 4	4 4	4 4	4 4	
	Edema	4 4	4 4	4 4	4 4	4 4	4 4	8.0
48 Hours	Erythema	4 4	4 4	4 4	4 4	4 4	4 4	
	Edema	4 4	4 4	4 4	4 4	4 4	4 4	8.0
72 Hours	Erythema	4 4	4 4	4 4	4 4	4 4	4 4	
	Edema	4 4	4 4	4 4	4 4	4 4	4 4	8.0
168 Hours	Erythema	C O R R O S I V E						
	Edema							

OBSERVATIONS/COMMENTS:

CORROSIVE - 168 - HOURS

MAC/Administration/EHL
(CO./DIV./DEPT./LOCATION)

Final
REPORT
(TYPE OF REPORT)

REPORT NO.: MSL-7067

JOB/PROJECT NO.: ML-83-180/EHL 83106

DATE: August 19, 1987

TITLE: Thirteen-Week Inhalation Toxicity Study of Azomethine in Sprague-Dawley Rats

AUTHORS: W. F. Heydens, Ph.D.
D. C. Thake, D.V.M., Dipl., A.C.V.P.

ABSTRACT: Four groups of 15 male and 15 female rats each were exposed to azomethine (2,6-diethylphenyl azomethine) atmospheres in 1.75 cubic meter inhalation chambers six hours a day, five days per week (except holidays) for approximately 13 weeks (maximum 62 exposure days). Mean analytical exposure levels were .0098, .049, and .15 mg azomethine per liter of air. The high level target concentration was changed from 0.20 to 0.10 mg/l on the 26th exposure day. Twenty-eight of the 30 high exposure level animals died or were sacrificed during the study. Other exposure-related signs of toxicity (observed primarily in high level animals) included discharges about the face, miscellaneous respiratory difficulties, hypoactivity, and opacity of the eyes. Significant decreases in mean body weights were noted during the entire study at the high level and throughout most of the study at the mid level. The following treatment-related changes in hematology and clinical chemistry values

(Continued on reverse side)

REPT. NO.: MSL-7067 AUTHORS: W. F. Heydens, D. C. Thake
TITLE: Thirteen-Week Inhalation Toxicity Study of Azomethine in Sprague-Dawley Rats
COPY NO.:

were noted: WBC counts decreased (low and mid level males); RBC parameters increased (two surviving high level females); glucose decreased (mid and high level females); BUN, alkaline phosphatase, SGPT and SGOT increased (high level females). The only organ weight changes which appeared to be exposure-related were increases in absolute (19%) and relative (23%) adrenal weights in mid level females. Gross and microscopic exposure-related lesions were observed in several organs. In the nasal passages, the following lesions were noted primarily at the mid and high exposure levels: inflammation, degeneration/ necrosis, metaplasia and hyperplasia. Trachea and lung lesions occurred only in the highest exposure level. Metaplasia, hyperplasia, epithelial degeneration, and inflammation with or without ulceration occurred in the tracheal mucosa. Prominent pulmonary lesions included epithelial degeneration/necrosis, inflammation with or without ulceration, metaplasia, hyperplasia and fibrosis. Corneal opacities and microscopic eye lesions were noted in several high level animals. Hepatic lesions were limited to the high exposure group and consisted of congestion and necrosis. Microscopic lesions in the spleen were also limited to the high exposure group and consisted of minimal to marked lymphoid depletion and occurrences of congestion and increased hematopoiesis. Gross and microscopic lesions occurred in the gastrointestinal tract, probably resulting from ingestion of the test chemical or secondary to debilitation and death. Bone marrow hypoplasia was evident in the high level animals. In summary, exposure to azomethine resulted in: (1) the deaths of most of the high level animals, and (2) various other manifestations of toxicity at this and lower exposure levels. A no-effect-level was not established, although changes at the low level consisted only of a mild decrease in WBC counts (males) and slight evidence of a direct irritant effect on the nasal passages (both sexes).

MONSANTO AGRICULTURAL COMPANY
ENVIRONMENTAL HEALTH LABORATORY
645 S. NEWSTEAD
ST. LOUIS, MISSOURI 63110

THIRTEEN-WEEK INHALATION TOXICITY STUDY OF AZOMETHINE IN SPRAGUE-DAWLEY RATS

Study Number: 83106

Project Number: ML-83-180

William F. Heydens 8/19/87

William F. Heydens, Ph.D. Study Director Date

D. C. Thake 8/21/87

D. C. Thake, D.V.M., Dipl., A.C.V.P. Date
Pathologist

SUMMARY

Four groups of 15 male and 15 female rats each were exposed to azomethine (2,6-diethylphenyl azomethine) atmospheres in 1.75 cubic meter inhalation chambers six hours a day, five days per week (except holidays) for approximately 13 weeks (maximum 62 exposure days). Mean analytical exposure levels were .0098, .049, and .15 mg azomethine per liter of air. The high level target concentration was changed from 0.20 to 0.10 mg/l on the 26th exposure day. Twenty-eight of the 30 high exposure level animals died or were sacrificed during the study. Other exposure-related signs of toxicity (observed primarily in high level animals) included discharges about the face, miscellaneous respiratory difficulties, hypoactivity, and opacity of the eyes. Significant decreases in mean body weights were noted during the entire study at the high level and throughout most of the study at the mid level. The following treatment-related changes in hematology and clinical chemistry values were noted: WBC counts decreased (low and mid level males); RBC parameters increased (two surviving high level females); glucose decreased (mid and high level females); BUN, alkaline phosphatase, SGPT and SGOT increased (high level females). The only organ weight changes which appeared to be exposure-related were increases in absolute (19%) and relative (23%) adrenal weights in mid level females. Gross and microscopic exposure-related lesions were observed in several organs. In the nasal passages, the following lesions were noted primarily at the mid and high exposure levels: inflammation, degeneration/necrosis, metaplasia and hyperplasia. Trachea and lung lesions occurred only in the highest exposure level. Metaplasia, hyperplasia, epithelial degeneration, and inflammation with or without ulceration occurred in the tracheal mucosa. Prominent pulmonary lesions included epithelial degeneration/necrosis, inflammation with or without ulceration, metaplasia, hyperplasia and fibrosis. Corneal opacities and microscopic eye lesions were noted in several high level animals. Hepatic lesions were limited to the high exposure group and consisted of congestion and necrosis. Microscopic lesions in the spleen were also limited to the high exposure group and consisted of minimal to marked lymphoid depletion and occurrences of congestion and increased hematopoiesis. Gross and microscopic lesions occurred in the gastrointestinal tract, probably resulting from ingestion of the test chemical or secondary to debilitation and death. Bone marrow hypoplasia was evident in the high level animals. In summary, exposure to azomethine resulted in: (1) the deaths of most of the high level animals, and (2) various other manifestations of toxicity at this and lower exposure levels. A no-effect-level was not established, although changes at the low level consisted only of a mild decrease in WBC counts (males) and slight evidence of a direct irritant effect on the nasal passages (both sexes).

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TRADEMARKS

The following registered trademarks are used in this report:

ITEM	REGISTERED TRADEMARK OF:
RODENT CHOW	Ralston Purina Co., St. Louis, MO
MIRAN	Foxboro Analytical, South Norwalk, CT
COULTER	Coulter Electronics, Hialeah, FL
KDA	American Monitor Corp., Indianapolis, IN

INTRODUCTION

Purpose: To evaluate the subchronic toxicity of Azomethine administered by inhalation to male and female Sprague/Dawley rats.
Date Inlife Portion Started: September 22, 1983

MATERIALS AND METHODS

Test Material

Name: Azomethine (2,6-diethylphenyl azomethine)
EHL Substance Identification Code: T830053
Lot Number: 7-26-8301
Stated Purity: 98.1%
Date Received: July 25, 1983
Description at Receipt: Light yellow liquid
Source: Monsanto Agricultural Company

Animals

Species: Albino rat
Strain: Sprague-Dawley
Source: Charles River Breeding Laboratory, Portage, MI
Date of Arrival at EHL: September 6, 1983
Number Used in Study: 120 (60 males, 60 females)
Method of Identification: Individual eartag, bar-coded cage card
Method of Assignment: Computer randomization by weight
Age at Study Start: Males - 51 days
Females - 56 days
Weight Range at Study Start: Males - 235 to 253 grams
Females - 164 to 182 grams
Type of Housing: All-wire mesh inhalation cages
Water Availability: ad libitum (St. Louis public water supply) except during inhalation exposures
Food Availability: Purina RODENT CHOW (5002) ad libitum except during inhalation exposures
Light Cycle: 12 hours daily (On at 6:30 A.M.)
Animal Room Environmental Specifications:
Temperature - 70 to 74 degrees F.
Relative Humidity - 35 to 60%
There were no excursions in animal room environmental conditions which had any obvious impact on the results of the study.

Exposure System

Exposure Chamber: 1.75 cubic meter New York University style stainless steel chambers with pyramidal tops and bottoms (Figure 1)
Test Atmosphere Generation: Test material was metered from a syringe pump (low and mid levels) or a pressurized tank (high level) through a capillary tube into a Laskin-style (1) nebulizer (Figures 2 and 3). This nebulizer was located in a vertical aerosol particle size separator. An airflow of approximately 150 l/min carried the test material upward through the separator and into the top of the chamber. The concentration of test material in the inhalation chamber was controlled by regulating the the flowrate of the test material into the nebulizer.
Chamber Airflow, Temperature, Pressure, Relative Humidity: Monitored continuously and recorded approximately every 30 minutes
Animal Placement During Exposure: Animals were positioned on the middle four rows of the cage racks. They were rotated weekly through the cage positions to insure that all animals received similar exposure to the test material.

Procedures for Monitoring Test Material in the Chambers

Nominal Concentration: Calculated once per exposure by determining the total amount of test material delivered to the chamber and dividing this amount by the total air volume passing through the chamber
Test Chamber Analytical Sampling: 4 per exposure at approximately 1.5 hour intervals
Control Chamber Analytical Sampling: Checked for the presence of test material once during the first week and approximately once every two weeks thereafter
Sampling Method: Test atmosphere was drawn at a known rate through iso-octane contained in a 15-ml glass impinger.
Sampling Location: Port halfway down on chamber door
Analytical Method: Gas Chromatography (Appendix 2, Exhibit 1)
Uniformity of Distribution: Determined by analyzing the chamber atmosphere at non-routine sampling sites
Chambers Sampled: All exposure chambers
Frequency: Once during the first week and approximately once every four weeks thereafter

Particle Size Analysis: Determined by drawing each sample for 10 minutes at a flowrate of approximately 1 CFM. The mass of material collected on each stage was determined gravimetrically and used to determine mass median aerodynamic diameter (MMAD), geometric standard deviation, and percentage of particles less than 10 microns.
Instrument Used: Non-viable, nine-stage Andersen cascade impactor
Chambers Analyzed: High exposure level chamber
Frequency: Once during the first week and approximately once every week thereafter

Stability of Test Substance: Confirmed by comparing results of analyses performed during and after the study with analyses provided before the study.

In-life Observations

Checks for Mortality and Moribundity: Twice daily
During Exposure Observations: Performed between second and fifth hour of exposure. Percentage estimates of observable animals exhibiting signs of toxicity were recorded
After Exposure Observations: Immediately after each exposure
Body Weights/Detailed Observations: Once a week

Hematology and Clinical Chemistry Analyses

Frequency: Once during the study, on the day of scheduled termination
Approximate Number of Animals: All survivors
Fasting: Food withheld overnight prior to blood collection
Collection Site: Posterior vena cava of anesthetized animals

Hematology Determinations: Whole blood was treated with anticoagulant (EDTA pretreated commercial tubes) and processed on a COULTER S Plus II blood cell counter using the manufacturer's methods. The following determinations were made: Red blood cell count (RBC), white blood cell count (WBC), platelet count (PLT), reticulocyte count, hematocrit (Hct), level of hemoglobin (HGB), and red blood cell indices [mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC)]. Leukocyte differentials were determined by microscopically examining stained (Wright's stain) blood smears on glass slides.

Blood Chemistry Determinations: Serum was harvested by centrifugation of blood samples submitted in commercial clot tubes and assayed with a KDA clinical analyzer using

the manufacturer's methods. The following determinations were made: albumin, total protein, blood urea nitrogen (BUN), total bilirubin, glucose, glutamic pyruvic transaminase (D-GPT/ALT), alkaline phosphatase, glutamic oxaloacetate transaminase (D-GOT/AST), and lactic dehydrogenase (LDH). Globulin was determined by subtraction of albumin from the total protein value.

Pathology

Scheduled Termination: All animals were terminated over a two day period. Animals were exposed through the day preceding necropsy.

Extent of Examination: At scheduled termination, all animals were given a gross necropsy, organ weights were determined, and tissues were obtained. At unscheduled terminations (animals found dead or sacrificed in extremis), animals were given a gross necropsy, and tissues were obtained. Tissues from control and high level animals were examined microscopically (condition of tissue permitting); target tissues from low and mid level animals were also examined.

Necropsy Procedures:

Gross Necropsy: Internal and external. Internal cavities (abdominal, thoracic, cranial, and scrotal) were opened, and organs were removed and examined.

Organs Weighed: adrenals, heart, kidneys, liver, spleen, testes with epididymides

Tissues Obtained (when present): aorta, adrenals, bone with marrow, brain, esophagus, eyes with optic nerve, gonads (ovaries, testes with epididymides), heart, intestine (colon and ileum) kidneys, liver, lung, lymph nodes (thymic and mesenteric), mammary gland, nasal passages, pancreas, pituitary, prostate, salivary gland (submandibular), sciatic nerve, skeletal muscle, skin, spinal cord (thoracolumbar), spleen, stomach, thymus, thyroid/parathyroid, trachea, urinary bladder, uterus, and gross lesions (at the discretion of the pathologist).

Histopathology Procedures:

Fixative:
Eyes - 1% glutaraldehyde in 10% neutral buffered formalin
All other tissues - 10% neutral buffered formalin

Tissue Preparation: Fixed tissues were washed, dehydrated, embedded in paraffin, sectioned at approximately 5 microns, and stained with hematoxylin and eosin.
Examination: Light microscopy

Statistics

The following statistical procedures were used to detect statistically significant differences between treated animals and their respective controls:

Dunnett's Multiple Comparison Test (two-tailed) (2):
Noncategorical clinical pathology data,
body weights,
Absolute organ weights,

Mann-Whitney Test(3) with Bonferroni Inequality Procedure (4):
Organ weight/body weight ratios;

Fisher's Exact Test(5) with Bonferroni Inequality Procedure:
Incidence of microscopic lesions

Other statistical routines used for some data were: Bartlett's Test (6) to evaluate homogeneity of variances, Analysis of Variance (5) to determine if the sample (group) means could be considered as an estimate of a common population, and Grubb's Test (7,8) to detect outliers.

RESULTS

Chamber Atmosphere Analysis and Environmental Data

The high level target concentration was reduced from 0.20 to 0.10 mg/L during the sixth week of exposure because of excessive toxicity. Mean nominal and analytical values for the three exposure levels of azomethine were:

	Concentration (mg/L)		
	Low	Mid	High
Target	0.01	0.05	0.10
Nominal (S.D.)	0.01 (.00)	0.12 (.01)	0.44 (.19)
Analytical (S.D.)	0.0098 (.001)	0.049 (.014)	0.15 (.051)
Nominal/Analytical	1.02	2.45	2.93

The uniformity of test material distribution in the chambers was found to be acceptable (+ 22%) at all exposure levels (Appendix 2, Exhibit 4, Table 2). The daily means for airflow, temperature and relative humidity were maintained throughout the

study at 340 l/min., 21.5-28.0 degrees C and 20-66%, respectively (Appendix 2, Exhibit 4, Table 3).

The mass median aerodynamic diameter (MMAD) was between 1.58 and 2.29 microns, and the percent of particles less than 10 microns ranged from 95.1 to 98.7, with two exceptions (Appendix 2, Exhibit 4, Table 4). The reason for the two irregular samples was not determined. Stability analysis indicated no decomposition of the test material.

Inlife Weights and Observations

Twenty-eight of the 30 high exposure level animals died or were sacrificed during the study. These included all 15 of the males and 13 of the females. Numerous other signs of toxicity were also noted during the study. Breathing difficulties and irritation of the eyes and/or nose were observed in high exposure animals during the exposure periods (Appendix 3, Table 1). Clinical abnormalities observed before and/or after exposure included discharges about the face, miscellaneous respiratory difficulties, hypoactivity, abnormalities of the skin and fur, opacity of the eyes, and emaciated appearance (Appendix 1, Table 1). These occurred primarily in high and somem id level animals. Similar signs were also observed weekly when the animals were weighed and given a thorough examination for signs of toxicity (Appendix 3, Table 3).

Significant decreases in mean body weights of high exposure males and females were noted throughout the entire study (Appendix 1, Table 2). The mean body weight of mid level animals was also significantly reduced throughout most of the study.

Hematology and Clinical Chemistry Determinations

The only changes in hematology determinations which may have been related to administration of the test material were decreases (approximately 16-27%) in WBC counts in low and mid level males and increases (14-15%) in erythrocyte parameters (RBC, HGB, HCT) in the two surviving high level females (Appendix 1, Table 3).

There was a dose-related decrease in blood glucose levels in females only. Significant increases in BUN, alkaline phosphatase, SGOT, and SGPT were detected in the two surviving high level females (Appendix 1, Table 4). All other changes were not dose-related and did not appear to be caused by test material exposure.

Gross and Microscopic Pathology

The only organ weight changes which appeared to be related to test material exposure were increases in absolute (19%) and

relative (23%) adrenal weights in mid level females. Slight decreases in other absolute organ weights were noted, but these were attributed to decreased body weight rather than a direct effect of the compound on the organs (Appendix 1, Tables 5 and 6).

Exposure-related lesions, both direct and indirect, were observed in several organs. These gross and microscopic lesions are discussed below and summarized in Appendix 1, Tables 7 and 8, respectively.

The following microscopic changes were noted in nasal passages at all exposure levels: inflammation, metaplasia, hyperplasia, and degeneration or necrosis. Other changes such as ulceration, hyperkeratosis and dysplasia occurred only in high level animals. In the tracheal mucosa, metaplasia, hyperplasia (surface and glandular epithelium) epithelial degeneration, and acute to chronic inflammation with or without ulceration were found in both males and females. The most prominent pulmonary lesions included epithelial degeneration or necrosis, inflammation with or without ulceration, metaplasia, hyperplasia and fibrosis, all of which occurred in bronchi or bronchioles. Congestion, pneumonia (including interstitial pneumonia), edema, emphysema and excessive mucous secretion were also observed. The trachea and lung lesions occurred only in the high exposure group.

At necropsy, corneal opacity was noted in 3 males and 2 females from the high exposure group. Microscopic lesions were noted in the eyes of several high level males and females. The findings included inflammation of the cornea or uveal tract with corneal ulceration and isolated occurrences of corneal mineralization, phthisis, posterior synechiae and exudate in the anterior chamber.

Hepatic lesions were limited to males and females from the high exposure group and consisted of congestion and necrosis which was either centrilobular or random.

Six instances of small spleens were recorded grossly in high exposure level males. Microscopic splenic lesions were also limited to rats from the high exposure group and consisted of minimal to marked lymphoid depletion in nearly all rats with a few occurrences of congestion and one instance of increased hematopoiesis.

Gross and microscopic lesions were found in the stomachs and/or intestines of a low number of high level males and females. At necropsy, gas distention, abnormal contents and ulcerations were noted. Microscopic changes in the stomach included necrosis, hemorrhage and inflammation of the gastric mucosa with or without

erosions or ulcerations. In the intestines, microscopic changes were mild and included sporadic occurrences of goblet cell hyperplasia, superficial mucosal necrosis, inflammation and congestion.

Bone marrow hypoplasia, involving either myeloid or myeloid and erythroid elements, occurred in 10 of 15 males and 4 of 15 females from the high exposure group. Increased pigment deposition was evident in bone and cartilage from 6 of 15 high exposure males. This pigment was brown, granular to globular, and occurred most prominently but not exclusively at the epiphyseal plate on or near the surface of trabecular bone. It appeared to be present in osteoblasts and osteocytes. This same pigment was present to a slight extent in control males.

The only other exposure-related lesions were congestion in kidneys and brains of both males and females from the highest exposure group. These were probably indirect effects related to the debilitated condition of the animals.

DISCUSSION

All but two of the high level animals died or were sacrificed during the study. In addition, the body weights of mid and high level animals were significantly reduced throughout virtually the entire study. These findings clearly demonstrate the debilitating effects of the compound.

Decreases in WBC counts in low and mid level males, although mild, may have been due to chemical exposure. Bone marrow hypoplasia and splenic lymphoid hypoplasia were observed in animals from the highest exposure group indicating the potential of this chemical to produce hematopoietic toxicity. Increased values for RBC parameters in the two surviving high exposure females apparently resulted from dehydration and hemoconcentration.

The decreased glucose levels in the mid and (two) high exposure level females were probably the result of debilitation. The increase in serum levels of alkaline phosphatase, SGOT, and SGPT in the two surviving high exposure females suggests liver damage such as that observed microscopically in other high exposure females. These lesions were not, however, observed microscopically in sections examined from the two surviving animals. The increased BUN in the high level females was probably related to debilitation.

Increased absolute and relative adrenal weights in mid level females were probably associated with compound-induced stress.

Lesions observed in the respiratory tract and eyes resulted primarily from irritant properties of the test chemical. These changes were limited to the highest exposure group except in the upper respiratory tract, where metaplasia, hyperplasia and degenerative changes, although mild, persisted through the low exposure group.

Lesions in the gastrointestinal tract probably resulted from ingestion of the test chemical or were secondary to debilitation and/or death.

Pigment deposition in bone tissue was increased in several high exposure level males. The location of this pigment indicated that it was deposited primarily in osteoblasts, osteocytes, areas of new bone formation, and to a lesser extent, in cartilage at the epiphyseal plate. The nature of this pigment was not determined.

In summary, exposure to the test material resulted in the deaths of most of the high level animals and other manifestations of toxicity at lower exposure levels. A no effect level was not established, although changes at the low level consisted only of a mild decrease in WBC counts (males) and slight evidence of a direct irritant effect on the nasal passages (both sexes).

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SUPPLEMENTAL STUDY INFORMATION

Study Performed at: Environmental Health Laboratory (EHL),
645 S. Newstead, St. Louis, MO 63110
Date Protocol Signed by Study Director: September 22, 1983
Date of Last Necropsy: December 22, 1983
Location of Study Protocol, Original Data, Tissue Specimens,
and Final Report: Environmental Health Laboratory Archives

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Since this study was initiated, the formats for EHL study numbers and animal identification numbers have been changed. Originally, study numbers were in the format YYXXXX where Y indicated the study year and X indicated the sequence number within that year. This has been changed to YYXXX; the third digit of the number (0) has been eliminated. The older animal identification format was YYXXXX-GSNNN where YYXXXX was the study number, G was the group code denoting the control or test group, S was the animal's sex, and N was the animal sequence number within the group. The current format is YYXXXSGAANNN where YYXXX is the study number, S represents the animal's sex, G is the primary group code, A's may represent the subgroup code (In most cases, these characters are blanks.), and N is the animal's sequence number within the group (subgroup). Thus, 990999-2M001 and 99999M2 001 are the same animal. In the report and the corresponding data package, both formats may be used for the EHL study number and animal identification numbers. In manually-generated tables and text, the animal designation may be further reduced by exclusion of the study number and blank subgroup codes, e.g., M2001. These abbreviated animal identifications will include five to seven characters, depending on the number of characters in the subgroup code.

DMEH QUALITY ASSURANCE AUDIT STATEMENT

Study Number:	83106 ML-83-180
Protocol Amendments:	One - 10-28-83
Study Title:	Thirteen-Week Inhalation Toxicity Study of Azomethine in Sprague-Dawley Rats
Dates of Inspections and Communication of Findings:	October 5, 27, 1983 November 8, 1983 December 19, 21, 1983 March 8, 18, 1985 December 3, 15, 1986 January 14, 16, 22, 1987 February 3, 1987 April 15, 24, 1987 July 31, 1987 August 5, 1987
Quality Assurance Review Conducted by:	S. R. Lee K. J. Perry C. K. Russell B. M. Williamson
Results:	The Quality Assurance review indicates the final report accurately presents the raw data as developed during the study. There appears to be no significant deviation from applicable GLP regulations that adversely affected study quality or integrity.

Arthur F. Yelner
Manager, Quality Assurance

August 7, 1987
Date

COMPLIANCE STATEMENT

To the best of our knowledge, the study EHL 83106 (ML-83-180) was conducted in general conformance with the Environmental Protection Agency Good Laboratory Practice Standards with the following exception:

Test substance characterization and stability are available but some were not developed under the Standards cited above.

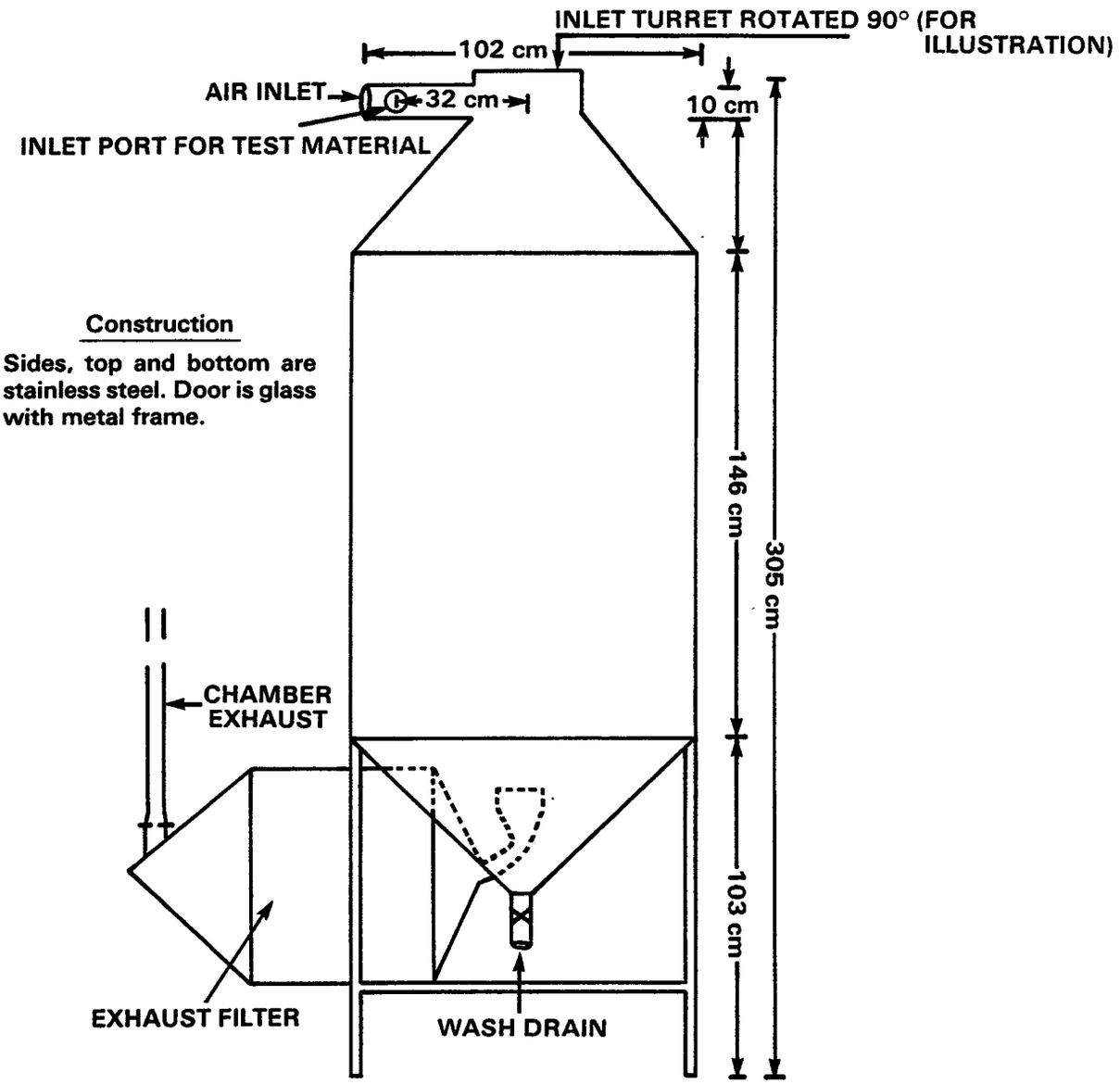
This deviation should not affect the results or conclusion of the study.

William F. Heydens
Study Director

APPENDIX 1: FIGURES AND SUMMARY TABLES

Figure 1

SUBACUTE INHALATION CHAMBER



(Side view of test chamber; side not shown is 102 cm wide)

FIGURE 2

SYRINGE PUMP GENERATION SYSTEM

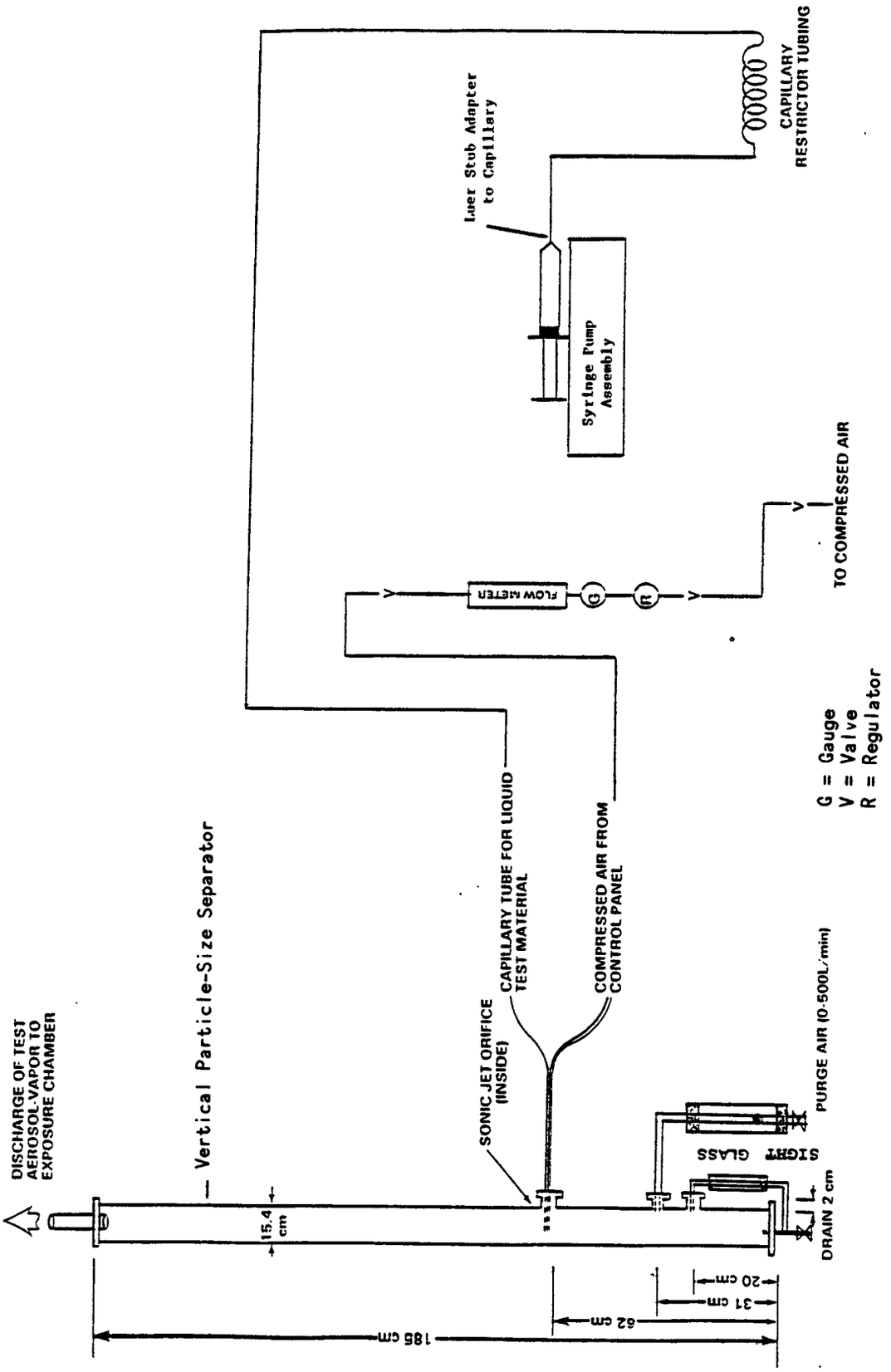


FIGURE 3

TANK GENERATION SYSTEM

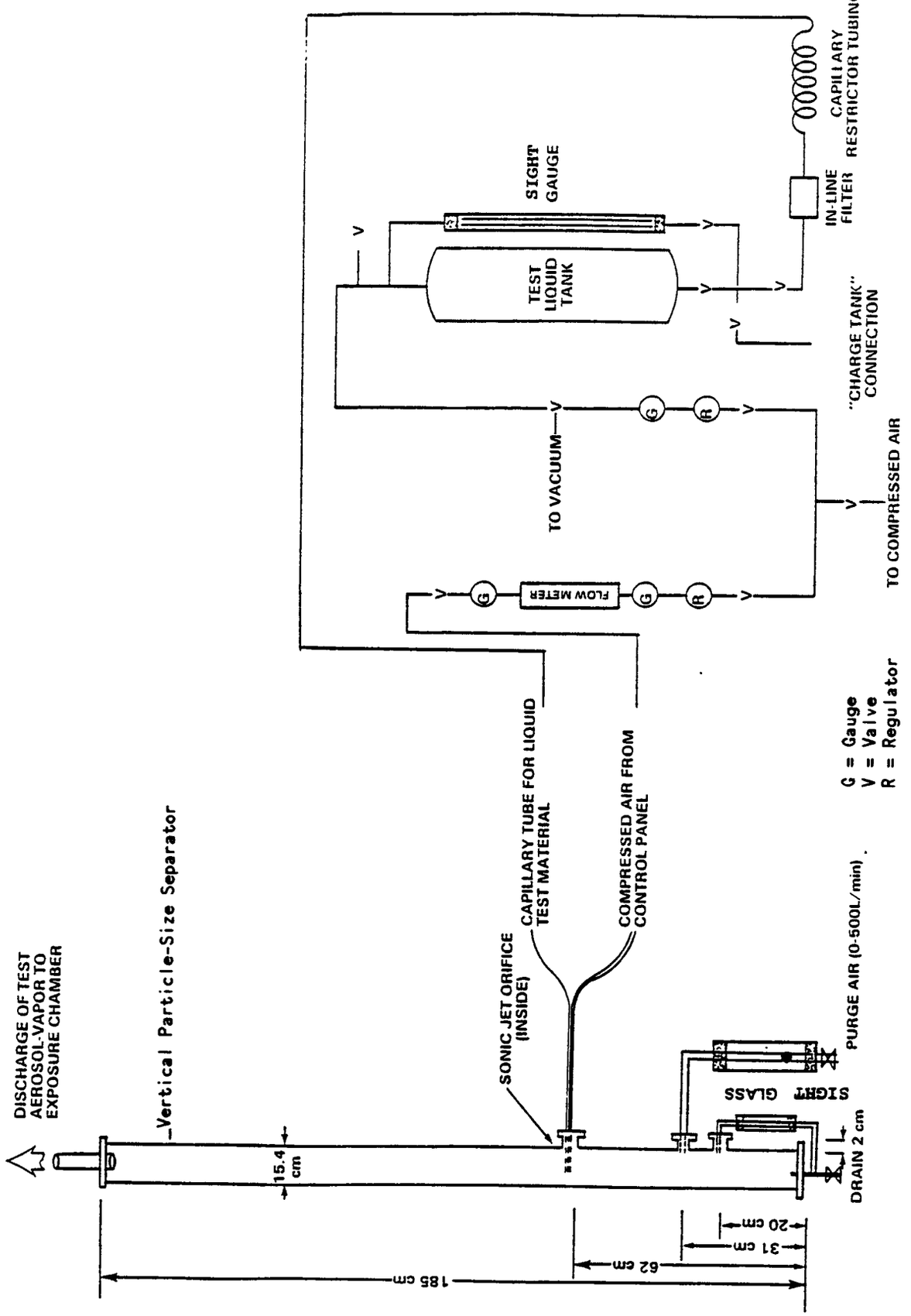


Table 1

Weekly Occurrences of Signs of Azomethine Toxicity Observed in Groups of Animals Before and After Exposure (by Exception)

Week No.	Date	Discharges About The Face [1]								Miscellaneous Respiratory Difficulty [2]								Hypoactivity [3]							
		Males				Females				Males				Females				Males				Females			
		N	1	2	3	N	1	2	3	N	1	2	3	N	1	2	3	N	1	2	3	N	1	2	3
1	9/22-9/28/83		3	1	15				14				4				6				15				12
2	9/29-10/5/83		5	1	15		1		14				7				2				15				8
3	10/6-10/12/83			1	15			1	14				14				10				15				11
4	10/13-10/19/83				14				14				14				14				13				10
5	10/20-10/26/83				10				13				11				13				6				9
6	10/27-11/2/83			1	9				9				9				11				1				2
7	11/3-11/9/83		1	2	5			3	2				9				5								
8	11/10-11/16/83			7	3			3				1	4				3								
9	11/17-11/23/83		1	8	1			4	2			4	3				3								
10	11/24-11/30/83			6				1				1	1			1	3								
11	12/1-12/7/83	1		7				1	1			2					3								
12	12/8-12/14/83	2	1	3								7					3								
13	12/15-12/21/83	1	2	2		1						4					2								
14	12/22/83	1	1																						

Week No.	Date	Abnormalities of the Skin and Fur [4]								Opacity of Eye(s)							
		Males				Females				Males				Females			
		N	1	2	3	N	1	2	3	N	1	2	3	N	1	2	3
1	9/22-9/28/83								2								
2	9/29-10/5/83			1					2								
3	10/6-10/12/83		1		4				2				2				2
4	10/13-10/19/83		1		6				10				3				2
5	10/20-10/26/83				4				9				4				5
6	10/27-11/2/83	1	1		2	1			5				3				2
7	11/3-11/9/83	1			3	1			3				1				
8	11/10-11/16/83		1			1											
9	11/17-11/23/83					1			1								
10	11/24-11/30/83					1			1								
11	12/1-12/7/83					1											
12	12/8-12/14/83					1											
13	12/15-12/21/83					1											

Table 1 (Cont.)

Weekly Occurrences of Signs of Azomethine Toxicity Observed
in Groups of Animals Before and After Exposure (by Exception)

Week No.	Date	Emaciated Appearance								Death							
		Males				Females				Males				Females			
		N	1	2	3	N	1	2	3	N	1	2	3	N	1	2	3
1	9/22-9/28/83																
2	9/29-10/5/83																
3	10/6-10/12/83												1				1
4	10/13-10/19/83								1				2				1
5	10/20-10/26/83												2				
6	10/27-11/2/83												1				8
7	11/3-11/9/83												5				2
8	11/10-11/16/83								1				1				
9	11/17-11/23/83												1				
10	11/24-11/30/83								1				2				
11	12/1-12/7/83								1								
12	12/8-12/14/83																1
13	12/15-12/21/83								1								

[1] Includes red/brown perinasal encrustation, blood-like nasal and/or oral discharge, red discharge about the eyes, yellow/brown nasal discharge, red/pink nasal discharge, clear nasal discharge, and salivation.

[2] Includes sneezing, gasping and labored breathing, rapid, slow and shallow breathing.

[3] Includes hypoactivity, prostrate, and non-responsive.

[4] Includes focal and generalized loss of hair, abrasions, blood-stained appearance, urine and/or feces-stained fur and urogenital discharge.

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

SEX: MALE

GROUP	TARGET DOSE	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48
MN		MEAN	242.5	300.7	338.5	378.1BT	406.1	430.2	456.6	480.8
NEGATIVE CONTROL		STD. DEV.	4.78	11.83	16.81	21.84	26.37	29.09	31.57	34.16
		SAMPLE SIZE	15	15	15	15	15	15	15	15
M1	0.0100 MG/L	MEAN	243.0	299.7	338.3	380.3	412.3	438.8	463.9	488.9
TEST GROUP		STD. DEV.	5.21	10.91	16.47	21.37	28.42	31.79	34.24	42.33
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	15	15	15	15	15
M2	0.0500 MG/L	MEAN	242.6	284.8**	318.2**	356.3	378.9*	402.5*	419.7**	440.1**
TEST GROUP		STD. DEV.	4.88	6.85	12.76	15.16	19.87	19.47	21.88	24.65
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	15	15	15	15	15
M3	0.2000 MG/L	MEAN	242.6	254.1**	273.4**	271.7**	248.2**	238.4**	225.7**	249.3**
TEST GROUP		STD. DEV.	5.11	8.85	17.74	40.53	41.37	34.51	24.04	25.02
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	15	12	10	9	4

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .05$)
** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

SEX: MALE

GROUP	TARGET DOSE	DATE (1983): DAY OF STUDY:	15-NOV 55	22-NOV 62	29-NOV 69	6-DEC 76	13-DEC 83	20-DEC 90
MN		MEAN	498.3	513.9	529.6	540.1	552.8	557.8
NEGATIVE CONTROL		STD. DEV.	37.56	37.60	43.98	49.08	50.34	51.26
		SAMPLE SIZE	15	15	15	15	15	15
M1	0.0100 MG/L	MEAN	504.2	522.4	536.7	553.1	558.3	562.3
TEST GROUP		STD. DEV.	43.94	45.22	48.45	51.35	45.60	47.69
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	15	15	15
M2	0.0500 MG/L	MEAN	454.5**	465.5**	482.8**	486.3**	493.3**	498.4**
TEST GROUP		STD. DEV.	27.62	27.62	29.79	33.70	31.23	34.38
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	15	15	15
M3	0.2000 MG/L	MEAN	245.0**	252.5**	227.0**	0.0NA	0.0NA	0.0NA
TEST GROUP		STD. DEV.	25.94	10.61	0.00	0.00	0.00	0.00
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	3	2	1	0	0	0

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P<.05$)
** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P<.01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P\leq.01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

SEX: FEMALE

GROUP	TARGET DOSE	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48
FN		MEAN	173.1	198.2	212.6	226.5BT	239.8	244.7	253.1	264.7
NEGATIVE CONTROL		STD. DEV.	5.06	7.46	10.79	13.88	13.92	14.19	17.46	19.11
		SAMPLE SIZE	15	15	15	15	15	15	15	15
F1	0.0100 MG/L	MEAN	173.2	195.1	207.7	220.9	231.4	239.8	249.2	257.2
TEST GROUP		STD. DEV.	4.99	6.39	9.43	12.91	15.55	14.75	18.83	20.56
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	15	15	15	15	15
F2	0.0500 MG/L	MEAN	173.1	189.3**	200.3**	217.9	223.4**	229.2*	235.3*	244.1*
TEST GROUP		STD. DEV.	5.44	7.00	6.40	7.24	11.95	17.03	16.13	15.36
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	15	15	15	15	15
F3	0.2000 MG/L	MEAN	173.3	179.5**	192.6**	199.0**	187.4**	173.6**	171.8**	171.7**
TEST GROUP		STD. DEV.	5.27	8.34	11.48	21.28	16.11	20.44	26.81	34.12
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	14	13	13	5	3

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .05$)
** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

SEX: FEMALE

GROUP	TARGET DOSE	DATE (1983): DAY OF STUDY:	15-NOV 55	22-NOV 62	29-NOV 69	6-DEC 76	13-DEC 83	20-DEC 90
FN		MEAN	272.7	280.1	282.3	289.1	295.4	296.4
NEGATIVE CONTROL		STD. DEV.	18.24	21.83	20.71	20.53	21.43	21.05
		SAMPLE SIZE	15	15	15	15	15	15
F1	0.0100 MG/L	MEAN	262.9	274.1	277.8	284.2	289.9	291.7
TEST GROUP		STD. DEV.	20.38	21.05	22.25	24.09	28.93	29.07
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	15	15	15
F2	0.0500 MG/L	MEAN	247.5**	254.1**	257.7**	262.3**	263.2**	265.2**
TEST GROUP		STD. DEV.	16.76	20.29	18.55	20.32	19.96	24.01
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	15	15	15	15	15	15
F3	0.2000 MG/L	MEAN	187.3**	182.3**	189.7**	190.0**	202.5**	188.0**
TEST GROUP		STD. DEV.	28.57	32.65	32.59	27.40	40.31	55.15
2,6 DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	3	3	3	3	2	2

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .05$)
** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

SUMMARY OF HEMATOLOGY DATA - GROUP MEANS
830106

	MALES			FEMALES			
	NM	1M	2M	NF	1F	2F	3F
WBC	12.1	10.2*	8.8**	5.9	6.5	7.7*	8.0
RBC	8.53	8.79	8.90	8.19	8.18	8.19	9.44*
HGB	15.6	16.1	15.9	15.6	15.4	15.6	17.8**
HCT	47.7	49.1	49.6	49.3	48.0	48.7	56.3*
MCV	55.8	55.8	55.7	60.2	58.6	59.4	59.7
MCH	18.3	18.3	17.9	19.0	18.9	19.1	18.9
MCHC	32.9	32.8	32.1*	31.5	32.2	32.1	31.5
PLT	824.	841.	797.	834.	815.	794.	803.
RETICS	1.82	1.47*	1.73	2.26	2.28	1.89	2.10

* SIGNIFICANTLY DIFFERENT, P LESS THAN OR EQUAL TO 0.05, COMPARED TO CONTROLS (TWO-TAILED DUNNETT'S TEST).
** SIGNIFICANTLY DIFFERENT, P LESS THAN OR EQUAL TO 0.01, COMPARED TO CONTROLS (TWO-TAILED DUNNETT'S TEST).

SUMMARY OF CHEMISTRY DATA -- GROUP MEANS
830106 PERIOD 1

	MALES			FEMALES			
	NM	1M	2M	NF	1F	2F	3F
GLUCOSE	174.	261.**	205.	169.	152.	127.*	80.8*
BUN	15.3	13.5*	16.2	12.9	13.1	15.3	29.6**
TOT BILI	0.09	0.10	0.10	0.10	0.11	0.10	0.10
TOT PROTEIN	6.6	6.7	6.6	6.8	6.9	6.4**	6.7
ALBUMIN	3.6	3.7	3.6	3.9	4.0	3.6*	3.5
ALK-PHOS	184.	165.	194.	106.	97.4	110.	231.**
D-GOT/AST	158.	132.	159.	118.	139.	117.	201.*
LDH	820.	440.**	789.	449.	473.	376.	261.
D-GPT/ALT	32.3	32.9	39.7	24.6	38.7**	29.3	59.8**
GLOBULIN	3.0	3.0	3.0	2.9	2.9	2.7*	3.3*

*. SIGNIFICANTLY DIFFERENT, P LESS THAN OR EQUAL TO 0.05 (TWO-TAILED DUNNETT'S TEST).
**. SIGNIFICANTLY DIFFERENT, P LESS THAN OR EQUAL TO 0.01 (TWO-TAILED DUNNETT'S TEST).

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

	M A L E ADRENALS , BOTH			
	MN	M1	M2	M3
001	0.058	0.091	0.039	NA
002	0.052	0.053	0.058	NA
003	0.062	0.075	0.050	NA
004	0.062	0.050	0.045	NA
005	0.076	0.076	0.066	NA
006	0.045	0.060	0.076	NA
007	0.088	0.064	0.075	NA
008	0.064	0.079	0.063	NA
009	0.044	0.075	0.048	NA
010	0.068	0.082	0.082	NA
011	0.077	0.070	0.056	NA
012	0.080	0.083	0.042	NA
013	0.081	0.081	0.056	NA
014	0.075	0.077	0.066	NA
015	0.063	0.070	0.068	NA
MEAN	0.066	0.072	0.059	0.000
S.E.	0.003	0.003	0.003	0.000
(N)	15	15	15	0

ANALYSIS OF VARIANCE: F = 4.06, P = 0.0245

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
M1	0.0061	1.321	2.29	2.94
M2	-0.0070	-1.524	2.29	2.94

NA = Indicates organ weight not available because animal did not meet the selection criteria.
NW = No organ weight available for animal.
E = Weight has been identified as an outlier (GRUBB'S TEST) and has been excluded from statistics.
* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
** = Significantly different from Control (P Less Than or Equal to 0.01) using the Dunnett's Test.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 2
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

-------- F E M A L E ADRENALS , BOTH --------

	FN	F1	F2	F3
001	0.071	0.080	0.084	NA
002	0.099	0.065	0.093	NA
003	0.092	0.067	0.096	NA
004	0.071	0.069	0.070	NA
005	0.065	0.100	0.078	0.043
006	0.070	0.072	0.097	NA
007	0.088	0.096	0.107	NA
008	0.080	0.100	0.064	NA
009	0.082	0.092	0.080	NA
010	0.091	0.080	0.076	0.068
011	0.051	0.098	0.081	NA
012	0.076	0.086	0.101	NA
013	0.074	0.079	0.082	NA
014	0.053	0.076	0.087	NA
015	0.029	0.057	0.116	NA
MEAN	0.073	0.081	0.087	0.056
S.E.	0.005	0.004	0.004	0.012
(N)	15	15	15	2

ANALYSIS OF VARIANCE: F = 3.88, P = 0.0153

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
F1	0.0083	1.468	2.43	3.08
F2	0.0147*	2.583	2.43	3.08
F3	-0.0173	-1.478	2.43	3.08

NA = Indicates organ weight not available because animal did not meet the selection criteria.
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* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
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THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 3
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

M A L E HEART

	MN	M1	M2	M3
001	1.414	1.866	1.568	NA
002	1.569	1.624	1.643	NA
003	1.725	1.586	1.433	NA
004	2.065	1.691	1.513	NA
005	1.965	1.764	1.495	NA
006	1.576	1.719	1.935	NA
007	1.599	1.349	1.558	NA
008	1.838	1.590	1.498	NA
009	1.610	1.728	1.708	NA
010	1.865	1.615	1.409	NA
011	1.663	2.058	1.465	NA
012	2.027	1.610	1.346	NA
013	1.434	1.893	1.530	NA
014	1.702	1.620	1.386	NA
015	1.666	1.644	1.479	NA
MEAN	1.715	1.690	1.531	0.000
S.E.	0.052	0.042	0.038	0.000
(N)	15	15	15	0

ANALYSIS OF VARIANCE: F = 5.07, P = 0.0106

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
M1	-0.0241	-0.384	2.29	2.94
M2	-0.1835*	-2.931	2.29	2.94

NA = Indicates organ weight not available because animal did not meet the selection criteria.
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THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 4
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

-------- F E M A L E HEART --------

	FN	F1	F2	F3
001	1.009	0.920	0.919	NA
002	1.106	0.806	0.833	NA
003	1.075	0.793	0.865	NA
004	0.768	0.898	0.781	NA
005	0.811	1.201	0.980	0.637
006	0.965	0.760	0.952	NA
007	0.921	1.061	0.914	NA
008	1.081	0.925	0.966	NA
009	1.000	0.886	0.964	NA
010	1.026	0.968	0.744	0.802
011	0.949	1.147	0.851	NA
012	0.920	0.891	0.933	NA
013	0.861	0.957	0.962	NA
014	0.878	0.824	0.847	NA
015	0.838	1.047	0.938	NA
MEAN	0.947	0.939	0.897	0.720
S.E.	0.027	0.033	0.019	0.082
(N)	15	15	15	2

ANALYSIS OF VARIANCE: F = 3.22, P = 0.0319

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
F1	-0.0083	-0.217	2.43	3.08
F2	-0.0506	-1.329	2.43	3.08
F3	-0.2277*	-2.901	2.43	3.08

NA = Indicates organ weight not available because animal did not meet the selection criteria.
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E = Weight has been identified as an outlier (GRUBB'S TEST) and has been excluded from statistics.
* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
** = Significantly different from Control (P Less Than or Equal to 0.01) using the Dunnett's Test.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 5
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

SELECTION CRITERIA: SCHEDULED SACRIFICES ** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

	M A L E KIDNEYS , BOTH			
	MN	M1	M2	M3
001	3.538	3.660	3.208	NA
002	3.651	3.470	3.473	NA
003	3.322	3.670	3.090	NA
004	4.036	3.808	3.015	NA
005	4.203	3.679	3.806	NA
006	3.099	3.595	4.021	NA
007	3.002	3.125	3.149	NA
008	3.105	3.405	3.200	NA
009	3.440	3.565	3.663	NA
010	4.849	3.294	2.729	NA
011	4.461	3.589	2.969	NA
012	3.616	3.256	2.983	NA
013	3.574	4.379	2.793	NA
014	3.533	3.731	3.093	NA
015	3.655	3.460	3.335	NA
MEAN	3.672	3.579	3.235	0.000
S.E.	0.134	0.075	0.095	0.000
(N)	15	15	15	0

ANALYSIS OF VARIANCE: F = 4.90, P = 0.0122

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
M1	-0.0932	-0.634	2.29	2.94
M2	-0.4371**	-2.972	2.29	2.94

NA = Indicates organ weight not available because animal did not meet the selection criteria.
NW = No organ weight available for animal.
E = Weight has been identified as an outlier (GRUBB'S TEST) and has been excluded from statistics.
* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
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THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 6
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

-------- F E M A L E KIDNEYS , BOTH --------

	FN	F1	F2	F3
001	2.056	1.767	1.930	NA
002	1.852	1.548	1.783	NA
003	1.987	1.598	1.544	NA
004	1.745	1.706	1.566	NA
005	1.648	2.191	1.862	1.281
006	1.941	1.589	1.918	NA
007	2.099	1.925	2.010	NA
008	2.075	1.921	1.685	NA
009	1.721	1.913	1.869	NA
010	2.225	2.041	1.657	1.642
011	1.853	2.213	1.630	NA
012	2.269	2.007	2.276	NA
013	2.119	1.940	1.808	NA
014	1.644	1.921	1.902	NA
015	1.958	1.904	2.037	NA
MEAN	1.946	1.879	1.832	1.462
S.E.	0.051	0.052	0.051	0.180
(N)	15	15	15	2

ANALYSIS OF VARIANCE: F = 3.65, P = 0.0198

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
F1	-0.0672	-0.914	2.43	3.08
F2	-0.1143	-1.556	2.43	3.08
F3	-0.4846**	-3.198	2.43	3.08

NA = Indicates organ weight not available because animal did not meet the selection criteria.
NW = No organ weight available for animal.
E = Weight has been identified as an outlier (GRUBB'S TEST) and has been excluded from statistics.
* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
** = Significantly different from Control (P Less Than or Equal to 0.01) using the Dunnett's Test.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 7
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

M A L E LIVER

	MN	M1	M2	M3
001	14.226	16.174	12.688	NA
002	14.827	17.622	14.755	NA
003	12.472	16.893	12.723	NA
004	16.232	16.359	14.702	NA
005	21.918	15.871	13.233	NA
006	18.084	15.881	20.803	NA
007	14.466	11.480	12.717	NA
008	14.567	12.739	14.020	NA
009	13.754	14.757	13.233	NA
010	24.050	15.873	12.141	NA
011	21.794	20.173	12.415	NA
012	15.516	15.785	12.549	NA
013	18.829	27.815	12.738	NA
014	15.438	16.276	11.271	NA
015	14.847	17.781	15.304	NA
MEAN	16.735	16.765	13.686	0.000
S.E.	0.889	0.946	0.581	0.000
(N)	15	15	15	0

ANALYSIS OF VARIANCE: F = 4.64, P = 0.0151

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
M1	0.0306	0.026	2.29	2.94
M2	-3.0485*	-2.626	2.29	2.94

NA = Indicates organ weight not available because animal did not meet the selection criteria.
NW = No organ weight available for animal.
E = Weight has been identified as an outlier (GRUBB'S TEST) and has been excluded from statistics.
* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
** = Significantly different from Control (P Less Than or Equal to 0.01) using the Dunnett's Test.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 8
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

F E M A L E LIVER

	FN	F1	F2	F3
001	7.700	8.706	8.641	NA
002	8.851	6.124	6.922	NA
003	7.400	6.816	10.199	NA
004	6.533	8.951	6.042	NA
005	6.710	13.010	7.773	4.264
006	7.705	8.841	7.820	NA
007	7.611	7.726	8.068	NA
008	8.814	10.203	7.016	NA
009	9.250	7.644	7.205	NA
010	9.256	8.423	6.463	7.104
011	8.264	13.121	7.109	NA
012	9.989	8.565	10.437	NA
013	10.082	8.948	6.874	NA
014	6.908	9.671	10.897	NA
015	8.951	7.620	7.099	NA
MEAN	8.268	8.945	7.904	5.684
S.E.	0.296	0.511	0.386	1.420
(N)	15	15	15	2

ANALYSIS OF VARIANCE: F = 2.93, P = 0.0443

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
F1	0.6763	1.165	2.43	3.08
F2	-0.3639	-0.627	2.43	3.08
F3	-2.5843	-2.159	2.43	3.08

NA = Indicates organ weight not available because animal did not meet the selection criteria.
NW = No organ weight available for animal.
E = Weight has been identified as an outlier (GRUBB'S TEST) and has been excluded from statistics.
* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
** = Significantly different from Control (P Less Than or Equal to 0.01) using the Dunnett's Test.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 9
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

M A L E SPLEEN

	MN	M1	M2	M3
001	0.664	0.883	0.749	NA
002	0.618	0.751	0.766	NA
003	0.750	0.915	0.670	NA
004	0.895	0.750	0.707	NA
005	0.717	0.730	0.675	NA
006	0.820	0.755	0.812	NA
007	0.639	0.666	0.825	NA
008	0.750	0.616	0.758	NA
009	0.826	0.846	0.667	NA
010	0.819	0.789	0.858	NA
011	0.825	0.797	0.582	NA
012	0.758	0.673	0.570	NA
013	0.641	0.898	0.637	NA
014	0.700	0.718	0.600	NA
015	0.658	0.710	0.728	NA
MEAN	0.739	0.766	0.707	0.000
S.E.	0.022	0.023	0.023	0.000
(N)	15	15	15	0

ANALYSIS OF VARIANCE: F = 1.74, P = 0.1884

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
M1	0.0278	0.870	2.29	2.94
M2	-0.0317	-0.993	2.29	2.94

NOTE: AMONG GROUPS, MEAN SQUARE IS NOT SIGNIFICANTLY GREATER THAN THE ERROR MEAN SQUARE (P>0.05)

NA = Indicates organ weight not available because animal did not meet the selection criteria.
NW = No organ weight available for animal.
E = Weight has been identified as an outlier (GRUBB'S TEST) and has been excluded from statistics.
* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
** = Significantly different from Control (P Less Than or Equal to 0.01) using the Dunnett's Test.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 10
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)

SELECTION CRITERIA: SCHEDULED SACRIFICES

SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

F E M A L E SPLEEN

	FN	F1	F2	F3
001	0.437	0.501	0.411	NA
002	0.395	0.460	0.527	NA
003	0.466	0.461	0.419	NA
004	0.335	0.476	0.460	NA
005	0.359	0.524	0.565	0.211
006	0.521	0.391	0.421	NA
007	0.499	0.526	0.511	NA
008	0.511	0.416	0.523	NA
009	0.404	0.601	0.487	NA
010	0.624	0.503	0.432	0.408
011	0.541	0.606	0.463	NA
012	0.451	0.474	0.485	NA
013	0.423	0.529	0.507	NA
014	0.587	0.597	0.489	NA
015	0.418	0.367	0.400	NA
MEAN	0.465	0.495	0.473	0.310
S.E.	0.021	0.019	0.013	0.098
(N)	15	15	15	2

ANALYSIS OF VARIANCE: F = 4.01, P = 0.0133

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
F1	0.0307	1.174	2.43	3.08
F2	0.0086	0.329	2.43	3.08
F3	-0.1552*	-2.877	2.43	3.08

NA = Indicates organ weight not available because animal did not meet the selection criteria.
NW = No organ weight available for animal.
E = Weight has been identified as an outlier (GRUBB'S TEST) and has been excluded from statistics.
* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
** = Significantly different from Control (P Less Than or Equal to 0.01) using the Dunnett's Test.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 11
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS AT NECROPSY ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

	M A L E TESTES, BOTH			
	MN	M1	M2	M3
001	5.223	6.179	5.451	NA
002	5.810	5.505	5.642	NA
003	6.125	5.734	5.041	NA
004	5.933	5.325	5.121	NA
005	6.419	5.925	5.703	NA
006	4.937	5.683	5.888	NA
007	5.688	5.830	6.915	NA
008	6.326	5.557	6.354	NA
009	5.296	6.101	5.438	NA
010	6.604	5.600	5.793	NA
011	5.604	5.467	6.009	NA
012	6.758	6.713	5.212	NA
013	5.892	6.234	5.748	NA
014	6.346	5.269	5.405	NA
015	5.602	5.820	5.680	NA
MEAN	5.904	5.796	5.693	0.000
S.E.	0.137	0.100	0.125	0.000
(N)	15	15	15	0

ANALYSIS OF VARIANCE: F = 0.75, P = 0.4765

	DUNNETT'S TEST			
	DIFF. FROM	CALCULATED	CRITICAL VALUES	
GROUP	CONTROL	T-VALUES	.05	.01
M1	-0.1081	-0.630	2.29	2.94
M2	-0.2109	-1.228	2.29	2.94

NOTE: AMONG GROUPS, MEAN SQUARE IS NOT SIGNIFICANTLY GREATER THAN THE ERROR MEAN SQUARE (P>0.05)

NA = Indicates organ weight not available because animal did not meet the selection criteria.
NW = No organ weight available for animal.
E = Weight has been identified as an outlier (GRUBB'S TEST) and has been excluded from statistics.
* = Significantly different from Control (P Less Than or Equal to 0.05) using the Dunnett's Test.
** = Significantly different from Control (P Less Than or Equal to 0.01) using the Dunnett's Test.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS RELATIVE TO TERMINAL BODY WEIGHT **
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

	MALE ANIMALS			
	MN	M1	M2	M3
ADRENALS , BOTH				
MEAN %	0.013	0.014	0.013	0.000
S.E.	0.001	0.001	0.001	0.000
(N)	15	15	15	0
P		0.290	0.983	0.000
HEART				
MEAN %	0.328	0.319	0.329	0.000
S.E.	0.008	0.006	0.006	0.000
(N)	15	15	15	0
P		0.395	0.917	0.000
KIDNEYS , BOTH				
MEAN %	0.701	0.676	0.695	0.000
S.E.	0.020	0.010	0.017	0.000
(N)	15	15	15	0
P		0.191	0.494	0.000
LIVER				
MEAN %	3.189	3.139	2.925	0.000
S.E.	0.140	0.116	0.074	0.000
(N)	15	15	15	0
P		0.885	0.165	0.000
SPLEEN				
MEAN %	0.141	0.145	0.152	0.000
S.E.	0.003	0.003	0.004	0.000
(N)	15	15	15	0
P		0.206	0.078	0.000
TESTES , BOTH				
MEAN %	1.132	1.099	1.225	0.000
S.E.	0.029	0.028	0.028	0.000
(N)	15	15	15	0
P		0.221	0.036	0.000

* = Significantly different from Control (P Less Than or Equal to 0.05) using Mann-Whitney Statistic and Bonferroni Inequality

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** ORGAN WEIGHTS RELATIVE TO TERMINAL BODY WEIGHT **
SELECTION CRITERIA: SCHEDULED SACRIFICES
SELECTED SACRIFICE PERIODS
13-DEC-1983 : 3-JAN-1984 :

F E M A L E A N I M A L S

	FN	F1	F2	F3
ADRENALS , BOTH				
MEAN %	0.026	0.030	0.036	0.032
S.E.	0.002	0.001	0.002	0.002
(N)	15	15	15	2
P		0.152	0.001*	0.180
HEART				
MEAN %	0.344	0.346	0.366	0.422
S.E.	0.006	0.009	0.008	0.023
(N)	15	15	15	2
P		0.820	0.054	0.025
KIDNEYS , BOTH				
MEAN %	0.710	0.694	0.747	0.856
S.E.	0.020	0.015	0.022	0.039
(N)	15	15	15	2
P		0.663	0.443	0.037
LIVER				
MEAN %	3.013	3.294	3.232	3.258
S.E.	0.106	0.167	0.179	0.276
(N)	15	15	15	2
P		0.178	0.443	0.297
SPLEEN				
MEAN %	0.169	0.183	0.193	0.175
S.E.	0.006	0.006	0.005	0.028
(N)	15	15	15	2
P		0.120	0.008*	0.766

* = Significantly different from Control (P Less Than or Equal to 0.05) using Mann-Whitney Statistic and Bonferroni Inequality

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **
SELECTION CRITERIA: ALL DEATHS REPORTED

	MALE			
	MN	M1	M2	M3
NO. IN GROUP AT RISK:	15	15	15	15
ADRENALS				
-CONGESTED	0	0	0	1
-ENLARGED	0	0	0	0
CECUM				
-GAS FILLED	0	0	0	0
-DISTENDED WITH GAS	0	0	0	1
COLON				
-IMPACTED	0	0	0	1
-BLOOD IN LUMEN	0	0	0	0
DUODENUM				
-HEMORRHAGE	0	0	0	1
-ABNORMAL CONTENT	0	0	0	3
EYES				
-CORNEAL OPACITY	0	0	0	3
-CONGESTED	0	0	0	1
ILEUM				
-ABNORMAL CONTENT	0	0	0	1
-GAS FILLED	0	0	0	0
-DISTENDED WITH GAS	0	0	0	1
JEJUNUM				
-ABNORMAL CONTENT	0	0	0	3
-FLACCID	0	0	0	1
KIDNEYS				
-DILATED PELVIS (HYDRONEPHROSIS)	0	0	1	0
-CYST(S)	0	0	1	0
LIVER				
-ABNORMAL COLOR	2	2	0	3

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 2
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **
SELECTION CRITERIA: ALL DEATHS REPORTED

	MALE			
	MN	M1	M2	M3
NO. IN GROUP AT RISK:	15	15	15	15
LIVER				
-FOCI	0	0	0	0
LYMPH NODE				
-CONGESTED	0	0	0	1
LUNG				
-ABNORMAL COLOR	0	0	0	4
-ABNORMAL CONSISTENCY	0	0	0	9
-INCOMPLETE COLLAPSE	0	0	0	2
-FOCUS(I)	0	0	0	0
-CONGESTED/RED	0	0	0	4
NOSE/TURBINATES				
-ABNORMAL COLOR	0	0	0	0
-ABNORMAL DISCHARGE	0	0	0	1
-ENCRUSTED	0	0	0	0
SKIN				
-ABNORMAL COLOR	0	0	0	0
SKELETAL MUSCLE				
-ATROPHIC	0	0	0	1
SPLEEN				
-SMALL	0	0	0	6
STOMACH				
-ULCERATED	0	0	0	2
-FOCI	0	0	0	1
-ABNORMAL CONTENT	0	0	0	0
-DISTENDED WITH GAS	0	0	0	1
-EROSIONS	0	0	0	0
SEMINAL VESICLES				
-ATROPHY / SMALL	0	0	0	1

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **
SELECTION CRITERIA: ALL DEATHS REPORTED

	MALE			
	MN	M1	M2	M3
NO. IN GROUP AT RISK:	15	15	15	15
TESTES				
-ABNORMAL COLOR	0	0	0	1
THYMUS				
-ABNORMAL COLOR	0	1	0	0
UTERUS				
-ABNORMAL COLOR	0	0	0	0
-HYDROMETRA	0	0	0	0
GROSS CONDITION				
-EMACIATION	0	0	0	0
-AUTOLYSIS	0	0	0	3
GI TRACT				
-DISTENDED WITH GAS	0	0	0	6
-FLACCID	0	0	0	1
SKIN AND HAIR				
-STAINED	0	0	0	0

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **
SELECTION CRITERIA: ALL DEATHS REPORTED

	---- F E M A L E ----			
	FN	F1	F2	F3
NO. IN GROUP AT RISK:	15	15	15	15
ADRENALS				
-CONGESTED	0	0	0	1
-ENLARGED	0	0	0	1
CECUM				
-GAS FILLED	0	0	0	1
-DISTENDED WITH GAS	0	0	0	0
COLON				
-IMPACTED	0	0	0	1
-BLOOD IN LUMEN	0	0	0	1
DUODENUM				
-HEMORRHAGE	0	0	0	0
-ABNORMAL CONTENT	0	0	0	1
EYES				
-CORNEAL OPACITY	0	0	0	2
-CONGESTED	0	0	0	0
ILEUM				
-ABNORMAL CONTENT	0	0	0	0
-GAS FILLED	0	0	0	1
-DISTENDED WITH GAS	0	0	0	0
JEJUNUM				
-ABNORMAL CONTENT	0	0	0	1
-FLACCID	0	0	0	0
KIDNEYS				
-DILATED PELVIS (HYDRONEPHROSIS)	2	0	0	2
-CYST(S)	0	0	0	0
LIVER				
-ABNORMAL COLOR	2	0	2	0

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 2
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **
SELECTION CRITERIA: ALL DEATHS REPORTED

	---- F E M A L E ----			
	FN	F1	F2	F3
NO. IN GROUP AT RISK:	15	15	15	15
LIVER				
-FOCI	0	0	0	1
LYMPH NODE				
-CONGESTED	0	0	0	0
LUNG				
-ABNORMAL COLOR	0	0	0	2
-ABNORMAL CONSISTENCY	0	0	0	3
-INCOMPLETE COLLAPSE	0	0	0	2
-FOCUS(I)	0	0	0	1
-CONGESTED/RED	0	0	0	5
NOSE/TURBINATES				
-ABNORMAL COLOR	0	0	0	1
-ABNORMAL DISCHARGE	0	0	0	4
-ENCRUSTED	0	0	0	1
SKIN				
-ABNORMAL COLOR	0	0	0	1
SKELETAL MUSCLE				
-ATROPHIC	0	0	0	1
SPLEEN				
-SMALL	0	0	0	0
STOMACH				
-ULCERATED	0	0	0	0
-FOCI	0	0	0	0
-ABNORMAL CONTENT	0	0	0	1
-DISTENDED WITH GAS	0	0	0	0
-EROSIONS	0	0	0	2
SEMINAL VESICLES				
-ATROPHY / SMALL	0	0	0	0

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 3
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **
SELECTION CRITERIA: ALL DEATHS REPORTED

	---- F E M A L E ----			
	FN	F1	F2	F3
NO. IN GROUP AT RISK:	15	15	15	15
TESTES				
-ABNORMAL COLOR	0	0	0	0
THYMUS				
-ABNORMAL COLOR	0	0	0	0
UTERUS				
-ABNORMAL COLOR	0	0	0	1
-HYDROMETRA	5	2	1	0
GROSS CONDITION				
-EMACIATION	0	0	0	1
-AUTOLYSIS	0	0	0	0
GI TRACT				
-DISTENDED WITH GAS	0	0	0	6
-FLACCID	0	0	0	0
SKIN AND HAIR				
-STAINED	0	0	0	1

THIS REPORT GENERATED FROM DATA LOCKED THRU 15-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1

P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***

SELECTION CRITERIA: ALL DEATHS REPORTED

T I S S U E S W I T H F I N D I N G S	ANIMAL SEX :	NUMBER OF ANIMALS AFFECTED — MALES			
	DOSAGE GROUP:	MN	M1	M2	M3
	NO. IN GROUP:	15	15	15	15
ADRENALS		(0)	(0)	(0)	(1)
-CONGESTION					1
BONE MARROW					
-MYELOID HYPOPLASIA		0	0	0	1
-HYPOPLASIA		0	0	0	9 **
BRAIN			(0)	(0)	
-CONGESTION		0			2
-HEMORRHAGE		0			1
-MENINGES, MONONUCLEAR CELL INFILTRATE		0			1
BONE					
-INCREASED PIGMENT DEPOSITION		0	0	0	6
CECUM		(0)	(0)	(0)	(0)
COLON		(0)	(0)	(0)	(14)
-AUTOLYSIS, CANNOT EVALUATE					4
-NECROSIS SUPERFICIAL EPITHELIUM					1
DUODENUM		(0)	(0)	(0)	(13)
-CONGESTION					1
-AUTOLYSIS, CANNOT EVALUATE					7
-ENTERITIS, SUBACUTE					1
EPIDIDYMIDES			(0)	(0)	
-HYPOSPERMIA		0			2
ESOPHAGUS			(0)	(0)	(0)
EYES					
-KERATITIS, NEUTROPHILIC		0	0	0	7 **
-CORNEAL VASCULARIZATION		0	0	0	6
-PHTHISIS		0	0	0	1
-CORNEAL ULCERATION		0	0	0	4
-UVEITIS, PURULENT		0	0	0	2
-POSTERIOR SYNECHIA		0	0	0	1
-INADEQUATE FOR EVALUATION		0	0	0	1

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 2
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***

SELECTION CRITERIA: ALL DEATHS REPORTED

T I S S U E S W I T H F I N D I N G S	ANIMAL SEX :	----- N U M B E R O F A N I M A L S A F F E C T E D ----- M A L E S			
	DOSAGE GROUP:	MN	M1	M2	M3
	NO. IN GROUP:	15	15	15	15
EYES					
HEART			(0)	(0)	
-MYOCARDIAL DEGENERATION		2			2
-INFLAMMATORY CELL INFILTRATION/MYOCARDITIS		3			0
-MINERALIZATION		0			1
-FIBROSIS		0			1
-CONGESTION		0			1
ILEUM		(0)	(0)	(0)	(14)
-CONGESTION					1
-GOBLET CELL HYPERPLASIA					2
-AUTOLYSIS, CANNOT EVALUATE					10
JEJUNUM		(0)	(0)	(0)	(12)
-CONGESTION					1
-GOBLET CELL HYPERPLASIA					1
-AUTOLYSIS CANNOT EVALUATE					9
KIDNEYS			(0)	(1)	
-NEPHROPATHY		1		0	0
-MONONUCLEAR CELLULAR INFILTRATION(CHRONIC INTERSTITIAL NEPHRITIS		4		0	0
-TUBULAR EPITHELIAL REGENERATION		4		0	0
-HYDRONEPHROSIS (UNI- OR BI- LATERAL)		0		1	1
-CONGESTION		0		0	9 **
-TUBULAR VACUOLIZATION		0		0	1
LIVER					
-MONONUCLEAR CELL INFILTRATION (RANDOM)		6	11	12	0
-CENTRILOBULAR VACUOLIZATION		4	2	0	0
-PERICHOLANGITIS		1	0	0	0
-HEPATOCELLULAR DEGENERATION, CENTRILOBULAR		1	0	0	0
-CONGESTION		0	0	0	12 **
-NECROSIS, CENTRILOBULAR		0	0	0	7 **
-FIBROSIS		0	0	0	1
-INLFLAMMATION WITH NECROSIS		0	0	1	0
LUNG					
-EXCESSIVE MUCOUS SECRETION		0	0	0	9 **

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 3
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***

SELECTION CRITERIA: ALL DEATHS REPORTED

T I S S U E S W I T H F I N D I N G S	ANIMAL SEX :	----- N U M B E R O F A N I M A L S A F F E C T E D ----- M A L E S -----				
	DOSAGE GROUP:	MN	M1	M2	M3	
	NO. IN GROUP:	15	15	15	15	
LUNG						
-BRONCHI, EPITHELIAL DEGENERATION/NECROSIS		0	0	0	5	
-BRONCHI/BRONCHIOLES, METAPLASIA		0	0	0	10	**
-CONGESTION		0	0	0	6	
-HEMORRHAGE		0	0	0	2	
-INTERSTITIAL INFILTRATION / PNEUMONIA		0	0	0	1	
-MONONUCLEAR CELL INFILTRATE		0	0	0	1	
-HEMOGLOBIN CRYSTALS, INTRAALVEOLAR/INTRAVASCULAR		0	0	0	1	
-EDEMA		0	0	0	1	
-BRONCHITIS/BRONCHIOLITIS, PURULENT		0	0	0	2	
-BRONCHI/BRONCHIOLES, ULCERATION		0	0	0	5	
-BRONCHI/BRONCHIOLES, FIBROSIS		0	0	0	2	
-PNEUMONIA, PURULENT		0	0	0	1	
-BRONCHI, POLYPOID HYPERPLASIA		0	0	0	1	
-PERIVASCULAR LYMPHOID INFILTRATE		0	0	1	0	
NOSE/TURBINATES						
-SUBACUTE INFLAMMATION		1	5	2	0	
-RHINITIS, PURULENT/MUCOPURULENT		0	2	6	15	**
-EPITHELIAL DEGENERATION/NECROSIS		0	1	1	11	**
-METAPLASIA		0	1	15	**15	**
-EPITHELIAL HYPERPLASIA		0	4	6	1	
-HYPERKERATOSIS		0	0	0	2	
-ULCERATION		0	0	0	8	**
-DYSPLASIA		0	0	0	1	
-NASOPALATINE DUCT, METAPLASIA		0	0	0	7	**
-NASOPALATINE DUCT, HYPERKERATOSIS		0	0	0	5	
-NASOPALATINE DUCT, PURULENT INFLAMMATION		0	0	0	6	
SPLEEN						
-LYMPHOID ATROPHY / DEPLETION		0	0	0	15	**
-CONGESTION		0	0	0	1	
-HEMATOPOIESIS, EXCESSIVE AND/OR UNEXPECTED		0	0	0	1	
STOMACH		(0)				
-NONGLANDULAR AREA, HEMORRHAGE			0	0	2	
-FUNDUS, NECROSIS			0	0	2	
-AUTOLYSIS, CANNOT EVALUATE			0	0	3	
-SUBMUCOSA, INFLAMMATION, ACUTE			0	0	1	

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***
SELECTION CRITERIA: ALL DEATHS REPORTED

T I S S U E S W I T H F I N D I N G S	ANIMAL SEX :	NUMBER OF ANIMALS AFFECTED				
	DOSAGE GROUP:	MALES				
	NO. IN GROUP:	MN 15	M1 15	M2 15	M3 15	
STOMACH		(0)				
-MUCOSAL ULCERATION			0	0	1	
-EROSION(S)			0	0	1	
-HEMORRHAGE			0	0	1	
-SUBMUCOSA, EPIDERMAL CYST			1	0	0	
SEMINAL VESICLES		(0)	(0)	(0)	(1)	
-HYPOSECRETION					1	
TESTES			(0)	(0)		
-SEMINIFEROUS TUBULES, DEGENERATION		1			1	
-HEMORRHAGE		0			1	
TRACHEA						
-MONONUCLEAR CELLULAR INFILTRATION / CHRONIC TRACHEITIS		1	0	0	1	
-EPITHELIUM, METAPLASIA		0	0	0	8	**
-HYPERPLASIA, SURFACE AND/OR GLANDULAR EPITHELIUM		0	0	0	2	
-PURULENT/MUCOPURULENT TRACHEITIS		0	0	0	3	
-EPITHELIAL DEGENERATION		0	0	0	5	
-GLANDULAR HYPERPLASIA		0	0	0	2	
-FIBROSIS		0	0	0	1	
-TRACHEITIS, ACUTE, ULCERATIVE		0	0	0	3	
-TRACHEITIS, CHRONIC ACTIVE WITH ULCERATION		0	0	0	3	
-POLYPOID MUCOSAL HYPERPLASIA		0	0	0	2	
-ARTERY, MEDIAL HYPERTROPHY/DEGENERATION		0	0	0	1	
-TRACHEITIS, CHRONIC ACTIVE		0	0	0	1	
URINARY BLADDER			(0)	(0)		
-TRANSITIONAL EPITHELIUM, EOSINOPHILIC CYTOPLASMIC GLOBULES		1			0	
-EPITHELIUM LOST IN PROCESSING		0			1	
OPTIC NERVE		(14)	(0)	(0)	(14)	
-GLIOSIS		0			1	

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 5

P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***

SELECTION CRITERIA: ALL DEATHS REPORTED

T I S S U E S W I T H F I N D I N G S	ANIMAL SEX :	----- N U M B E R O F A N I M A L S A F F E C T E D ----- F E M A L E S			
	DOSAGE GROUP:	FN	F1	F2	F3
	NO. IN GROUP:	15	15	15	15
ADRENALS		(Ø)	(Ø)	(Ø)	(1)
-CONGESTION					1
BONE MARROW					
-HYPOPLASIA		Ø	Ø	Ø	4
BRAIN			(Ø)	(Ø)	
-CONGESTION		Ø			2
-HEMORRHAGE		Ø			1
BONE					
-OSSEOUS CLOSURE OF EPIPHYSEAL PLATE		Ø	Ø	Ø	1
CECUM		(Ø)	(Ø)	(Ø)	(3)
-AUTOLYSIS CANNOT EVALUATE					2
COLON		(Ø)	(Ø)	(Ø)	
-AUTOLYSIS, CANNOT EVALUATE					8
DUODENUM		(Ø)	(Ø)	(Ø)	(14)
-AUTOLYSIS, CANNOT EVALUATE					5
-GOBLET CELL HYPERPLASIA					1
ESOPHAGUS			(Ø)	(Ø)	
-DEGENERATION		Ø			1
EYES					
-KERATITIS, NEUTROPHILIC		Ø	Ø	Ø	6
-CORNEAL VASCULARIZATION		Ø	Ø	Ø	3
-CORNEAL ULCERATION		Ø	Ø	Ø	3
-UVEITIS, PURULENT		Ø	Ø	Ø	1
-INADEQUATE FOR EVALUATION		Ø	Ø	Ø	4
-ANTERIOR CHAMBER, PURULENT EXUDATE		Ø	Ø	Ø	2
-AUTOLYSIS, CANNOT EVALUATE		Ø	Ø	Ø	1
-MINERALIZATION, CORNEA		Ø	Ø	Ø	1
HEART			(Ø)	(Ø)	
-MYOCARDIAL DEGENERATION		Ø			1
-INFLAMMATORY CELL INFILTRATION/MYOCARDITIS		2			Ø

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***

SELECTION CRITERIA: ALL DEATHS REPORTED

T I S S U E S W I T H F I N D I N G S	ANIMAL SEX : FEMALES DOSAGE GROUP: FN NO. IN GROUP: 15	F1 15	F2 15	F3 15	
	NUMBER OF ANIMALS AFFECTED				
HEART		(0)	(0)		
ILEUM	(0)	(0)	(0)	(14)	
-AUTOLYSIS, CANNOT EVALUATE				10	
JEJUNUM	(0)	(0)	(0)	(10)	
-GOBLET CELL HYPERPLASIA				1	
-AUTOLYSIS CANNOT EVALUATE				8	
KIDNEYS		(0)	(0)		
-MONONUCLEAR CELLULAR INFILTRATION(CHRONIC INTERSTITIAL NEPHRITIS	1			0	
-TUBULAR EPITHELIAL REGENERATION	0			1	
-HYDRONEPHROSIS (UNI- OR BI- LATERAL)	2			2	
-CONGESTION	0			7	**
-MINERALIZATION/MICROCALCULUS	1			0	
-PYELONEPHRITIS	0			1	
LIVER					
-MONONUCLEAR CELL INFILTRATION (RANDOM)	8	9	7	1	
-CENTRILOBULAR VACUOLIZATION	3	1	1	0	
-HEPATOCELLULAR DEGENERATION, CENTRILOBULAR	1	0	0	0	
-CONGESTION	0	0	0	10	**
-NECROSIS, CENTRILOBULAR	0	0	0	1	
-HEMORRHAGE	0	0	0	2	
-HEMATOPOIESIS, EXTRAMEDULLARY	0	0	0	1	
-NECROSIS	0	0	0	2	
-HEPATOCELLULAR VACUOLIZATION	0	1	1	0	
LUNG					
-EXCESSIVE MUCOUS SECRETION	0	0	0	9	**
-BRONCHI, EPITHELIAL DEGENERATION/NECROSIS	0	0	0	7	**
-BRONCHI/BRONCHIOLES, METAPLASIA	0	0	0	10	**
-CONGESTION	0	0	0	8	**
-INTERSTITIAL INFILTRATION / PNEUMONIA	0	0	0	2	
-EDEMA	0	0	0	2	
-BRONCHITIS/BRONCHIOLITIS, PURULENT	0	0	0	7	**
-BRONCHI/BRONCHIOLES, ULCERATION	0	0	0	8	**
-BRONCHI/BRONCHIOLES, FIBROSIS	0	0	0	2	
-PNEUMONIA, PURULENT	0	0	0	4	

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***

SELECTION CRITERIA: ALL DEATHS REPORTED

TISSUES WITH FINDINGS	ANIMAL SEX :	NUMBER OF ANIMALS AFFECTED				
		FEMALES				
	DOSAGE GROUP:	FN	F1	F2	F3	
	NO. IN GROUP:	15	15	15	15	
LUNG						
-BRONCHI, POLYPOID HYPERPLASIA		0	0	0	1	
-EMPHYSEMA		0	0	0	2	
-ALVEOLAR MACROPHAGE ACCUMULATIONS		0	0	0	1	
-GRANULOMA		0	0	0	1	
-MINERALIZATION		0	0	0	1	
NOSE/TURBINATES		(14)	(13)		(13)	
-SUBACUTE INFLAMMATION		0	3	1	0	
-RHINITIS, PURULENT/MUCOPURULENT		0	1	3	13	**
-EPITHELIAL DEGENERATION/NECROSIS		0	0	1	12	**
-METAPLASIA		0	0	13	**13	**
-EPITHELIAL HYPERPLASIA		0	1	3	1	
-ULCERATION		0	0	0	8	**
-HEMORRHAGE		0	0	0	1	
-NASOPALATINE DUCT, METAPLASIA		0	0	0	9	**
-NASOPALATINE DUCT, HYPERKERATOSIS		0	0	0	6	
-NASOPALATINE DUCT, PURULENT INFLAMMATION		0	0	0	6	
-NASOPALATINE DUCT, ULCERATION		0	0	0	2	
-SEROUS FLUID		0	1	0	0	
OVARIES			(0)	(0)		
-LEUTEAL CYST		1			0	
-CONGESTION		0			1	
SPLEEN						
-LYMPHOID ATROPHY / DEPLETION		0	0	0	13	**
-CONGESTION		0	0	0	3	
-PRESENCE OF EXCESSIVE HEMOSIDERIN		0	1	0	0	
STOMACH		(0)				
-NONGLANDULAR AREA, HEMORRHAGE			0	0	1	
-FUNDUS, NECROSIS			0	0	3	
-AUTOLYSIS, CANNOT EVALUATE			0	0	1	
-HEMORRHAGE			0	0	1	
-CONGESTION			0	0	1	
-MUCOSA, INFLAMMATION, ACUTE			0	0	1	
TRACHEA						
-MONONUCLEAR CELLULAR INFILTRATION / CHRONIC TRACHEITIS		0	2	0	1	

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 8
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***

SELECTION CRITERIA: ALL DEATHS REPORTED

T I S S U E S W I T H F I N D I N G S	ANIMAL SEX : DOSAGE GROUP: NO. IN GROUP:	NUMBER OF ANIMALS AFFECTED — FEMALES FN 15	F1 15	F2 15	F3 15	
TRACHEA						
-EPITHELIUM, METAPLASIA		Ø	Ø	Ø	7	**
-HYPERPLASIA, SURFACE AND/OR GLANDULAR EPITHELIUM		Ø	Ø	Ø	1	
-PURULENT/MUCOPURULENT TRACHEITIS		Ø	Ø	Ø	1	
-EPITHELIAL DEGENERATION		Ø	Ø	Ø	3	
-GLANDULAR HYPERPLASIA		Ø	Ø	Ø	4	
-TRACHEITIS, ACUTE, ULCERATIVE		Ø	Ø	Ø	3	
-TRACHEITIS, CHRONIC ACTIVE WITH ULCERATION		Ø	Ø	Ø	6	
-TRACHEITIS, CHRONIC ACTIVE		Ø	Ø	Ø	1	
-GLANDULAR DILATATION		Ø	Ø	Ø	1	
-ULCERATION		Ø	Ø	Ø	1	
-TRACHEITIS, CHRONIC		Ø	Ø	Ø	1	
URINARY BLADDER			(Ø)	(Ø)	(14)	
UTERUS		(5)	(2)	(1)	(2)	
-DILATATION OF THE UTERINE LUMEN (HYDROMETRA)		5	2	1	Ø	
OPTIC NERVE		(14)	(Ø)	(Ø)	(13)	
-GLIOSIS		Ø			1	

NOTE: A NUMBER IN PARENTHESES OPPOSITE A TISSUE NAME INDICATES THE TOTAL NUMBER EXAMINED WHEN LESS THAN THE NUMBER OF ANIMALS IN THE GROUP.

** = SIGNIFICANTLY DIFFERENT [P LESS THAN OR EQUAL TO Ø.Ø1] FROM CONTROL USING FISHER'S EXACT TEST WITH THE BONFERRONI INEQUALITY.

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: NO SUBSTANCE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	MALE NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
BONE MARROW		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIDES		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
ESOPHAGUS		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYES		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HEART		N	N	F	F	N	N	N	F	N	F	N	N	N	N	N
--MYOCARDIAL DEGENERATION				1	1											
--INFLAMMATORY CELL INFILTRATION/MYOCARDITIS					(1				1		(1					
KIDNEYS		N	N	F	F	N	N	N	N	N	F	N	F	F	F	F
--NEPHROPATHY				2												
--MONONUCLEAR CELLULAR INFILTRATION(CHRONIC INTERSTITIAL NEPHRITIS					1						(1		1	(1		
--TUBULAR EPITHELIAL REGENERATION											(2			(1	1	1
LIVER		N	N	N	F	F	F	F	N	F	N	F	F	F	F	F
--MONONUCLEAR CELL INFILTRATION (RANDOM)					(1		(1	(1				(1	(1		(1	
--CENTRILOBULAR VACUOLIZATION						(1)						(1)		(2)		(1)
--PERICHOLANGITIS										(1						
--HEPATOCELLULAR DEGENERATION, CENTRILOBULAR														(1		
LUNG		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
NOSE/TURBINATES		N	N	N	N	N	N	N	N	N	N	N	N	F	N	N
--SUBACUTE INFLAMMATION														1		
OVARIES																
PARATHYROIDS		N	N	N	N	N	N	N	N	N	N	N	N	N	*	N
SPLEEN		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTES		F	N	N	N	N	N	N	N	N	N	N	N	N	N	N
--SEMINIFEROUS TUBULES, DEGENERATION		1														

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 2
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: NO SUBSTANCE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	MALE NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
THYROIDS		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA		N	N	N	N	N	N	N	N	N	F (2)	N	N	N	N	N
--MONONUCLEAR CELLULAR INFILTRATION / CHRONIC TRACHEITIS																
URINARY BLADDER		N	N	N	N	N	N	N	N	N	N	N	N	N	N	F (1
--TRANSITIONAL EPITHELIUM, EOSINOPHILIC CYTOPLASMIC GLOBULES																
OPTIC NERVE		N	N	*	N	N	N	N	N	N	N	N	N	N	N	N

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 3
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	1	1	1	1	1	1	1	1	1	1	1	1	1	1
			2		4		6		8		10		12		14	
	MALE NUMBERS :	1		3		5		7		9		11		13		15
BONE MARROW		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN																
BONE		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIDES																
EYES		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HEART																
KIDNEYS																
LIVER		F	F	N	F	N	F	F	F	F	F	F	N	F	F	F
--MONONUCLEAR CELL INFILTRATION (RANDOM)		(1	(1		(2		(1	(1	(1	(1	(1			(1	(1	(1
--CENTRILOBULAR VACUOLIZATION												(1		(2)		
LUNG		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
NOSE/TURBINATES		N	F	N	F	N	F	N	N	N	F	N	N	F	N	F
--SUBACUTE INFLAMMATION			(1		1		(1							(1		(2
--RHINITIS, PURULENT/MUCOPURULENT											(1					(2
--EPITHELIAL DEGENERATION/NECROSIS																(1
--METAPLASIA											(1					
--EPITHELIAL HYPERPLASIA					1		(1				(1			(2		
OVARIES																
PARATHYROIDS																
SPLEEN		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
STOMACH		N	N	F	N	N	N	N	N	N	N	N	N	N	N	N
--SUBMUCOSA, EPIDERMAL CYST				P												
TESTES																
THYROIDS																
TRACHEA		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

THIS REPORT GENERATED FROM DATA LOCKED THRU 15-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 4

P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	MALE NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
URINARY BLADDER																

Table 9 Appendix 1 PAGE 62
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STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 5

P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	MALE NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
BONE MARROW		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIDES																
EYES		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HEART																
KIDNEYS																
--HYDRONEPHROSIS (UNI- OR BI- LATERAL)										F 3						
LIVER		N	N	F	F	F	F	F	F	F	F	F	F	N	F	F
--MONONUCLEAR CELL INFILTRATION (RANDOM)				(1	(1	(2	(1	(1	(1	(1	(1	(1	(1		(1	(1
--INLFLAMMATION WITH NECROSIS						(2										
LUNG		N	N	N	N	F	N	N	N	N	N	N	N	N	N	N
--PERIVASCULAR LYMPHOID INFILTRATE						1										
NOSE/TURBINATES		F	F	F	F	F	F	F	F	F	F	F	F	F	F	F
--SUBACUTE INFLAMMATION			(2						(1							
--RHINITIS, PURULENT/MUCOPURULENT					2					(1	1			(2	(1	1
--EPITHELIAL DEGENERATION/NECROSIS					(1											
--METAPLASIA		(2	(2	(2	(2	(3	(2	(2	(3	(2	(2	(2	(2	(2	(2	(2
--EPITHELIAL HYPERPLASIA			(3		(2					(1				(2	(2	(1
OVARIES																
PARATHYROIDS																
SPLEEN		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
STOMACH		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTES																
THYROIDS																

THIS REPORT GENERATED FROM DATA LOCKED THRU 15-JAN-87

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 6
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	MALE NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
TRACHEA		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
URINARY BLADDER																

Table 9 Appendix 1 PAGE 64
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STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 7

P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
			2		4		6		8		10		12		14	
	MALE NUMBERS :	1		3		5		7		9		11		13		15
ADRENALS																
--CONGESTION													F 1			
BONE MARROW		N	F	F	N	F	N	N	F	N	F	F	F	F	F	F
--MYELOID HYPOPLASIA				2												
--HYPOPLASIA			1			2			3		2	2	2	1	2	1
BRAIN		N	N	F	N	N	F	N	N	N	N	N	N	F	N	N
--CONGESTION				(2			(1)									
--HEMORRHAGE				(1												
--MENINGES, MONONUCLEAR CELL INFILTRATE														1		
BONE		N	F	F	N	N	N	F	N	N	F	F	N	N	N	F
--INCREASED PIGMENT DEPOSITION			(2	(2				(2			(2	(2				(3
COLON		N	N	N	N	F	N	F	F	*	F	N	N	N	F	N
--AUTOLYSIS, CANNOT EVALUATE						P		P	P						P	
--NECROSIS SUPERFICIAL EPITHELIUM											(1)					
DUODENUM		F	F	F	F	F	F	F	N	*	F	N	N	N	F	*
--CONGESTION					(1)											
--AUTOLYSIS, CANNOT EVALUATE		P	P	P		P		P			P				P	
--ENTERITIS, SUBACUTE							(1									
EPIDIDYMIDES		N	N	F	N	F	N	N	N	N	N	N	N	N	N	N
--HYPOSPERMIA				2		1										
EYES		N	F	N	F	F	F	F	F	F	F	F	N	F	F	N
--KERATITIS, NEUTROPHILIC			2		(2)	2			1	1	(3)			2	2	
--CORNEAL VASCULARIZATION			3			2			2			2		2		
--PHTHISIS			3													
--CORNEAL ULCERATION					1	2					3				2	
--UVEITIS, PURULENT					1										(2	
--POSTERIOR SYNECHIA							P									
--INADEQUATE FOR EVALUATION								P								
HEART		N	N	F	N	N	N	F	F	N	N	N	N	F	N	N
--MYOCARDIAL DEGENERATION								(1	(1							
--MINERALIZATION				(1												
--FIBROSIS									(1							

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 8
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / FINDINGS	COMPOUND DOSAGE GROUP :	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
			2		4		6		8		10		12		14	
	MALE NUMBERS :	1		3		5		7		9		11		13		15
HEART		N	N	F	N	N	N	F	F	N	N	N	N	F	N	N
--CONGESTION														(2		
ILEUM		F	F	F	F	F	N	F	F	*	F	F	N	F	F	F
--CONGESTION					1											
--GOBLET CELL HYPERPLASIA					1											1
--AUTOLYSIS, CANNOT EVALUATE		P	P	P		P		P	P		P	P		P	P	
JEJUNUM		F	F	*	F	F	N	F	F	*	F	F	N	F	F	*
--CONGESTION					2											
--GOBLET CELL HYPERPLASIA					1											
--AUTOLYSIS CANNOT EVALUATE		P	P			P		P	P		P	P		P	P	
KIDNEYS		F	F	F	F	N	F	N	F	F	F	F	N	N	F	N
--HYDRONEPHROSIS (UNI- OR BI- LATERAL)		(1														
--CONGESTION			(3)	(2)	(2)		(1)		(1)	(1)	(1)	(2)			(1)	
--TUBULAR VACUOLIZATION										(1						
LIVER		F	F	F	F	F	F	F	N	F	F	F	F	F	F	F
--CONGESTION		(2)	(2)	(2)	(2)	(4)	(2)	(1)		(3)	(3)	(4)		(2)	(1)	
--NECROSIS, CENTRILOBULAR				(3	(1			(3			(1		(1		(3	(2
--FIBROSIS													1			
LUNG		N	F	F	F	F	F	F	F	F	F	F	F	F	F	F
--EXCESSIVE MUCOUS SECRETION			(2	(3	(2		(3	(1	(2		(2	(3				(1
--BRONCHI, EPITHELIAL DEGENERATION/NECROSIS				(2		(2	(2	(2							(3	
--BRONCHI/BRONCHIOLES, METAPLASIA				(2	(2		(2		(1	(1		(3	(2	(2	(3	(2
--CONGESTION				(3)			(2)	(2)	(2)	(2		(3)				
--HEMORRHAGE				(2			(2									
--INTERSTITIAL INFILTRATION / PNEUMONIA					1											
--MONONUCLEAR CELL INFILTRATE						(2										
--HEMOGLOBIN CRYSTALS, INTRAALVEOLAR/INTRAVASCULAR						(3										
--EDEMA								(1								
--BRONCHITIS/BRONCHIOLITIS, PURULENT									(2			(2				
--BRONCHI/BRONCHIOLES, ULCERATION											(2	(3	(3	2	(3	
--BRONCHI/BRONCHIOLES, FIBROSIS													1	1		
--PNEUMONIA, PURULENT															3	
--BRONCHI, POLYPOID HYPERPLASIA																(3
NOSE/TURBINATES		F	F	F	F	F	F	F	F	F	F	F	F	F	F	F

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 9
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
			2		4		6		8		10		12		14	
	MALE NUMBERS :	1		3		5		7		9		11		13		15
NOSE/TURBINATES		F	F	F	F	F	F	F	F	F	F	F	F	F	F	F
--RHINITIS, PURULENT/MUCOPURULENT		(2	(3	(2	(2	(2	(3	(3	(2	(2	(3	(2	(2	(2	(2	(2
--EPITHELIAL DEGENERATION/NECROSIS		(3	(3	(2	(1	(2	(2	(3		(2				(3	(3	(2
--METAPLASIA		(2	(2	(2	(2	(3	(3	(3	(3	(3	(2	(3	(2	(3	(3	(3
--EPITHELIAL HYPERPLASIA			(2													
--HYPERKERATOSIS			3			4										
--ULCERATION				(3	(2			(3	(2		(2	(2		(3	(3	
--DYSPLASIA					(1											
--NASOPALATINE DUCT, METAPLASIA							(3)	3	(2)	(3)				3	(2)	(3)
--NASOPALATINE DUCT, HYPERKERATOSIS							4		1	4				1		(3
--NASOPALATINE DUCT, PURULENT INFLAMMATION							3	3	2					3	1	1
OVARIES																
PARATHYROIDS		N	N	N	N	N	*	N	N	N	N	N	N	N	N	N
SKELETAL MUSCLE						N										
SPLEEN		F	F	F	F	F	F	F	F	F	F	F	F	F	F	F
--LYMPHOID ATROPHY / DEPLETION		(3)	(3)	(3)	(2)	(4)	(4)	(3)	(4)	(3)	(4)	(1)	(2)	(2)	(3)	(3)
--CONGESTION				2												
--HEMATOPOIESIS, EXCESSIVE AND/OR UNEXPECTED					(2)											
STOMACH		N	F	F	N	F	N	N	F	N	N	N	F	N	F	N
--NONGLANDULAR AREA, HEMORRHAGE			(4)										(2)			
--FUNDUS, NECROSIS			(2	1												
--AUTOLYSIS, CANNOT EVALUATE						P			P						P	
--SUBMUCOSA, INFLAMMATION, ACUTE													3			
--MUCOSAL ULCERATION													(1			
--EROSION(S)			(1													
--HEMORRHAGE			(1													
SEMINAL VESICLES									F							
--HYPOSECRETION									P							
TESTES		N	N	F	N	N	N	N	N	N	N	N	N	N	N	N
--SEMINIFEROUS TUBULES, DEGENERATION				(1												
--HEMORRHAGE				(3												
THYROIDS		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 10
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

MALE

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
TRACHEA		F	F	F	F	F	F	F	F	F	F	F	F	F	F	F
--MONONUCLEAR CELLULAR INFILTRATION / CHRONIC TRACHEITIS		(1														
--EPITHELIUM, METAPLASIA		2	(3)	2			(3)		(3)	(3)		(3)				3
--HYPERPLASIA, SURFACE AND/OR GLANDULAR EPITHELIUM			(3)											2		
--PURULENT/MUCOPURULENT TRACHEITIS				(3	2		1									
--EPITHELIAL DEGENERATION				(3)	(4)	(2)	2						(3)			
--GLANDULAR HYPERPLASIA					2					3						
--FIBROSIS							2									
--TRACHEITIS, ACUTE, ULCERATIVE								(3)							(3)	2
--TRACHEITIS, CHRONIC ACTIVE WITH ULCERATION									(2		(4)			(4)		
--POLYPOID MUCOSAL HYPERPLASIA									1	1						
--ARTERY, MEDIAL HYPERTROPHY/DEGENERATION										2						
--TRACHEITIS, CHRONIC ACTIVE												(3)				
URINARY BLADDER		N	N	N	N	N	N	N	N	N	N	N	N	N	F	N
--EPITHELIUM LOST IN PROCESSING															P	
OPTIC NERVE		N	N	N	N	N	N	*	N	N	N	N	N	F	N	N
--GLIOSIS														1		

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 11
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: NO SUBSTANCE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	FEMALE NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
BONE MARROW		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIDES																
ESOPHAGUS		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EYES		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HEART																
--INFLAMMATORY CELL INFILTRATION/MYOCARDITIS		N	N	N	N	N	N	F 1	N	N	F 1	N	N	N	N	N
KIDNEYS		N	F	N	N	N	N	F	N	N	N	N	F (1	N	N	N
--MONONUCLEAR CELLULAR INFILTRATION(CHRONIC INTERSTITIAL NEPHRITIS																
--HYDRONEPHROSIS (UNI- OR BI- LATERAL)								(3					3			
--MINERALIZATION/MICROCALCULUS			1													
LIVER		N	F	N	N	F	F	N	F	N	F	F	F	F	F	F
--MONONUCLEAR CELL INFILTRATION (RANDOM)			(1			(1	(1		(1		(2	(1	(1	(1	(1	(1
--CENTRILOBULAR VACUOLIZATION														(1		
--HEPATOCELLULAR DEGENERATION, CENTRILOBULAR														(1		
LUNG		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
NOSE/TURBINATES		N	N	*	N	N	N	N	N	N	N	N	N	N	N	N
OVARIES		N	N	N	N	N	N	N	N	N	N	F	N	N	N	N
--LEUTEAL CYST												P				
PARATHYROIDS		N	N	N	N	N	*	N	N	N	N	N	N	N	N	N
SPLEEN		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTES																
THYROIDS		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 12

P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: NO SUBSTANCE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
	FEMALE NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
URINARY BLADDER		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
UTERUS																
--DILATATION OF THE UTERINE LUMEN (HYDROMETRA)					F 1		F 1			F 1			F 1			F 3
OPTIC NERVE		N	N	N	*	N	N	N	N	N	N	N	N	N	N	N

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 13
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	1	1	1	1	1	1	1	1	1	1	1	1	1	1
			2		4		6		8		10		12		14	
	FEMALE NUMBERS :	1		3		5		7		9		11		13		15
BONE MARROW		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN																
BONE		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIDES																
EYES		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HEART																
KIDNEYS																
LIVER		N	F	F	N	F	N	F	N	F	F	F	F	F	F	F
--MONONUCLEAR CELL INFILTRATION (RANDOM)			(1	(1				(1		(1	(1		(1	(1	(1	(1
--CENTRILOBULAR VACUOLIZATION						(1)						(2)				
--HEPATOCELLULAR VACUOLIZATION																
LUNG		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
NOSE/TURBINATES		*	F	N	N	N	F	*	N	F	F	N	N	N	N	F
--SUBACUTE INFLAMMATION										(1	(1					1
--RHINITIS, PURULENT/MUCOPURULENT							1									
--EPITHELIAL HYPERPLASIA																1
--SEROUS FLUID			1													
OVARIES																
PARATHYROIDS																
SPLEEN		N	N	F	N	N	N	N	N	N	N	N	N	N	N	N
--PRESENCE OF EXCESSIVE HEMOSIDERIN				(1)												
STOMACH		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTES																
THYROIDS																
TRACHEA		N	N	N	F	N	N	F	N	N	N	N	N	N	N	N

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****

P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	1	1 2	1 3	1 4	1 5	1 6	1 7	1 8	1 9	1 10	1 11	1 12	1 13	1 14	1 15
	FEMALE NUMBERS :	1		3		5		7		9		11		13		15
TRACHEA		N	N	N	F 1	N	N	F 1	N	N	N	N	N	N	N	N
--MONONUCLEAR CELLULAR INFILTRATION / CHRONIC TRACHEITIS																
URINARY BLADDER																
UTERUS					F 3							F 2				
--DILATATION OF THE UTERINE LUMEN (HYDROMETRA)																

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 15
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / FINDINGS	COMPOUND DOSAGE GROUP :	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	FEMALE NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
BONE MARROW		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BRAIN																
BONE		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EPIDIDYMIDES																
EYES		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
HEART																
KIDNEYS																
LIVER		F	F	F	F	N	N	F	F	N	F	N	F	F	N	N
--MONONUCLEAR CELL INFILTRATION (RANDOM)		(1	(1		(1			(1	(1		(1			(1		
--CENTRILOBULAR VACUOLIZATION													(2			
--HEPATOCELLULAR VACUOLIZATION				(2)												
LUNG		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
NOSE/TURBINATES		F	F	F	N	F	F	F	N	F	F	F	F	F	F	F
--SUBACUTE INFLAMMATION						(1										
--RHINITIS, PURULENT/MUCOPURULENT				(1				(1						(1		
--EPITHELIAL DEGENERATION/NECROSIS			(1													
--METAPLASIA		(2	(2	(2		(1	(2	(2		(2	(1	(2	(2	(2	(2	(2
--EPITHELIAL HYPERPLASIA							(1	(1						(2		
OVARIES																
PARATHYROIDS																
SPLEEN		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
STOMACH		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TESTES																
THYROIDS																
TRACHEA		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	FEMALE NUMBERS :	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
URINARY BLADDER																
UTERUS																
--DILATATION OF THE UTERINE LUMEN (HYDROMETRA)							F 1									

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 17
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
			2		4		6		8		10		12		14	
	FEMALE NUMBERS :	1		3		5		7		9		11		13		15
ADRENALS																
--CONGESTION									F 1							
BONE MARROW		N	N	F	F	N	N	N	N	F	N	N	F	N	N	N
--HYPOPLASIA				2	2					2			4			
BRAIN		N	N	N	N	N	F	F	N	N	N	N	N	N	F	N
--CONGESTION							(2)								(2)	
--HEMORRHAGE								1								
BONE		N	N	N	N	N	N	N	N	N	N	N	N	N	F	N
--OSSEOUS CLOSURE OF EPIPHYSEAL PLATE															P	
CECUM			F	*	*			F	N							
--AUTOLYSIS CANNOT EVALUATE			P					P								
COLON		N	F	N	F	N	F	F	N	F	N	N	F	N	F	F
--AUTOLYSIS, CANNOT EVALUATE			P		P		P	P		P			P		P	P
DUODENUM		N	F	F	F	N	N	F	N	N	N	N	*	N	F	F
--AUTOLYSIS, CANNOT EVALUATE			P	P	P			P							P	
--GOBLET CELL HYPERPLASIA																(1)
EPIDIDYMIDES																
ESOPHAGUS		N	N	N	N	N	N	N	N	F	N	N	N	N	N	N
--DEGENERATION										(1)						
EYES		F	N	F	F	F	F	F	F	N	N	F	F	N	F	F
--KERATITIS, NEUTROPHILIC				4	1		2	1				3	2			
--CORNEAL VASCULARIZATION				3				2				3				
--CORNEAL ULCERATION							3					3	2			
--UVEITIS, PURULENT												3				
--INADEQUATE FOR EVALUATION						P			P						P	P
--ANTERIOR CHAMBER, PURULENT EXUDATE							2					1				
--AUTOLYSIS, CANNOT EVALUATE		P														
--MINERALIZATION, CORNEA							1									
HEART		N	N	N	N	N	N	N	N	N	N	N	N	N	F	N
--MYOCARDIAL DEGENERATION															1	

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 18
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / FINDINGS	COMPOUND DOSAGE GROUP :	3	3	3	3	3	3	3	3	3	3	3	3	3	3
			2		4		6		8		10		12		14	
	FEMALE NUMBERS :	1		3		5		7		9		11		13		15
ILEUM																
--AUTOLYSIS, CANNOT EVALUATE		F P	F P	F P	F P	N	F P	*	N	F P	N	F P	F P	N	F P	F P
JEJUNUM																
--GOBLET CELL HYPERPLASIA		F	F	F	F	*	*	F	F (1)	*	*	F	*	N	F	F
--AUTOLYSIS CANNOT EVALUATE		P	P	P	P			P				P			P	P
KIDNEYS																
--TUBULAR EPITHELIAL REGENERATION		F	F	F	N	N	F	N	F	N	N	N	N	F	F	N
--HYDRONEPHROSIS (UNI- OR BI- LATERAL)							2		2					1		
--CONGESTION		(1)	(1)	(2)			(1)		(1)					(1)	(2)	
--PYELONEPHRITIS			1													
LIVER																
--MONONUCLEAR CELL INFILTRATION (RANDOM)		F	F	F	N	F	F	F	F	F	F (1	F	F	F	F	N
--CONGESTION		(1)	(2)	(1			(1)	(1)		(1)		(1	(1	(1)	(3)	
--NECROSIS, CENTRILOBULAR				(3												
--HEMORRHAGE				(2											2	
--HEMATOPOIESIS, EXTRAMEDULLARY						P										
--NECROSIS									1				1			
LUNG																
--EXCESSIVE MUCOUS SECRETION		F	F	F	F	F	F	F	F	F	F	F	F	F	F	F
--BRONCHI, EPITHELIAL DEGENERATION/NECROSIS		(1	(1	(2		(2		(1			(1	(1		(1	(3	
--BRONCHI/BRONCHIOLES, METAPLASIA		(2		(1		(1				1	(2	(2	(2			
--CONGESTION		(3	(2		(2			1		2	(2	(2	(2	1		(2
--INTERSTITIAL INFILTRATION / PNEUMONIA			(2)	(3)	(3)		(2)			(2)		(2)			(2)	(2
--EDEMA								1						(3)		
--BRONCHITIS/BRONCHIOLITIS, PURULENT			(2				1									
--BRONCHI/BRONCHIOLES, ULCERATION							(3		(1			(2	(2	(2	(3	(2
--BRONCHI/BRONCHIOLES, FIBROSIS		2			(3				(2			(2	(2	(3	(3	(1
--PNEUMONIA, PURULENT		(3	1													
--BRONCHI, POLYPOID HYPERPLASIA							(1		(1				(1		(3	
--EMPHYSEMA		1														
--ALVEOLAR MACROPHAGE ACCUMULATIONS							(2	(2								
--GRANULOMA											(1					
--MINERALIZATION															1	
															1	
NOSE/TURBINATES																
--RHINITIS, PURULENT/MUCOPURULENT		F 2	*	F 2	F (2	F (3	F (2	F (4	F (2	F (1	F (3	F (3	*	F (3	F (3	F (2

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
			2		4		6		8		10		12		14	
	FEMALE NUMBERS :	1		3		5		7		9		11		13		15
NOSE/TURBINATES		F	*	F	F	F	F	F	F	F	F	F	*	F	F	F
--EPITHELIAL DEGENERATION/NECROSIS				(3	(2	(2	(3	(2	(2	(2	(3	(3		(2	(3	(3
--METAPLASIA		(3		(2	(3	(3	(3	(3	(3	(2	(3	(3		(3	(3	(3
--EPITHELIAL HYPERPLASIA		(1														
--ULCERATION		(2					(2		(2	(2		(3		1	(3	(3
--HEMORRHAGE															(2	
--NASOPALATINE DUCT, METAPLASIA		(3)		2	(3)		2		(3)	(3)	(3)	3		(3)		
--NASOPALATINE DUCT, HYPERKERATOSIS		(1)			(2)					3	2	2		2		
--NASOPALATINE DUCT, PURULENT INFLAMMATION				4	3		4		4		2			1		
--NASOPALATINE DUCT, ULCERATION							4		(3							
OVARIES		N	N	N	N	N	N	N	N	N	N	N	N	N	F	N
--CONGESTION															(3)	
PARATHYROIDS		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SKIN									N							N
SKELETAL MUSCLE									N							
SPLEEN		F	F	F	F	N	F	F	F	F	N	F	F	F	F	F
--LYMPHOID ATROPHY / DEPLETION		(2)	(4)	(3)	(4)		(4)	(3)	(4)	(4)		(3)	(4)	(2)	(2)	(4)
--CONGESTION				2					(3)							(3)
STOMACH		N	F	F	N	N	N	N	F	F	N	N	N	N	F	F
--NONGLANDULAR AREA, HEMORRHAGE				1												
--FUNDUS, NECROSIS									(2	(2						(2
--AUTOLYSIS, CANNOT EVALUATE															P	
--HEMORRHAGE			(1													
--CONGESTION			(1													
--MUCOSA, INFLAMMATION, ACUTE			1													
TESTES																
THYROIDS		N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA		F	F	F	F	F	F	F	F	F	F	F	F	F	F	F
--MONONUCLEAR CELLULAR INFILTRATION / CHRONIC TRACHEITIS									1							
--EPITHELIUM, METAPLASIA			(3)	(3		(2)		(2	(3)		(3)				(3)	
--HYPERPLASIA, SURFACE AND/OR GLANDULAR EPITHELIUM															2	

STUDY NO:83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 20
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

*** MICROSCOPIC EVALUATION OF TISSUES ***

TISSUE / F I N D I N G S	COMPOUND DOSAGE GROUP :	3	3	3	3	3	3	3	3	3	3	3	3	3	3
			2		4		6		8		10		12		14	
	FEMALE NUMBERS :	1		3		5		7		9		11		13		15
TRACHEA		F	F	F	F	F	F	F	F	F	F	F	F	F	F	F
--PURULENT/MUCOPURULENT TRACHEITIS			2													
--EPITHELIAL DEGENERATION			(1						2		(2					
--GLANDULAR HYPERPLASIA			1	3				1								2
--TRACHEITIS, ACUTE, ULCERATIVE												(4)	(4)			(3)
--TRACHEITIS, CHRONIC ACTIVE WITH ULCERATION		(4)		(3	(4		(4)	(3						(4)		
--TRACHEITIS, CHRONIC ACTIVE						(2)										
--GLANDULAR DILATATION						2										
--ULCERATION										(3)						
--TRACHEITIS, CHRONIC															(1)	
URINARY BLADDER		N	N	N	N	N	N	N	N	N	N	N	*	N	N	N
UTERUS					N			N								
OPTIC NERVE		N	N	N	N	N	*	F	N	N	N	N	N	N	*	N
--GLIOSIS								1								

** KEY TO MICROSCOPIC FINDINGS OBSERVED IN INDIVIDUAL ANIMALS **

- = PARTICULAR FINDING NOT PRESENT FOR GIVEN TISSUE.
( ) = CHANGE APPEARS DIFFUSELY THROUGHOUT THE SECTION.
(= CHANGE IS MULTIFOCAL IN APPEARANCE.
NO PARENTHESIS = FINDING IS A FOCAL OBSERVATION.
* = TISSUE NOT AVAILABLE FOR MICROSCOPIC EVALUATION (IE. EITHER MISSING OR INSUFFICIENT TISSUE IN THE PLANE OF SECTION).
P = INDICATES THAT CHANGE IS PRESENT OR CONFIRMED.
# = INDICATES A PRESUMED PRIMARY NEOPLASM (#M = MALIGNANT, #B = BENIGN)
N = TISSUE NORMAL (I.E., HISTOLOGICALLY NOT REMARKABLE).
F = TISSUE HAS FINDINGS AS INDICATED.

* GRADING THE SEVERITY OR DEGREE OF CHANGE *

1 = MINIMAL OR VERY SLIGHT (VERY SMALL)
2 = SLIGHT (SMALL)
3 = MODERATE (MEDIUM)
4 = CONSIDERABLE OR SIZEABLE (LARGE AMOUNT)
5 = MARKED OR VERY SEVERE (OVERLY ABUNDANT)

APPENDIX 2: CHAMBER ATMOSPHERE ANALYSIS AND ENVIRONMENTAL DATA

Exhibit 1

Analytical Procedure for Azomethine

Study Number: 830106 Page Number: 1

Description

This GC method is designed to measure Azomethine in air. It is based upon trapping Azomethine from about 10 l of air in an impinger containing iso-octane. Quantification is achieved with a GC utilizing a nitrogen-phosphorus detector and integration of the two largest chromatographic peaks, azomethine and diethylaniline (DEA).

Instrumentation:

Typical GC Operating Parameters

Column: Glass, 2 M x 2 mm ID, containing 3% OV-101 (w/w) on 80/100 mesh Gas Chrom Q.

Gas flows: He - 30 ml/min
H_2 - 4-5 ml/min
Air - 300 ml/min

Temperature: Detector - 280 degrees C, Bead Current: 500-600 MA
Injector - 230 degrees C
Column - 100 degrees C for 7.0 min; program to 130 degrees at 30 degrees C/min

Injection volume: 3 ul

Chromatograph: Varian 3700 or HP 5880 with autosampler, with integration by HP21 MX-E microcomputer

Materials:

Benzeneamine, 2,6-diethyl-N-methylene (Azomethine) EHL Test Substance Number T830053.

Iso-octane: Burdick and Jackson, Inc., UV Grade

Required Standard Solutions

Study Number: 830106 Page Number: 2

Stock Standards

Identification	Approx. Sample Weight (mg)*	Volume of Stock Standard (ml)	Approx. Stock Standard Concentration (mg/l)
Stock A	25.0	100	250
QC	18.0	100	180

Working Standards

Ident.	Stock Standard	Volume of Stock Standard (ml)	Volume of Working Standard (ml)	Approx. Concentration of Working Standard (mg/l)
WS-1	A	2	100	5.0
WS-2	A	8	100	20
WS-3	A	20	100	50
WS-4	A	25	50	125
WS-5	A	-	-	250
QC-L	QC	5	100	9
QC-M	QC	25	100	45
QC-H	QC	-	-	180

*Azomethine to the nearest 0.1 mg.

Comments:

Fresh stock and working standards will be prepared every week. Azomethine (1st peak) and it's degradation product, diethylaniline (DEA), are both observed in the chromatogram. If the area percent of DEA (2nd peak) increases above 50%, contact a professional from the chemistry group.

CALCULATIONS

Study Number: 830106 Page Number: 3

1. Working Standard Concentration

$C_w = (C_s * V_s)/V_w$

C_w = concentration working std. (mg/l)
C_s = concentration stock std. (mg/l)
V_s = volume stock std. (ml)
V_w = volume working std. (ml)

Values are reported to 4 significant figures.

2. Peak Area Sum

As = Area peak A + Area peak B
Peak A = Azomethine at ca. 5.5 minutes
Peak B = Diethylaniline at ca. 6.5 minutes

3. Regression Coefficients

A linear regression will be calculated from the standard concentrations C_w (in mg/l) and the corresponding area sum A_s. The A_s and C_w will be treated as X and Y, respectively. The expression $C_w = mA_s+b$ where m = slope and b = y-intercept will be used to calculate the concentrations of the impinger solutions.

Standards 1-3 will be used to calculate the regression coefficients for the first and second impinger samples, blanks and/or any solution producing a peak area less than that of WS-3. Standards 1-5 will be used to calculate regression coefficients for samples with concentrations equal to or greater than WS-3 (ca. 50 mg/l).

Regression coefficients are reported to 4 significant figures for the slope and 3 significant figures for the intercept.

4. Solution Concentration

The solution concentration C_x will be calculated directly from the regression equation.

Solution concentrations for all test samples, standards and QC's will be reported to three significant figures. Solution concentrations of less than the lowest standard will be reported as NM (not measurable) and treated as zero.

Study Number: 830106 Page Number: 4

5. Air Concentration

$C_{air} = C_x * V_{imp} * 10\text{-}3 \text{ liter/ml} * 1/V_{air}$

where: C_x = Solution concentration (mg/l)
C_{air} = Air concentration of Azomethine (mg/l air)
V_{imp} = Impinger sample volume (ml)
V_{air} = Volume of air sampled (l)

Air concentrations will be reported to two significant figures.

COMMENTS

Reserve samples and standards will be refrigerated overnight in case reanalysis is necessary.

It is necessary to reanalyze QC's if the values differ from expected by 10% or greater. The study director, upon comparison of nominal and analytical results may recommend reanalysis of samples.

Different standard weights and volumes of stocks and volumetric flasks may be used as long as the approximate concentrations of the stocks and working standards still correspond to those given on page 2.

This method was developed by Karen L. Crabtree and Bradford A. Najar. The following technician was assisted in the use of this method by Mr. Najar and is judged capable of performing this analysis.

Technician	Date Training Completed
Karen L. Crabtree	9-19-83

Prepared By: Roger D. Hollin Date: 16 March 1987

Reviewed By: Martha M. Peterson Date: 3/23/87

530106

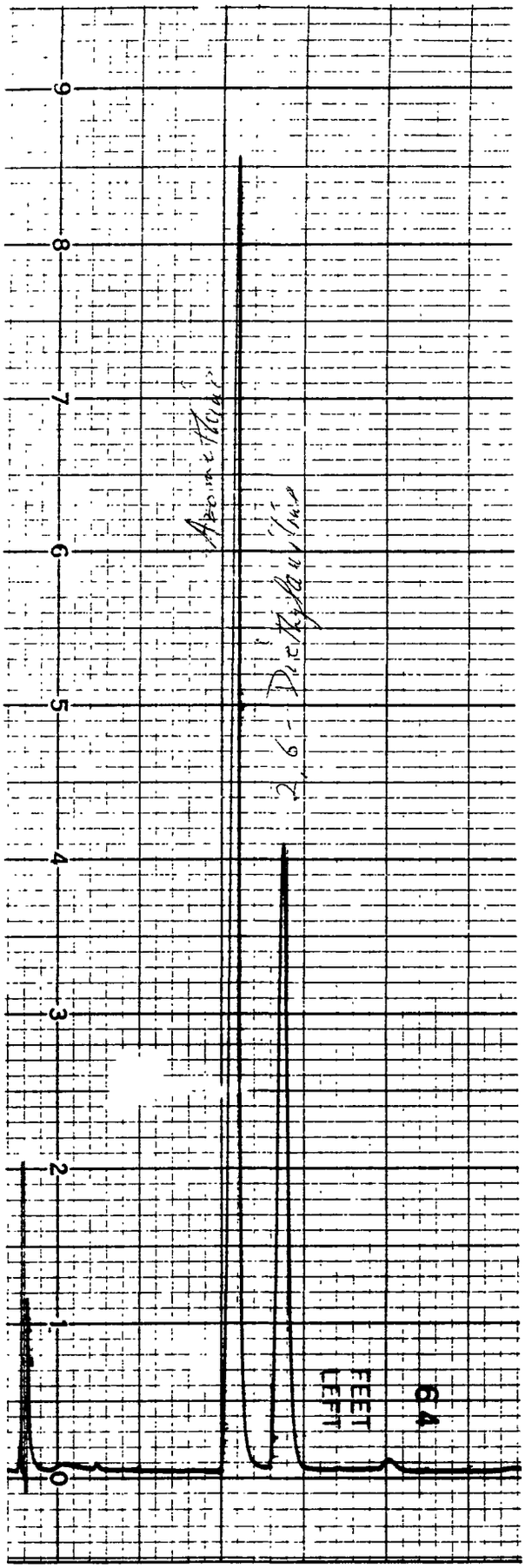


Exhibit 2

Analytical Procedure for Test Substance Stability

Study Number: 830106 Page Number: 1

Description

This GC method is designed to measure the stability of Azomethine. Quantification is achieved with a GC utilizing a Nitrogen phosphorus detector and integration of the two largest chromatographic peaks, azomethine and diethylaniline (DEA). Stability is verified by comparison with the original assay of the test substance.

Instrumentation:

Typical GC Operating Parameters

Column: Glass, 2 M x 2 mm ID, containing 3% OV-101 (w/w) on 80/100 mesh gas chrom Q.

Gas flows: He - 30 ml/min
H_2 - 4-5 ml/min
Air - 300 ml/min

Temperature: Detector - 280°C, Bead Current: 500-600 MA
Injector - 230°C
Column - 100°C for 7.0 min; program to 130° at 30° C/min

Injection volume: 3 ul

Chromatograph: Varian 3700 or HP 5880 with autosampler, with integration by HP21 MX-E microcomputer

Materials:

Benzeneamine, 2,6-diethyl-N-methylene (Azomethine) EHL Test Substance Number T830053.

Iso-octane: Burdick and Jackson, Inc., UV Grade

Required Standard Solutions

Study Number: 830106 Page Number: 2

Stock Standards

Identification	Approximate Sample Weight (mg)[a]	Volume of Stock Standard (ml)	Approximate Stock Standard Concentration (mg/l)
Stock A	25.0	100	250

Working Standards

Identification	Stock Standard	Volume of Stock Standard (ml)	Volume of Working Standard (ml)	Approximate Concentration of Working Standard (mg/l)
WS-1	A	2	100	5.0
WS-2	A	8	100	20
WS-3	A	20	100	50
WS-4	A	25	50	125
WS-5	A	-	-	250

[a]Azomethine to the nearest 0.1 mg.

Comments:

Sample Preparation

Study Number: 830106 Page Number: 3

Sample Preparation:

Accurately weigh 25 mg of test substance (to the nearest 0.1 mg) into a properly labeled 100 ml volumetric flask. Add isooctane to the mark.

CALCULATIONS

Study Number: 830106 Page Number: 4

1. Working Standard Concentration

$C_W = (C_S * V_S)/V_W$

C_W = concentration working std. (mg/l)
C_S = concentration stock std. (mg/l)
V_S = volume stock std. (ml)
V_W = volume working std. (ml)

Values are reported to 4 significant figures.

2. Regression Coefficients

A linear regression will be calculated from the standard concentrations C_W (in mg/l) and the corresponding area sum A_S. The A_S and C_W will be treated as X and Y, respectively. The expression $C_W = mA_S+b$ where m = slope and b = y-intercept will be used to calculate the concentrations of the impinger solutions.

Regression coefficients are reported to 4 significant figures for the slope and 3 significant figures for the intercept.

3. Solution Concentration

The solution concentration C_X will be calculated directly from the regression equation.

Solution concentrations for all test samples, standards and QC's will be reported to three significant figures.

Study Number: 830106 Study Day: _____ Page Number: 5

4. Azomethine Purity

% Difference = $(C_M - C_T) \times 100$

% Purity = 100 + % Difference

where: C_M = solution concentration of Azomethine measured (mg/l)
C_T = theoretical solution concentration of Azomethine (mg/l) assuming purity = 100%

Azomethine purity will be reported to three significant figures.

COMMENTS

Different standard weights and volumes of stocks and volumetric flasks may be used as long as the approximate concentrations of the stocks and working standards still correspond to those given on page 2.

This method was developed by Karen L. Crabtree and Bradford A. Najar. The following technician was assisted in the use of this method by Mr. Najar and is judged capable of performing this analysis.

Technician	Date Training Completed
Karen L. Crabtree	9-19-83

Prepared By: Bradford A Najar Date: 1-9-84

Reviewed By: Martin W Lentz Date: 1-13-84

jr/6092A-2

Amendment 1

Analytical Procedure for Test Substance Stability

Study Number: 830106 Page Number: 1

Description

This GC method is designed to measure the stability of Azomethine. Quantification is achieved with a GC utilizing a Nitrogen phosphorus detector and integration of the two largest chromatographic peaks, azomethine and diethylaniline (DEA). Stability is verified by comparison with the original assay of the test substance.

Instrumentation:

Typical GC Operating Parameters

Column: Glass, 2 M x 2 mm ID, containing 3% OV-101 (w/w) on 80/100 mesh gas chrom Q.

Gas flows: He - 30 ml/min
H_2 - 4-5 ml/min
Air - 300 ml/min

Temperature: Detector - 280°C, Bead Current: 500-600 MA
Injector - 230°C
Column - 100°C for 7.0 min; program to 130° at 30° C/min

Injection volume: syringe needle volume of neat azomethine

Chromatograph: Varian 3700

Materials:

Benzeneamine, 2,6-diethyl-N-methylene (Azomethine) EHL Test Substance Number T830053.

Study Number: 830106 Page Number: 2

4. Azomethine Purity

$P_M = (A_{AZ}/A_T) \times 100$

% Difference = $P_R - P_M$

where: P_M = measured purity of Azomethine
P_R = reported purity of Azomethine (98.1%)
A_{AZ} = peak area of Azomethine
A_{DEA} = peak area of Diethylaniline
A_{UNK} = sum of peak areas of unknowns
$A_T = A_{AZ} + A_{DEA} + A_{UNK}$

Azomethine purity will be reported to three significant figures. % difference will be reported to two significant figures.

COMMENTS

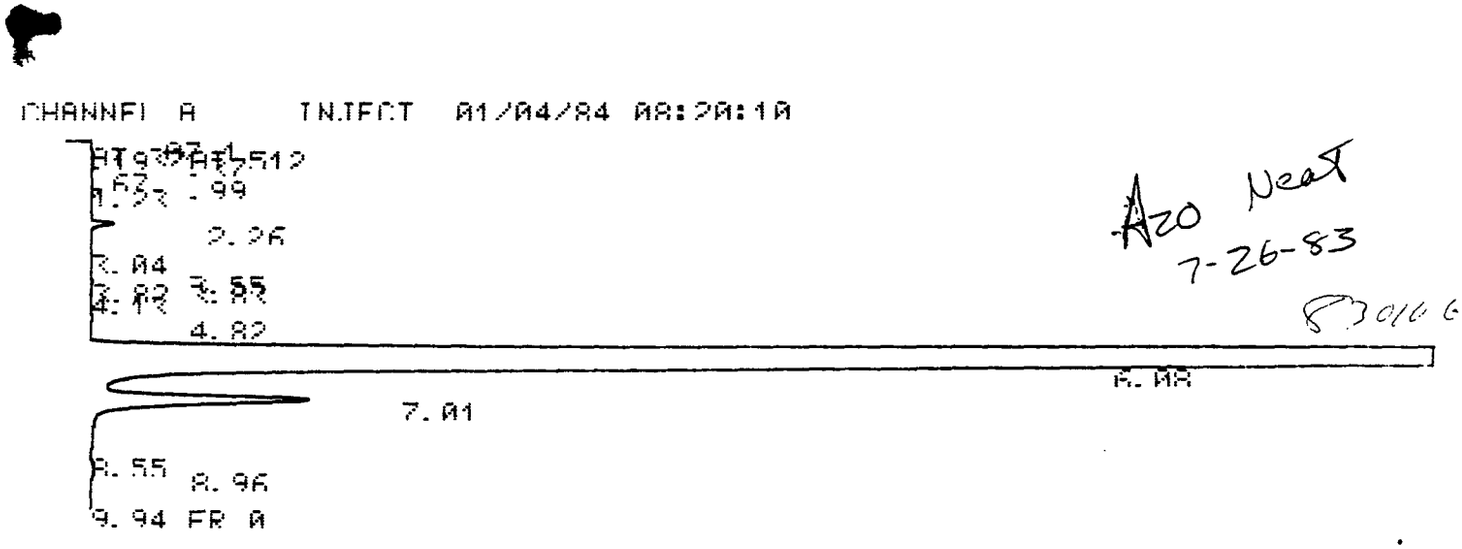
A comment page with analysis results and calculations will be found in the study notebook. This amendment was necessary due to the observed degradation of Azomethine in isooctane. The degradation appears to be due to hydrolysis by water found in isooctane. This amendment also allows comparison of EHL data to that provided by Monsanto Agricultural Products Company. Stability measured by the original method may not be accurate.

This method was developed by Bradford A. Najar.

Prepared By: Bradford A Najar Date: 2/8/84

Reviewed By: Martin [illegible] Date: 2/8/84

jr/6092A-6



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FILE 4. METHOD 0. RUN 9 INDEX 9

PEAK#	AREA%	RT	AREA	BC
1	0.	0.19	49	02
2	0.014	0.37	9007	08
3	0.	0.67	84	05
4	0.001	0.99	730	06
5	0.002	1.23	1496	07
6	0.188	2.26	124460	08
7	0.005	3.04	2985	05
8	0.001	3.55	568	06
9	0.009	3.82	6074	06
10	0.012	3.87	7679	06
11	0.002	4.13	1463	06
12	0.033	4.82	21512	06
13	96.107	6.08	63604643	08
14	3.584	7.01	2371712	05
15	0.	8.55	7	05
16	0.042	8.96	28017	05
17	0.	9.94	253	05

TOTAL 100. 66188739

Exhibit 3

Results of the Analysis of Azomethine in a
Three-Month Inhalation Study

Prepared by: B. A. Najar
B. A. Najar, M. S., Research Chemist

Reviewed by: M W Dietrich
M. W. Dietrich, Ph.D., Chemistry Group Leader

RESULTS AND DISCUSSION

Impinger samples of azomethine in iso-octane collected by the inhalation toxicology group over 62 exposure days were analyzed using a gas chromatographic procedure. Quality control samples, prepared by the Chemistry group, were analyzed together with the study samples to provide a measure of the precision and accuracy of the procedure.

Data obtained from the analyses of study samples are found in Tables 1-3. Table 1 shows the daily assay values. Table 2 shows the daily mean chamber concentrations and Table 3 shows the study mean chamber concentration at each exposure level. The study mean values agreed well with the target values. Analyses of control chamber samples indicated that no test material was present (a).

Results of the analyses of quality control samples are given in Table 4 (daily values and study mean values). The largest percent difference from the expected value on any day was 10.3 and the largest study mean percent difference was 0.3. This showed that the method used had no significant bias and was capable of providing analyses that were both accurate and precise.

The stability of the test substance was confirmed by comparison of data obtained by analyses conducted during and after the completion of the study, to analyses provided by the sponsor prior to the start of the study. These data are found in Table 5 and indicate the test substance was stable under the conditions of storage.

(a) See Analytical Chemistry Study notebook for supporting data.

Table 1

Daily Assays of Azomethine in Chamber Atmosphere
(mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.20
1	.014	.070	.24
	.014	.067	.24
	.013	.080	.26
	.011	.081	.27
2	.0096	.058	.19
	.0081	.060	.18
	.0078	.059	.17
	.0075	.062	.17
3	.0073	.047	.17
	.0096	.063	.16
	.0099	.060	.18
	.010	.056	.18
4	.0097	.057	.16
	.010	.063	.15
	.011	.056	.17
	.0094	.054	.17
5	.0098	.061	.17
	.010	.064	.18
	.0097	.070	.20
	.0096	.069	.21
6	.0096	.073	.17
	.0089	.072	.16
	.0091	.065	.17
	.0092	.066	.16
7	.0081	.051	.13
	.0080	.052	.16
	.0083	.045	.20
	.0082	.052	.19
8	.0076	.034	.060
	.0076	.041	.060
	.0078	.045	.065
	.0077	.045	.057

Table 1 (cont.)

Daily Assays of Azomethine in Chamber Atmosphere
(mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.20
9	.0074	.040	.13
	.0080	.045	.16
	.0079	.044	.21
	.0078	.046	.18
10	.0073	.041	.14
	.0096	.042	.21
	.010	.046	.21
	.010	.045	.19
11	.010	.044	.19
	.010	.049	.21
	.010	.049	.22
	.011	.049	.23
12	.0073	.040	.17
	.0095	.042	.19
	.0099	.044	.22
	.010	.044	.21
13	.011	.036	.16
	.010	.041	.19
	.010	.044	.20
	.010	.045	.21
14	.0080	.039	.20
	.0076	.040	.22
	.0095	.053	.25
	.011	.049	.24
15	.013	.039	.17
	.013	.039	.15
	.014	.044	.18
	.014	.044	.20
16	.012	.038	.19
	.010	.043	.20
	.011	.045	.18
	.011	.048	.21

Table 1 (cont.)

Daily Assays of Azomethine in Chamber Atmosphere
(mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.20
17	.0087	.036	.15
	.0093	.043	.17
	.0096	.047	.18
	.0094	.046	.22
18	.010	.046	.16
	.0093	.046	.17
	.0091	.047	.19
	.0090	.045	.16
19	.0094	.043	.20
	.0092	.045	.22
	.0092	.048	.21
	.0095	.051	.22
20	.010	.048	.19
	.0094	.045	.22
	.0096	.049	.21
	.0097	.051	.23
21	.0076	.045	.19
	.0085	.049	.22
	.0086	.044	.21
	.0085	.044	.24
22	.011	.021	.19
	.0095	.025	.20
	.0094	.032	.22
	.0096	.039	.22
23	.0099	.042	.23
	.0089	.045	.26
	.0093	.046	.28
	.0091	.050	.28
24	.010	.049	.18
	.010	.056	.21
	.010	.055	.20
	.0097	.055	.23

Table 1 (cont.)

Daily Assays of Azomethine in Chamber Atmosphere
(mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.10*
25	.013	.047	.23
	.0096	.049	.25
	.0092	.052	.27
	.0087	.051	.24
26	.0091	.044	.17
	.0090	.052	.15
	.0098	.052	.15
	.0095	.048	.14
27	.010	.044	.12
	.0088	.052	.13
	.0085	.051	.13
	.0080	.052	.14
28	.0095	.046	.11
	.0092	.047	.11
	.0094	.044	.11
	.0096	.047	.11
29	.0091	.042	.099
	.0093	.053	.12
	.0089	.050	.12
	.0096	.046	.14
30	.011	.042	.12
	.0097	.048	.13
	.0095	.045	.12
	.0095	.044	.13
31	.011	.050	.12
	.011	.059	.14
	.011	.053	.13
	.011	.057	.15
32	NM	.039	.12
	NM	.045	.12
	NM	.049	.13
	NM	.048	.13

* Target level for high level chamber changed from 0.20 to 0.10 mg/L on exposure day 26.

Table 1 (cont.)

Daily Assays of Azomethine in Chamber Atmosphere
(mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.10
33	NM	.052	.12
	NM	.045	.13
	.029	.044	.11
	.016	.051	.12
34	.0081	.045	.11
	.010	.047	.11
	.0098	.049	.11
	.010	.049	.11
35	.010	.051	.10
	.0088	.050	.11
	.0085	.051	.11
	.0087	.053	.11
36	.010	.052	.11
	.0096	.061	.11
	.010	.056	.12
	.011	.053	.12
37	.011	.049	.099
	.0091	.054	.11
	.010	.055	.11
	.0097	.056	.11
38	.010	.054	.11
	.010	.050	.12
	.010	.053	.12
	.010	.055	.12
39	.0099	.055	.11
	.0099	.057	.11
	.010	.059	.12
	.011	.060	.12
40	.010	.053	.097
	.0090	.054	.097
	.0086	.054	.10
	.0098	.055	.095

Table 1 (cont.)

Daily Assays of Azomethine in Chamber Atmosphere
(mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.10
41	.011	.051	.11
	.011	.054	.11
	.0091	.055	.11
	.0094	.055	.10
42	.012	.048	.092
	.0097	.053	.091
	.0097	.056	.099
	.010	.051	.097
43	.0071	.056	.093
	.010	.054	.099
	.0096	.050	.10
	.010	.052	.095
44	.0091	.048	.097
	NM	.053	.10
	.011	.051	.10
	.010	.052	.10
45	.0057	.044	.088
	.0087	.052	.098
	.0087	.053	.097
	.0096	.051	.10
46	.0092	.053	.11
	.0078	.055	.11
	.0060	.052	.11
	.0090	.052	.11
47	NM	.053	.11
	NM	.053	.11
	NM	.054	.11
	NM	.056	.12
48	NM	.055	.095
	NM	.056	.10
	NM	.057	.11
	NM	.057	.11

Table 1 (cont.)

Daily Assays of Azomethine in Chamber Atmosphere
(mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.10
49	.0074	.055	.12
	.0081	.057	.10
	.0097	.062	.11
	.0097	.056	.12
50	.011	.052	.091
	.012	.054	.095
	.010	.055	.098
	.011	.053	.10
51	.010	.061	.11
	.010	.057	.11
	.011	.059	.12
	.010	.058	.12
52	NM	.054	.11
	NM	.055	.078
	NM	.054	(a)
	NM	.050	(a)
53	NM	.039	.10
	NM	.055	.11
	.0090	.053	.11
	.0090	.056	.10
54	.0064	.058	.10
	.010	.056	.11
	.0097	.053	.11
	.0096	.047	.11
55	NM	.054	.10
	NM	.053	.10
	NM	.056	.11
	NM	.053	.11
56	NM	.016	.10
	NM	.012	.12
	NM	.0095	.13
	NM	.0078	.13

Table 1 (cont.)

Daily Assays of Azomethine in Chamber Atmosphere
(mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.10
57	.019	.055	.14
	.0058	.055	.13
	.010	.055	.13
	.010	.055	.14
58	.0084	.038	.13
	.0089	.042	.13
	.0087	.027	.13
	.0090	.030	.13
59	NM	.012	.14
	NM	.0080	.14
	NM	.0050	.14
	NM	.0042	.13
60	NM	.042	.13
	.011	.044	.13
	.0095	.047	(a)
	.010	.053	(a)
61	.011	.051	.13
	.010	.054	.14
	.010	.052	.14
	.010	.054	.14
62	.038	.054	(b)
	.021	.054	
	.016	.059	
	.014	.042	

(a) No sample provided

(b) High level chamber not run

NM = Not Measurable

Table 2

Mean Daily Concentrations of Azomethine in Test Chamber Atmospheres (mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.20
1	.013	.075	.25
2	.0083	.060	.18
3	.0092	.057	.17
4	.010	.058	.16
5	.0098	.066	.19
6	.0092	.069	.17
7	.0082	.050	.17
8	.0077	.041	.061
9	.0078	.044	.17
10	.0092	.044	.19
11	.010	.048	.21
12	.0092	.043	.20
13	.010	.042	.19
14	.0090	.045	.23
15	.014	.042	.18
16	.011	.044	.20
17	.0093	.043	.18
18	.0094	.046	.17
19	.0093	.047	.21
20	.0097	.048	.21
21	.0083	.046	.22
22	.0099	.029	.21
23	.0093	.046	.26
24	.0099	.054	.21
25	.010	.050	.25
26	.0094	.049	.15 (a)
27	.0088	.050	.13
28	.0094	.046	.11
29	.0092	.048	.12
30	.0099	.045	.13
31	.011	.055	.14
32	NM	.045	.13
33	.011	.048	.12
34	.0095	.048	.11
35	.0090	.051	.11
36	.010	.056	.12
37	.010	.054	.11
38	.010	.053	.12
39	.010	.058	.12

Table 2 (cont.)

Mean Daily Concentrations of Azomethine in Test Chamber Atmospheres (mg/1 air)

Exposure Day	Low Target 0.010	Mid Target 0.050	High Target 0.20
40	.0094	.054	.097
41	.010	.054	.11
42	.010	.052	.095
43	.0092	.053	.097
44	.0075	.051	.099
45	.0082	.050	.096
46	.0080	.053	.11
47	NM	.054	.11
48	NM	.056	.10
49	.0087	.058	.11
50	.011	.054	.096
51	.010	.059	.12
52	NM	.053	.094
53	.0045	.051	.11
54	.0089	.054	.11
55	NM	.054	.11
56	NM	.011	.12
57	.011	.055	.14
58	.0088	.034	.13
59	NM	.0073	.14
60	.0076	.047	.13
61	.010	.053	.14
62	.022	.052	(b)

(a) Target changed to 0.10 on exposure day 26.
(b) High level not run.
NM = Not measurable.

Table 3

Azomethine Study Mean Chamber Concentrations

	Chamber Concentration (mg/1 air)(a)		
	Low	Mid	High
Target	.010	.050	.20-.10 (b)
Analytical	.0098	.049	.15
Standard Deviation	.0010	.014	.051

(a) Calculated from daily mean values.

(b) Target level for high exposure reduced from 0.20 to 0.10 mg/l air on exposure day 26.

Table 4

Quality Control Results (mg/1 solution)(a)

Exposure Day	QC Low Expected	QC Low Found	QC Low % Diff.(b)	QC Mid Expected	QC Mid Found	QC Mid % Diff.	QC High Expected	QC High Found	QC High % Diff.
1	9.50	9.04	-4.8	47.5	45.3	-4.6	190	180	-5.3
2	10.5	10.1	-3.8	52.5	50.3	-4.2	210	191	-9.0
3	11.0	11.7	6.4	55.0	57.6	4.7	220	234	6.4
4-5	11.0	11.9	8.2	55.0	56.4	2.5	220	217	-1.4
6	11.0	11.1	.9	55.0	57.6	4.7	188	198	5.3
7	9.40	9.60	2.1	47.0	46.5	-1.1	188	198	5.3
8	9.40	8.93	-5.0	47.0	47.6	1.3	188	198	5.3
9	9.40	8.92	-5.1	47.0	47.9	1.9	188	201	6.9
10	9.40	9.10	-3.2	47.0	47.7	1.5	188	201	6.9
11	9.40	9.52	1.3	47.0	49.5	5.3	188	203	8.0
12	9.25	9.68	4.6	46.3	44.9	-3.0	185	187	1.1
13	9.25	10.2	10.3	46.3	46.9	1.3	185	194	4.9
14	10.4	10.2	-1.9	46.3	47.2	1.9	185	193	4.3
15	10.4	10.2	-1.9	51.8	51.4	-0.8	207	205	-1.0
16	10.4	10.0	-3.8	51.8	50.6	-2.3	207	209	1.0
17	10.4	9.96	-4.2	51.8	50.4	-2.7	207	208	0.5
18	10.4	9.83	-5.5	51.8	50.0	-3.5	207	212	2.4
19	10.4	9.77	-6.1	51.8	51.2	-1.2	207	206	-0.5
20	10.4	10.6	1.9	51.8	51.8	0	207	212	2.4
21	10.5	11.3	7.6	52.5	55.1	5.0	210	219	4.3
22-23	10.5	9.83	-6.4	52.5	50.0	-4.8	210	214	1.9
24	10.5	10.7	1.9	52.5	52.2	-0.6	210	208	-1.0
25	11.8	11.4	-3.4	59.0	59.8	1.4	236	237	0.4
26	11.8	11.5	-2.5	59.0	60.7	2.9	236	245	3.8
27	11.8	10.7	-9.3	59.0	60.6	2.7	118	114	-3.4
28	11.8	11.5	-2.5	59.0	60.9	3.2	118	121	2.5
29	11.8	11.5	-2.5	59.0	60.6	2.7	118	114	-3.4
30	11.7	10.9	-6.8	58.3	57.0	-2.2	117	115	-1.7
31	11.7	11.7	0	58.3	59.3	1.7	117	118	0.9
32	11.7	12.1	3.4	58.3	59.2	1.5	117	116	-0.9
33	11.7	11.1	-5.1	58.3	60.5	3.8	117	119	1.7
34	11.7	11.6	-0.9	58.3	55.1	-5.5	117	111	-5.1
35	10.4	10.3	-1.0	52.0	50.6	-2.7	104	99.4	-4.4
36	10.4	10.1	-2.9	52.0	49.5	-4.8	104	103	-1.0
37	10.4	9.60	-7.7	52.0	50.9	-2.1	104	104	0
38	10.4	11.0	5.8	52.0	48.7	-6.3	104	101	-2.9
39	10.4	10.9	4.8	52.0	50.7	-2.5	104	100	-3.8
40	11.0	10.7	-2.7	55.0	55.2	0.4	110	109	-0.9
41	11.0	10.7	-2.7	55.0	55.2	0.4	110	111	0.9
42	11.0	11.1	0.9	55.0	54.2	-1.5	110	110	0
43	11.0	11.3	2.7	55.0	56.7	3.1	110	111	0.9
44	11.0	11.3	2.7	55.0	52.2	-5.1	110	107	-2.7

Table 4 (cont.)

Quality Control Results (mg/1 solution) (a)

Exposure Day	QC Low Expected	QC Low Found	QC Low % Diff. (b)	QC Mid Expected	QC Mid Found	QC Mid % Diff.	QC High Expected	QC High Found	QC High % Diff.
45	9.10	9.38	3.1	45.5	46.8	2.9	91.0	91.8	0.9
46	9.10	9.06	-0.4	45.5	46.8	2.9	91.0	94.0	3.3
47	13.6	14.3	5.1	68.0	69.0	1.5	136	140	2.9
48	13.6	13.6	0	68.0	66.4	-2.4	136	135	-0.7
49	13.6	13.3	-2.2	68.0	68.3	0.4	136	143	5.1
50	13.6	13.4	-1.5	68.0	66.7	-1.9	136	134	-1.5
51	13.6	13.2	-2.9	68.0	68.6	0.9	136	141	3.7
52	7.70	7.50	-2.6	53.5	51.0	-4.7	107	104	-2.8
53	7.70	7.94	3.1	38.5	38.3	-0.5	77.0	70.2	-8.8
54	7.70	8.20	6.5	38.5	38.3	-0.5	77.0	74.5	-3.2
55	7.70	7.83	1.7	38.5	38.5	0	77.0	72.5	-5.8
56	7.70	7.93	3.0	38.5	38.7	0.5	77.0	71.6	-7.0
57	7.70	8.29	7.7	38.5	36.8	-4.4	77.0	72.7	-5.6
58-59	11.7	12.4	6.0	58.5	60.5	3.4	117	126	7.7
60	11.7	12.5	6.8	58.5	58.6	0.2	117	118	0.9
61	11.7	12.4	6.0	58.5	58.1	-0.7	117	118	0.9
62	11.7	12.5	6.8	58.5	59.6	1.9	-	-	-
Study Mean			+0.2			-0.1			+0.3

(a) Values are reported in solution concentration. These solution concentrations correspond approximately to those obtained from samples at the three study levels.

(b) $\%\text{Difference} = \frac{(\text{Found}-\text{Expected})\ (100)}{\text{Expected}}$

Table 5

Test Substance Stability

CONTAINER	SAMPLE BOTTLE	DATE ANALYZED	% AZOMETHINE
		ca 7/83	98.1 (a)
33	8/3	12/30/83	96.2
	8/3	12/30/83	93.9
	10/3	12/30/83	96.4
	10/3	12/30/83	98.2
	12/8	12/30/83	98.8
	12/8	12/30/83	98.0
	7/26	1/4/84	96.1
22	12/13	12/30/83	98.0
	12/13	12/30/83	97.8

(a) Analyses Provided by Sponsor (Monsanto Agricultural Products Co.)

Exhibit 4

Daily Nominal Azomethine Concentrations

Exposure Day	Low Level (.01 mg/l)	Mid Level (.05 mg/l)	High Level (.10-.20 mg/l)
1	0.01	0.16	0.69
2	0.01	0.13	0.50
3	0.01	0.12	0.59
4	0.01	0.12	0.47
5	0.01	0.16	0.57
6	0.01	0.13	0.56
7	0.01	0.12	0.71
8	0.01	0.12	0.36
9	0.01	0.12	0.65
10	0.01	0.12	0.70
11	0.01	0.12	0.77
12	0.01	0.12	0.72
13	0.01	0.10	0.63
14	0.01	0.12	0.65
15	0.01	0.12	0.67
16	0.01	0.12	0.69
17	0.01	0.12	0.58
18	0.01	0.12	0.45
19	0.01	0.12	0.75
20	0.01	0.12	0.74
21	0.01	0.12	0.76
22	0.01	0.12	0.76
23	0.01	0.12	0.75
24	0.01	0.12	0.69
25	0.01	0.12	0.73
26	0.01	0.12	0.39
27	0.01	0.12	0.47
28	0.01	0.12	0.31
29	0.01	0.12	0.17
30	0.01	0.12	0.32
31	0.01	0.11	0.36
32	0.01	0.12	0.31

High level exposure target concentration changed from 0.20 to 0.10 mg/l on day 26.

Daily Nominal Azomethine Concentrations (cont.)

Exposure Day	Low Level (.01 mg/l)	Mid Level (.05 mg/l)	High Level (.10-.20 mg/l)
33	0.01	0.12	0.20
34	0.01	0.12	0.31
35	0.01	0.12	0.30
36	0.01	0.12	0.25
37	0.01	0.12	0.33
38	0.01	0.12	0.28
39	0.01	0.12	0.29
40	0.01	0.12	0.29
41	0.01	0.12	0.29
42	0.01	0.12	0.29
43	0.01	0.12	0.28
44	0.01	0.12	0.28
45	0.01	0.12	0.29
46	0.01	0.12	0.24
47	0.01	0.12	0.29
48	0.01	0.12	0.28
49	0.01	0.12	0.29
50	0.01	0.12	0.28
51	0.01	0.12	0.29
52	0.01	0.12	* not taken
53	0.01	0.12	0.28
54	0.01	0.12	0.28
55	0.01	0.12	0.29
56	0.01	0.12	0.29
57	0.01	0.12	0.28
58	0.01	0.12	0.28
59	0.01	0.12	0.28
60	0.01	0.12	0.28
61	0.01	0.12	0.28
62	0.01	0.12	*level not run*
$\bar{X} \pm SD$	0.01 ± 0.00	0.12 ± 0.01	0.44 ± 0.19

High level exposure target concentration changed from 0.20 to 0.10 mg/l on day 26.

Distribution of Azomethine in the Test Chambers

Level Target (mg/l)	Low (0.01)			
Sampling Location	Date			
	(9/26/83)	(10/24/83)	(11/21/83)	(12/19/83)
Front Center of Door	0.0095	0.0095	0.0097	0.011
Left, Top, Front of Chamber	0.0099	0.0087	0.0093	0.011
Middle of Chamber	0.0096	0.0079	0.0078	0.011
Right, Rear, Bottom of Chamber	0.0097	0.0095	0.0097	0.010
Right, Top, Middle of Chamber	0.0086	0.0094	0.0099	0.011
Front Center of Door	0.0096	0.0092	0.0097	0.0098
Mean Concentration	0.0095	0.0090	0.0094	0.0106
Standard Deviation	0.0005	0.0006	0.0008	0.0006
% Range *	13.7	17.8	22.3	11.3

* % Range = [(High Value - Low Value)/Mean] X 100%

Distribution of Azomethine in the Test Chambers

Level Target (mg/l)	Mid (0.05)			
Sampling Location	Date			
	(9/28/83)	(10/21/83)	(11/18/83)	(12/20/83)
Front Center of Door	0.062	0.049	0.054	0.051
Left, Top, Front of Chamber	0.057	0.052	0.055	0.053
Middle of Chamber	0.060	0.045	0.051	0.047
Right, Rear, Bottom of Chamber	0.059	0.046	0.048	0.051
Right, Top, Middle of Chamber	0.063	0.046	0.049	0.047
Front Center of Door	0.064	0.046	0.053	0.053
Mean Concentration	0.061	0.047	0.052	0.050
Standard Deviation	0.003	0.003	0.003	0.003
% Range *	11.5	14.9	13.5	12.0

* % Range = [(High Value - Low Value)/Mean] X 100%

Distribution of Azomethine in the Test Chambers

Level Target (mg/l)	High (0.20-0.10)			
Sampling Location	Date			
	(9/28/83)	(10/20/83)	(11/17/83)	(12/15/83)
Front Center of Door	0.18	0.22	0.097	0.13
Left, Top, Front of Chamber	0.21	0.23	0.091	0.13
Middle of Chamber	0.17	0.21	0.10	0.13
Right, Rear, Bottom of Chamber	0.19	0.23	0.095	0.13
Right, Top, Middle of Chamber	0.20	0.23	0.10	0.13
Front Center of Door	0.19	0.21	0.096	0.13
Mean Concentration	0.19	0.22	0.096	0.13
Standard Deviation	0.01	0.01	0.003	0.00
% Range *	21.1	9.1	9.4	0.0

* % Range = [(High Value - Low Value)/Mean] X 100%

High level target concentration was reduced from 0.2 to 0.1 mg/l on 10/28/83.

SUMMARY OF CHAMBER ENVIRONMENTAL MEASUREMENTS

LEVEL		FLOW (L/M)	RH (%)	TEMP (DEG C)
LOW	MEAN	340	36	25.2
	STD DEV	0	10	0.6
	MINIMUM	340	23	22.5
	MAXIMUM	340	66	26.0
MID	MEAN	340	38	26.8
	STD DEV	0	6	0.5
	MINIMUM	340	22	25.0
	MAXIMUM	340	51	28.0
HIGH	MEAN	340	40	25.0
	STD DEV	0	9	0.4
	MINIMUM	340	26	23.5
	MAXIMUM	340	54	26.0
CONTROL	MEAN	340	41	24.4
	STD DEV	0	11	0.6
	MINIMUM	340	20	21.5
	MAXIMUM	340	59	25.5

PARTICLE-SIZE ANALYSIS

High Level (0.20-0.10 mg/l)

Exposure Day	Mass Median Aerodynamic Diameter (um)	Geometric Standard Deviation (um)	% Particles Less Than 10 um
1	2.100	2.030	98.6
2	1.662	2.691	96.5
3	1.762	2.243	98.4
4	1.753	2.178	98.7
5	2.037	2.179	97.9
10	2.152	2.173	97.6
14	2.207	2.125	97.7
19	6.716	4.905	59.9
24	2.011	2.309	97.2
29	2.123	2.303	96.8
34	1.822	2.320	97.9
39	1.579	2.589	97.4
44	4.030	4.119	74.0
47	1.687	2.666	96.5
53	1.952	2.417	96.8
57	2.288	2.438	95.1
61	1.644	2.514	97.5

High level target concentration changed from 0.20 to 0.10 mg/l on day 26.

APPENDIX 3: IN-LIFE OBSERVATIONS

Gross Signs of Toxicity Observed During
Exposure to Azomethine (By Exception)

Exposure Number	Exposure Levels							
	Males				Females			
	Control	Low	Mid	High	Control	Low	Mid	High
Miscellaneous Respiratory Difficulty								
1								
2				B				B
3-4								
5								B
6-9								
10-11				B				B
12				B				C
13-15				C				C
16				D				D
17-24				E				E
25-46				F				F
47-61				G				F
62				G				G
Eye And/or Nasal Irritation								
1-5								
7-11				C				C
12-16				D				D
17-24				E				E
25-46				F				F
47-61				G				F
62				G				G

Key: B=1-25% of the observable animals have this effect.
C=26-50% of the observable animals have this effect.
D=51-75% of the observable animals have this effect.
E=76-99% of the observable animals have this effect.
F=100% of the observable animals have this effect.
G=no animals remaining in these levels.

Weekly Occurrences of Signs of Azomethine Toxicity Observed
in Individual Animals Before and After Exposure

Week No.	Dates	
		Red/Brown Perinasal Encrustation
1	9/22-9/28/83	1M011; 3M002-7,9-15; 3F001-3,5-7,9-12,14,15
2	9/29-10/5/83	1M011; 3M001-12,14,15; 3F001-5,7-12,14,15
3	10/6-10/12/83	3M001-3,5-12,15; 3F001-7,9-13,15
4	10/13-10/19/83	3M001-5,9,10,13,15; 3F001-7,9-14
5	10/20-10/26/83	3M001-3,5,6,8,9,11,13,15; 3F002-7,9-14
6	10/27-11/2/83	3M001-3,6,8,9,11,15; 3F002-5,10-14
7	11/3-11/9/83	1M007; 2M011,12; 2F003,8,14; 3M001,3,9,11,15; 3F005,10
8	11/10-11/16/83	2M005-8,11,13; 2F003,7,8; 3M006,9,11
9	11/17-11/23/83	1M010; 2M001-4,11,14; 2F003,6,10; 3M009
10	11/24-11/30/83	2M007,10,12,13; 2F002
11	12/1-12/7/83	2M011,13,15; 2F009
12	12/8-12/14/83	NM005; 1M007; 2M008,13
13	12/15-12/21/83	1M005; 2M010,11
		Yellow/Brown Nasal Discharge
4	10/13-10/19/83	3M007; 3F003,7
		Blood-Like Nasal Discharge
1	9/22-9/28/83	2M003; 3M001,3-6,8-15; 3F001,2,7-12
2	9/29-10/5/83	1M006,13,15; 1F014; 2M001; 3M001,2,5,6,8-15; 3F001,2,6,7,10-12,15
3	10/6-10/12/83	2M011; 3M001-5,7,8,12-15; 3F002,4,5,7,9-13,15
4	10/13-10/19/83	3M001-6,8,10,11,13-15; 3F001-14
5	10/20-10/26/83	3M001-3,6,8,11,13,15; 3F001-7,9-11
6	10/27-11/2/83	3F004,5
8	11/10-11/16/83	2M013
9	11/17-11/23/83	3F005,14
11	12/1-12/7/83	2M002,10

Weekly Occurrences of Signs of Azomethine Toxicity Observed in Individual Animals Before and After Exposure

Week No.	Dates	
		Red Discharge around Eyes
1	9/22-9/28/83	1M008; 3M002,11,13; 3F004-6
2	9/29-10/5/83	1M008; 3M002,6,10,11; 3F005
3	10/6-10/12/83	3M002,6,9; 3F002,4,5,9
4	10/13-10/19/83	3M001,9; 3F005
5	10/20-10/26/83	3M002; 3F013
6	10/27-11/2/83	3M001,6; 3F012
8	11/10-11/16/83	2M009
9	11/17-11/23/83	2M002; 2F002,6
10	11/24-11/30/83	2M009
11	12/1-12/7/83	NM013; 2M004; 3F005
12	12/8-12/14/83	NM013
13	12/15-12/20/83	NM013; NF013; 1M011
14	12/22/83	NM013; 1M011
		Red/Pink Nasal Discharge
1	9/22-9/28/83	3F001,2
		Clear Nasal Discharge
1	9/22-9/28/83	3F014
		Salivation
3	10/6-10/12/83	3M009,10; 3F002,5,11,14
4	10/13-10/19/83	3M001,9-11,13; 3F002,5,6,10-12,14
5	10/20-10/26/83	3M001,9,13; 3F002,10
13	12/15-12/21/83	1M005

Weekly Occurrences of Signs of Azomethine Toxicity Observed in Individual Animals Before and After Exposure

Week No.	Dates	
		Blood-Like Oral Discharge
1	9/22-9/28/83	1M011,12; 3M001-6,9,11,15; 3F001,2,7,8,11
2	9/29-10/5/83	1M011; 3M004-6,11,15; 3F001,5,6,9,15
3	10/6-10/12/83	2F002; 3M005,7,9,14,15; 3F001-3,5,9,10
4	10/13-10/19/83	3M004,9,10,14,15; 3F001,3,4,9,11
5	10/20-10/26/83	3M001,9
6	10/27-11/2/83	2M009
9	11/17-11/23/83	2M007,8
10	11/24-11/30/83	2M002
11	12/1-12/7/83	2M007,11
12	12/8-12/14/83	2M007
		Sneezing
1	9/22-9/28/83	3M012,13,15; 3F006
2	9/29-10/5/83	3M001-3,9,12,13; 3F002,14
3	10/6-10/12/83	3M001-5,9-13,15; 3F001,5,7,9,10,14
4	10/13-10/19/83	3M001-6,8-11,13-15; 3F001-6,8-14
5	10/20-10/26/83	3M001-6,8,9,11,13,15; 3F001-7,9-14
6	10/27-11/2/83	3M001-3,5,6,8,9,11,15; 3F001-5,7,10,12-14
7	11/3-11/9/83	3M002,5,6,8,9,11,15; 3F005,7,10
8	11/10-11/16/83	3M009,11; 3F005,10,14
9	11/17-11/23/83	2M001,2,6,11; 3M011; 3F005,10,14
10	11/24-11/30/83	2M008; 2F009; 3F005,10,14
11	12/1-12/7/83	2M004,5; 3F005,10,14
12	12/8-12/14/83	2M002,4,6,9-11,14; 3F005,10,14
13	12/15-12/22/83	2M002,4,9,14; 3F005,10
		Gasping
1	9/22-9/28/83	3F002,7,10,11
2	9/20-10/5/83	3M004
3	10/6-10/12/83	3M004,12-14; 3F004,8,15
4	10/13-10/19/83	3M001,2,4,7,8,10,13,14; 3F003-5,7-9,11
5	10/20-10/26/83	3M001-4,6,8,11,13,15; 3F003-5,7,9-14
6	10/27-11/2/83	3M001-3,5,6,8,9,11,15; 3F001,3-5,7,11-14
7	11/3-11/9/83	3M001,2,5,6,8,9,11; 3F002,5,7,10,14
8	11/10-11/16/83	2M009; 3M005,6,9,11; 3F005,14
9	11/17-11/23/83	3M006,9,11; 3F005,10,14
10	11/24-11/30/83	3M011; 3F010,14
11	12/1-12/7/83	3F010,14
12	12/8-12/14/83	3F005,14
13	12/15-12/21/83	3F005

Weekly Occurrences of Signs of Azomethine Toxicity Observed in Individual Animals Before and After Exposure

Week No.	Dates	
		Labored Breathing
1	9/22-9/28/83	3M004,12; 3F002,7,10,11
2	9/29-10/5/83	3M004
3	10/6-10/12/83	3M001,4,6,7,12-14; 3F003,4,8,15
4	10/13-10/19/83	3M001,2,4-8,10,11,13-15; 3F001,3-8,11
5	10/20-10/26/83	3M001-6,8,9,11,13,15; 3F001,3-7,9-13
6	10/27-11/2/83	3M001-3,5,6,8,9,11,15; 3F001,3-5,7,10-14
7	11/3-11/9/83	3M001-3,5,6,8,9,11,15; 3F002,5,7,10,14
8	11/10-11/16/83	3M005,6,9,11; 3F005,10,14
9	11/17-11/23/83	3M006,9,11; 3F005,10,14
10	11/24-11/30/83	3M011; 3F005,10,14
11	12/1-12/7/83	3F005,10,14
12	12/8-12/14/83	3F005,10,14
13	12/15-12/21/83	3F005,10
		Rapid Breathing
1	9/22-9/28/83	3F010-12
3	10/6-10/12/83	3M004,7; 3F003,8,15
4	10/13-10/19/83	3M002,4,5,7
5	10/20-10/26/83	3M003; 3F001,9
6	10/27-11/2/83	3M001-3,5,6,8,9,11,15; 3F001-5,7,10-14
7	11/3-11/9/83	3M002,3,5,6,9,11; 3F002,5,7,10,14
8	11/10-11/16/83	3M005,6,9,11; 3F005,10,14
9	11/17-11/23/83	3M006,11; 3F005,10,14
10	11/24-11/30/83	3F005,10,14
11	12/1-12/7/83	3F005,10,14
12	12/8-12/14/83	3F005,10
13	12/15-12/21/83	3F005,10
		Shallow Breathing
6	10/27-11/2/83	3M015
		Slow Breathing
6	10/27-11/2/83	3M015

Weekly Occurrences of Signs of Azomethine Toxicity Observed in Individual Animals Before and After Exposure

Week No.	Dates	
		Hypoactivity
1	9/22-9/28/83	3M001-15; 3F001-3,5-7,9,10,12-15
2	9/29-10/5/83	3M001-15; 3F001,3-7,9,12
3	10/6-10/12/83	3M001-15; 3F001-5,7-9,13-15
4	10/13-10/19/83	3M001-6,8-11,13-15; 3F001-5,7,8,10,12,14
5	10/20-10/26/83	3M003,5,9,13,15; 3F001,7,9-14
6	10/27-11/2/83	3M001; 3F007,12
		Prostrate
3	10/6-10/12/83	3F008
4	10/13-10/19/83	3F008
5	10/20-10/26/83	3F006
		Non-Responsive
5	10/20-10/26/83	3M015
		Aggressive Activity
3	10/6-10/12/83	3M006
		Focal Loss of Hair
2	9/29-10/5/83	3F005,15
3	10/6-10/12/83	1M011; 3M009-11; 3F005,14
4	10/13-10/19/83	1M011; 3M001,7,10,14; 3F001,2,5,14
5	10/20-10/26/83	3F006,13
6	10/27-11/2/83	NF013; 3M001
7	11/3-11/9/83	3F007,14

Weekly Occurrences of Signs of Azomethine Toxicity Observed in Individual Animals Before and After Exposure

Week No.	Dates	
		Generalized Loss of Hair
6	10/27-11/2/83	1M011
7	11/3-11/9/83	NF013; 3M011
8	11/10-11/16/83	NF013; 1M011
9	11/17-11/23/83	NF013
10	11/24-11/30/83	NF013
11	12/1-12/7/83	NF013
12	12/8-12/14/83	NF013
13	12/15-12/21/83	NF013
		Abrasion(s)
3	10/6-10/12/83	1M011
4	10/13-10/19/83	1M011
5	10/20-10/26/83	3M006
		Blood-Stained Appearance
1	9/22-9/28/83	3F008,9
2	9/29-10/5/83	2M012
4	10/13-10/19/83	3F001,3,14; 3M007,14
6	10/27-11/2/83	3F012
		Urine-Stained Fur
3	10/6-10/12/83	3M004
4	10/13-10/19/83	3M001,4,5,10; 3F003-5,8,9,11,13
5	10/20-10/26/83	3M001,2,6,13; 3F003-5,9,11-14
6	10/27-11/2/83	NM010; 3M001,2; 3F002,3,5,12,14
7	11/3-11/9/83	NM010; 3F005,14
9	11/17-11/23/83	3F014
10	11/24-11/30/83	3F014
		Feces-Stained Fur
5	10/20-10/26/83	3M002; 3F013
7	11/3-11/9/83	3M005,9

Weekly Occurrences of Signs of Azomethine Toxicity Observed in Individual Animals Before and After Exposure

Week No.	Dates	
		Urogenital Discharge
5	10/20-10/26/83	3M013
		Opacity of Eyes
3	10/6-10/12/83	3M007,14; 3F008,15
4	10/13-10/19/83	3M007,8,14; 3F003,8
5	10/20-10/26/83	3M002,8,9,15; 3F003,6,7,11,12
6	10/27-11/2/83	3M002,9,15; 3F003,12
7	11/3-11/9/83	3M002
		Emaciated Appearance
4	10/13-10/19/83	3F011
8	11/10-11/16/83	3F014
10	12/1-12/7/83	3F014
11	11/10-11/16/83	3F014
13	12/15-12/21/83	3F005
		Death
3	10/6-10/12/83	3M012; 3F015
4	10/13-10/19/83	3M007,14; 3F008
5	10/20-10/26/83	3M004,10
6	10/27-11/2/83	3M013; 3F001,3,4,6,9,11-13
7	11/3-11/9/83	3M001-3,8,15; 3F002,7
8	11/20-11/16/83	3M005
9	11/17-11/23/83	3M009
10	11/24-11/30/83	3M006,11
12	12/8-12/14/83	3F014

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: MALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
EYE(S)	RED DISCHARGE	13-DEC-83	83	83106MN Ø13
		20-DEC-83	90	83106MN Ø13
INTEGUMENT	URINE-STAINED HAIR	1-NOV-83	41	83106MN Ø10
		8-NOV-83	48	83106MN Ø10

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0100 MG/L

SEX: MALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
NOSE	RED/BROWN PERINASAL ENCRUSTATION	20-DEC-83	90	83106M1 005
INTEGUMENT	FOCAL LOSS OF HAIR	11-OCT-83	20	83106M1 011
	GENERALIZED LOSS OF HAIR	1-NOV-83	41	83106M1 011
		8-NOV-83	48	83106M1 011
		15-NOV-83	55	83106M1 011
	ABRASION(S)	11-OCT-83	20	83106M1 011

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0500 MG/L

SEX: MALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
** NO ABNORMAL CLINICAL SIGNS RECORDED **				

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	SACRIFICED IN EXTREMIS	11-OCT-83	20	83106M3 012
		3-NOV-83	43	83106M3 015
	SPONTANEOUS - BODY INTACT	14-OCT-83	23	83106M3 007
		17-OCT-83	26	83106M3 014
		20-OCT-83	29	83106M3 004
				83106M3 010
		27-OCT-83	36	83106M3 013
		3-NOV-83	43	83106M3 001
				83106M3 003
		4-NOV-83	44	83106M3 002
				83106M3 008
		15-NOV-83	55	83106M3 005
		17-NOV-83	57	83106M3 009
		26-NOV-83	66	83106M3 006
		29-NOV-83	69	83106M3 011
RESPIRATION	LABORED	11-OCT-83	20	83106M3 012
				83106M3 004
		18-OCT-83	27	83106M3 001
				83106M3 004
				83106M3 008
				83106M3 010
				83106M3 013
		25-OCT-83	34	83106M3 001
				83106M3 003
				83106M3 006
				83106M3 013
		1-NOV-83	41	83106M3 001
				83106M3 002
				83106M3 003
				83106M3 005
				83106M3 006

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
RESPIRATION	LABORED	1-NOV-83	41	83106M3 008
				83106M3 009
				83106M3 011
				83106M3 015
		8-NOV-83	48	83106M3 005
				83106M3 011
		15-NOV-83	55	83106M3 006
				83106M3 009
				83106M3 011
		22-NOV-83	62	83106M3 006
				83106M3 011
		29-NOV-83	69	83106M3 011
	GASPING	11-OCT-83	20	83106M3 012
				83106M3 004
		18-OCT-83	27	83106M3 001
				83106M3 004
				83106M3 008
				83106M3 010
				83106M3 013
		25-OCT-83	34	83106M3 001
		1-NOV-83	41	83106M3 001
				83106M3 005
				83106M3 006
				83106M3 008
				83106M3 011
				83106M3 015
		8-NOV-83	48	83106M3 005
				83106M3 011
	RAPID	1-NOV-83	41	83106M3 002
		8-NOV-83	48	83106M3 006
				83106M3 009
				83106M3 011

STUDY NUMBER: 83106 INDIVIDUAL CLINICAL SIGNS
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
RESPIRATION	RAPID	15-NOV-83	55	83106M3 006
				83106M3 009
				83106M3 011
	SHALLOW	8-NOV-83	48	83106M3 005
	SNEEZING	18-OCT-83	27	83106M3 001
		25-OCT-83	34	83106M3 002
				83106M3 013
NOSE	BLOOD-LIKE DISCHARGE	11-OCT-83	20	83106M3 012
		18-OCT-83	27	83106M3 001
		25-OCT-83	34	83106M3 001
				83106M3 003
				83106M3 006
	RED/BROWN PERINASAL ENCRUSTATION	11-OCT-83	20	83106M3 012
		18-OCT-83	27	83106M3 001
				83106M3 002
				83106M3 004
				83106M3 013
				83106M3 015
		25-OCT-83	34	83106M3 001
				83106M3 002
				83106M3 008
				83106M3 013
		1-NOV-83	41	83106M3 003
				83106M3 011
		15-NOV-83	55	83106M3 009
EYE(S)	OPACITY	18-OCT-83	27	83106M3 004
		25-OCT-83	34	83106M3 002
				83106M3 009
				83106M3 015
		1-NOV-83	41	83106M3 002

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
EYE(S)	OPACITY	1-NOV-83	41	83106M3 009
				83106M3 015
INTEGUMENT	GENERALIZED LOSS OF HAIR	8-NOV-83	48	83106M3 011
	URINE-STAINED HAIR	11-OCT-83	20	83106M3 004
		18-OCT-83	27	83106M3 001
				83106M3 010
		25-OCT-83	34	83106M3 001
				83106M3 002
				83106M3 006
		1-NOV-83	41	83106M3 001
				83106M3 002
	FECES-STAINED HAIR	25-OCT-83	34	83106M3 002
		8-NOV-83	48	83106M3 005
				83106M3 009
GENITALIA	UROGENITAL DISCHARGE	25-OCT-83	34	83106M3 013

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: FEMALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
EYE(S)	RED DISCHARGE	20-DEC-83	90	83106FN 013
INTEGUMENT	GENERALIZED LOSS OF HAIR	1-NOV-83	41	83106FN 013
		8-NOV-83	48	83106FN 013
		15-NOV-83	55	83106FN 013
		22-NOV-83	62	83106FN 013
		29-NOV-83	69	83106FN 013
		6-DEC-83	76	83106FN 013
		13-DEC-83	83	83106FN 013
		20-DEC-83	90	83106FN 013

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0100 MG/L

SEX: FEMALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL

** NO ABNORMAL CLINICAL SIGNS RECORDED **

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0500 MG/L

SEX: FEMALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL

** NO ABNORMAL CLINICAL SIGNS RECORDED **

STUDY NUMBER: 83106 INDIVIDUAL CLINICAL SIGNS
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	SPONTANEOUS - BODY INTACT	9-OCT-83	18	83106F3 015
		15-OCT-83	24	83106F3 008
		27-OCT-83	36	83106F3 001
				83106F3 006
				83106F3 009
		28-OCT-83	37	83106F3 011
				83106F3 013
		31-OCT-83	40	83106F3 004
		1-NOV-83	41	83106F3 003
				83106F3 012
		6-NOV-83	46	83106F3 002
		7-NOV-83	47	83106F3 007
		10-DEC-83	80	83106F3 014
RESPIRATION	LABORED	18-OCT-83	27	83106F3 011
		25-OCT-83	34	83106F3 011
				83106F3 012
		1-NOV-83	41	83106F3 005
				83106F3 010
				83106F3 014
		8-NOV-83	48	83106F3 010
				83106F3 014
		15-NOV-83	55	83106F3 005
				83106F3 010
				83106F3 014
		22-NOV-83	62	83106F3 014
		29-NOV-83	69	83106F3 005
				83106F3 014
		6-DEC-83	76	83106F3 005
				83106F3 010
				83106F3 014
		20-DEC-83	90	83106F3 005

STUDY NUMBER: 83106 INDIVIDUAL CLINICAL SIGNS
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
RESPIRATION	GASPING	18-OCT-83	27	83106F3 009
				83106F3 011
		25-OCT-83	34	83106F3 009
				83106F3 012
				83106F3 013
				83106F3 014
		8-NOV-83	48	83106F3 014
		22-NOV-83	62	83106F3 014
		20-DEC-83	90	83106F3 005
	RAPID	1-NOV-83	41	83106F3 002
				83106F3 007
				83106F3 010
		8-NOV-83	48	83106F3 005
				83106F3 010
		15-NOV-83	55	83106F3 005
				83106F3 010
				83106F3 014
		22-NOV-83	62	83106F3 005
				83106F3 010
		29-NOV-83	69	83106F3 010
		6-DEC-83	76	83106F3 005
				83106F3 010
				83106F3 014
		13-DEC-83	83	83106F3 010
		20-DEC-83	90	83106F3 010
	SNEEZING	18-OCT-83	27	83106F3 013
				83106F3 014
		25-OCT-83	34	83106F3 001
				83106F3 004
				83106F3 005
				83106F3 009
				83106F3 011

STUDY NUMBER: 83106 INDIVIDUAL CLINICAL SIGNS
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
RESPIRATION	SNEEZING	20-DEC-83	90	83106F3 005
NOSE	YELLOW/BROWN DISCHARGE	18-OCT-83	27	83106F3 003
	BLOOD-LIKE DISCHARGE	18-OCT-83	27	83106F3 005
				83106F3 013
	RED/BROWN PERINASAL ENCRUSTATION	18-OCT-83	27	83106F3 004
				83106F3 009
				83106F3 011
				83106F3 013
		25-OCT-83	34	83106F3 004
				83106F3 005
				83106F3 006
				83106F3 009
				83106F3 011
				83106F3 012
				83106F3 013
MOUTH	BLOOD-LIKE DISCHARGE	18-OCT-83	27	83106F3 003
EYE(S)	OPACITY	25-OCT-83	34	83106F3 003
				83106F3 011
INTEGUMENT	FOCAL LOSS OF HAIR	4-OCT-83	13	83106F3 005
				83106F3 015
		11-OCT-83	20	83106F3 005
		18-OCT-83	27	83106F3 001
	URINE-STAINED HAIR	18-OCT-83	27	83106F3 003
				83106F3 004
				83106F3 009
				83106F3 011
				83106F3 013
		25-OCT-83	34	83106F3 003

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
INTEGUMENT	URINE-STAINED HAIR	25-OCT-83	34	83106F3 004
				83106F3 005
				83106F3 009
				83106F3 011
				83106F3 012
				83106F3 013
				83106F3 014
		1-NOV-83	41	83106F3 002
				83106F3 005
				83106F3 014
		8-NOV-83	48	83106F3 005
				83106F3 014
		22-NOV-83	62	83106F3 014
		29-NOV-83	69	83106F3 014
	FECES-STAINED HAIR	25-OCT-83	34	83106F3 013
GENERAL APPEARANCE	EMACIATED	18-OCT-83	27	83106F3 011
		8-NOV-83	48	83106F3 014
		15-NOV-83	55	83106F3 014
		29-NOV-83	69	83106F3 014
		6-DEC-83	76	83106F3 014
		20-DEC-83	90	83106F3 005

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : NEGATIVE CONTROL SEX: MALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48	15-NOV 55	22-NOV 62	29-NOV 69	6-DEC 76
83106MN	001	247.0	299.0	337.0	372.0	406.0	420.0	444.0	460.0	477.0	495.0	505.3	522.0
83106MN	002	239.0	298.0	337.0	373.0	393.0	416.0	437.0	463.0	476.0	484.0	493.2	503.0
83106MN	003	243.0	293.0	326.0	360.0	378.0	409.0	427.0	461.0	463.0	473.0	471.6	500.0
83106MN	004	251.0	326.0	367.0	421.0	455.0	481.0	504.0	545.0	571.0	582.0	599.8	627.0
83106MN	005	245.0	303.0	341.0	380.0	403.0	431.0	459.0	478.0	505.0	520.0	545.0	550.0
83106MN	006	242.0	310.0	347.0	372.0	401.0	430.0	457.0	484.0	492.0	517.0	535.5	556.0
83106MN	007	238.0	285.0	316.0	354.0	380.0	400.0	423.0	442.0	460.0	460.0	466.0	484.0
83106MN	008	237.0	290.0	327.0	366.0	406.0	429.0	459.0	484.0	515.0	538.0	561.0	569.0
83106MN	009	242.0	294.0	320.0	360.0	377.0	381.0	415.0	442.0	464.0	481.0	495.0	500.0
83106MN	010	245.0	325.0	378.0	431.0	470.0	498.0	540.0	567.0	592.0	599.0	628.0	644.0
83106MN	011	239.0	298.0	350.0	389.0	422.0	445.0	471.0	491.0	496.0	521.0	538.0	557.0
83106MN	012	238.0	297.0	335.0	376.0	405.0	438.0	456.0	477.0	495.0	510.0	522.0	540.0
83106MN	013	235.0	290.0	324.0	358.0	387.0	413.0	441.0	459.0	481.0	501.0	509.0	464.0
83106MN	014	247.0	305.0	336.0	377.0	412.0	432.0	459.0	481.0	502.0	522.0	540.0	547.0
83106MN	015	249.0	298.0	337.0	383.0	397.0	430.0	457.0	478.0	486.0	505.0	535.0	538.0

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 23-JAN-87

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: MALE

ANIMAL	DATE (1983): DAY OF STUDY:	13-DEC 83	20-DEC 90
83106MN	001	529.4	538.0
83106MN	002	513.8	515.0
83106MN	003	520.1	528.0
83106MN	004	642.3	645.0
83106MN	005	559.8	564.0
83106MN	006	560.0	568.0
83106MN	007	503.2	505.0
83106MN	008	590.4	603.0
83106MN	009	515.6	506.0
83106MN	010	671.3	679.0
83106MN	011	566.8	563.0
83106MN	012	548.5	553.0
83106MN	013	488.0	499.0
83106MN	014	553.2	558.0
83106MN	015	530.1	543.0

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0100 MG/L

SEX: MALE

ANIMAL	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48	15-NOV 55	22-NOV 62	29-NOV 69	6-DEC 76
83106M1	001	243.0	295.0	324.0	365.0	393.0	414.0	444.0	464.0	483.0	498.0	522.0	540.0
83106M1	002	247.0	307.0	350.0	386.0	419.0	451.0	467.0	495.0	504.0	530.0	546.0	557.0
83106M1	003	240.0	296.0	341.0	382.0	424.0	456.0	482.0	501.0	520.0	540.0	554.0	580.0
83106M1	004	242.0	299.0	339.0	389.0	416.0	436.0	459.0	488.0	507.0	523.0	530.0	548.0
83106M1	005	246.0	306.0	354.0	390.0	420.0	435.0	470.0	497.0	509.8	531.0	542.0	549.0
83106M1	006	245.0	307.0	352.0	389.0	417.0	447.0	474.0	499.0	521.0	536.0	550.0	570.0
83106M1	007	239.0	282.0	311.0	338.0	359.0	379.0	397.0	409.0	421.5	434.0	446.0	456.0
83106M1	008	238.0	287.0	319.0	348.0	371.0	391.0	419.0	433.0	448.5	462.0	472.0	491.0
83106M1	009	249.0	310.0	328.0	384.0	418.0	450.0	465.0	494.0	514.1	530.0	545.0	557.0
83106M1	010	236.0	290.0	326.0	367.0	392.0	421.0	447.0	476.0	484.1	495.0	508.0	526.0
83106M1	011	239.0	291.0	330.0	373.0	412.0	439.0	464.0	492.0	509.0	530.0	546.0	565.0
83106M1	012	242.0	300.0	343.0	387.0	416.0	456.0	473.0	501.0	513.0	538.0	555.0	573.0
83106M1	013	250.0	321.0	375.0	431.0	486.0	518.0	556.0	608.0	628.0	643.0	670.0	696.0
83106M1	014	253.0	314.0	351.0	394.0	427.0	450.0	477.0	494.0	507.0	535.0	548.0	560.0
83106M1	015	236.0	291.0	332.0	381.0	414.0	439.0	464.0	482.0	493.0	511.0	517.0	528.0

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0100 MG/L

ANIMAL	DATE (1983): 13-DEC	20-DEC
	DAY OF STUDY: 83	90
83106M1 001	548.0	546.0
83106M1 002	573.0	582.0
83106M1 003	577.0	589.0
83106M1 004	557.0	567.0
83106M1 005	571.0	561.0
83106M1 006	581.0	580.0
83106M1 007	459.0	458.0
83106M1 008	495.0	504.0
83106M1 009	566.0	577.0
83106M1 010	536.0	546.0
83106M1 011	576.0	568.0
83106M1 012	584.0	589.0
83106M1 013	665.0	679.0
83106M1 014	559.0	557.0
83106M1 015	527.0	531.0

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0500 MG/L

ANIMAL	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48	15-NOV 55	22-NOV 62	29-NOV 69	6-DEC 76
83106M2	001	235.0	273.0	302.0	335.0	354.0	380.0	393.0	416.0	431.0	440.0	499.0	451.0
83106M2	002	245.0	286.0	319.0	359.0	389.0	409.0	424.0	452.0	474.0	483.0	505.0	519.0
83106M2	003	237.0	278.0	308.0	348.0	369.0	388.0	406.0	422.0	435.0	447.0	452.0	452.0
83106M2	004	241.0	292.0	330.0	367.0	384.0	406.0	428.0	445.0	464.0	476.0	484.0	499.0
83106M2	005	250.0	290.0	326.0	362.0	390.0	409.0	430.0	442.0	456.0	461.0	470.0	469.0
83106M2	006	239.0	289.0	336.0	381.0	409.0	432.0	462.0	495.0	517.0	528.0	546.0	558.0
83106M2	007	246.0	292.0	330.0	376.0	404.0	423.0	447.0	467.0	480.0	490.0	508.0	506.0
83106M2	008	250.0	288.0	326.0	361.0	374.0	396.0	420.0	443.0	463.0	475.0	485.0	498.0
83106M2	009	237.0	280.0	308.0	344.0	370.0	402.0	422.0	433.0	450.0	462.0	474.0	489.0
83106M2	010	243.0	287.0	316.0	349.0	380.0	395.0	407.0	436.0	447.0	458.0	463.0	476.0
83106M2	011	248.0	289.0	328.0	367.0	392.0	414.0	420.0	436.0	443.0	454.0	467.0	467.0
83106M2	012	238.0	271.0	307.0	342.0	355.0	386.0	395.0	410.0	431.0	440.0	461.0	461.0
83106M2	013	246.0	285.0	312.0	351.0	372.0	397.0	410.0	432.0	435.0	445.0	469.0	463.0
83106M2	014	244.0	280.0	293.0	330.0	339.0	364.0	383.0	400.0	405.0	421.0	432.0	446.0
83106M2	015	240.0	292.0	332.0	373.0	402.0	437.0	449.0	472.0	487.0	503.0	527.0	541.0

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 23-JAN-87

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0500 MG/L

ANIMAL	DATE (1983): DAY OF STUDY:	13-DEC 83	20-DEC 90
83106M2	001	458.0	472.0
83106M2	002	524.0	530.0
83106M2	003	469.0	477.0
83106M2	004	503.0	509.0
83106M2	005	483.0	485.0
83106M2	006	556.0	573.0
83106M2	007	509.0	516.0
83106M2	008	506.0	509.0
83106M2	009	493.0	500.0
83106M2	010	488.0	487.0
83106M2	011	483.0	477.0
83106M2	012	467.0	471.0
83106M2	013	473.0	476.0
83106M2	014	443.0	441.0
83106M2	015	544.0	553.0

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

SEX: MALE

ANIMAL	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48	15-NOV 55	22-NOV 62	29-NOV 69
83106M3	001	239.0	241.0	226.0	210.0	192.0	195.0	192.0				
83106M3	002	248.0	252.0	279.0	274.0	217.0	188.0	214.0				
83106M3	003	240.0	249.0	274.0	298.0	293.0	266.0	219.0				
83106M3	004	245.0	258.0	287.0	246.0	199.0						
83106M3	005	242.0	265.0	292.0	325.0	268.0	268.0	243.0	232.0			
83106M3	006	243.0	272.0	300.0	319.0	318.0	271.0	255.0	275.0	266.0	260.0	
83106M3	007	250.0	260.0	280.0	239.0							
83106M3	008	246.0	258.0	274.0	303.0	249.0	241.0	215.0				
83106M3	009	237.0	254.0	277.0	303.0	292.0	265.0	266.0	266.0	216.0		
83106M3	010	237.0	240.0	260.0	277.0	208.0						
83106M3	011	238.0	254.0	277.0	305.0	269.0	268.0	221.0	224.0	253.0	245.0	227.0
83106M3	012	246.0	262.0	266.0	185.0							
83106M3	013	241.0	244.0	253.0	263.0	217.0	193.0					
83106M3	014	252.0	253.0	286.0	243.0							
83106M3	015	235.0	249.0	270.0	285.0	256.0	231.0	206.0				

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 23-JAN-87

STUDY NUMBER: 83106 INDIVIDUAL BODY WEIGHT DATA (GM)
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : NEGATIVE CONTROL SEX: FEMALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48	15-NOV 55	22-NOV 62	29-NOV 69	6-DEC 76
83106FN	001	169.0	191.0	211.0	210.0	225.0	226.0	243.0	250.0	264.0	262.0	275.0	283.0
83106FN	002	180.0	200.0	215.0	231.0	237.0	240.0	252.0	263.0	267.0	270.0	287.0	293.0
83106FN	003	171.0	199.0	217.0	225.0	252.0	250.0	250.0	277.0	286.0	286.0	286.0	301.0
83106FN	004	166.0	183.0	189.0	193.0	209.0	215.0	221.0	221.0	231.0	242.0	243.0	241.0
83106FN	005	178.0	204.0	219.0	220.0	232.0	242.0	240.0	244.0	258.0	263.0	272.0	268.0
83106FN	006	179.0	200.0	215.0	242.0	249.0	257.0	266.0	281.0	292.0	300.0	294.0	301.0
83106FN	007	173.0	202.0	215.0	240.0	242.0	237.0	254.0	263.0	266.0	277.0	268.0	282.0
83106FN	008	175.0	206.0	223.0	244.0	258.0	266.0	282.0	294.0	302.0	318.0	322.0	330.0
83106FN	009	176.0	203.0	217.0	230.0	248.0	255.0	267.0	273.0	286.0	299.0	299.0	303.0
83106FN	010	181.0	211.0	226.0	228.0	249.0	258.0	270.0	273.0	285.0	298.0	296.0	295.0
83106FN	011	167.0	198.0	224.0	239.0	255.0	256.0	279.0	294.0	291.0	313.0	314.0	310.0
83106FN	012	173.0	199.0	193.0	235.0	243.0	254.0	251.0	264.0	273.0	277.0	273.0	287.0
83106FN	013	169.0	188.0	210.0	213.0	223.0	230.0	230.0	252.0	255.0	260.0	263.0	277.0
83106FN	014	174.0	200.0	215.0	230.0	248.0	251.0	255.0	267.0	275.0	278.0	280.0	292.0
83106FN	015	166.0	189.0	200.0	218.0	227.0	234.0	237.0	254.0	260.0	259.0	262.0	273.0

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: FEMALE

ANIMAL	DATE (1983): 13-DEC	20-DEC
	DAY OF STUDY: 83	90
83106FN 001	282.6	285.0
83106FN 002	295.8	299.0
83106FN 003	310.8	304.0
83106FN 004	251.1	254.0
83106FN 005	276.4	277.0
83106FN 006	307.7	305.0
83106FN 007	293.6	296.0
83106FN 008	337.7	343.0
83106FN 009	309.3	314.0
83106FN 010	308.4	313.0
83106FN 011	321.9	315.0
83106FN 012	288.3	291.0
83106FN 013	277.0	280.0
83106FN 014	293.0	292.0
83106FN 015	278.0	278.0

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0100 MG/L

ANIMAL	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48	15-NOV 55	22-NOV 62	29-NOV 69	6-DEC 76
83106F1	001	172.0	196.0	206.0	214.0	232.0	239.0	243.0	248.0	267.0	281.0	284.0	288.0
83106F1	002	165.0	184.0	194.0	194.0	207.0	215.0	222.0	220.0	235.0	243.0	243.0	245.0
83106F1	003	169.0	190.0	193.0	208.0	208.0	221.0	224.0	230.0	225.0	238.0	250.0	252.0
83106F1	004	171.0	196.0	212.0	232.0	246.0	251.0	270.0	278.0	285.0	294.0	302.0	304.0
83106F1	005	169.0	194.0	210.0	234.0	244.0	252.0	264.0	284.0	262.0	292.0	300.0	308.0
83106F1	006	167.0	188.0	189.0	203.0	213.0	217.0	219.0	232.0	240.0	245.0	246.0	248.0
83106F1	007	168.0	195.0	209.0	222.0	237.0	243.0	262.0	268.0	269.0	286.0	285.0	291.0
83106F1	008	174.0	192.0	202.0	211.0	209.0	223.0	225.0	234.0	235.0	248.0	246.0	259.0
83106F1	009	174.0	190.0	211.0	229.0	230.0	242.0	252.0	265.0	270.0	284.0	283.0	297.0
83106F1	010	177.0	194.0	216.0	227.0	237.0	248.0	256.0	272.0	278.0	278.0	285.0	294.0
83106F1	011	180.0	208.0	220.0	241.0	253.0	264.0	273.0	274.0	283.0	286.0	292.0	301.0
83106F1	012	175.0	193.0	212.0	222.0	242.0	248.0	264.0	266.0	286.0	292.0	291.0	310.0
83106F1	013	177.0	205.0	220.0	234.0	251.0	256.0	269.0	280.0	285.0	300.0	313.0	316.0
83106F1	014	181.0	202.0	209.0	222.0	232.0	240.0	247.0	247.0	257.0	261.0	270.0	265.0
83106F1	015	179.0	199.0	213.0	220.0	230.0	238.0	248.0	260.0	267.0	283.0	277.0	285.0

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 23-JAN-87

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0100 MG/L

SEX: FEMALE

ANIMAL	DATE (1983): 13-DEC DAY OF STUDY: 83	20-DEC 90
83106F1 001	300.0	307.0
83106F1 002	257.0	264.0
83106F1 003	251.0	248.0
83106F1 004	310.0	316.0
83106F1 005	339.0	346.0
83106F1 006	244.0	249.0
83106F1 007	289.0	291.0
83106F1 008	254.0	253.0
83106F1 009	297.0	295.0
83106F1 010	295.0	302.0
83106F1 011	310.0	314.0
83106F1 012	315.0	305.0
83106F1 013	327.0	322.0
83106F1 014	272.0	273.0
83106F1 015	289.0	291.0

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0500 MG/L

ANIMAL	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48	15-NOV 55	22-NOV 62	29-NOV 69	6-DEC 76
83106F2	001	175.0	195.0	207.0	228.0	242.0	253.0	244.0	267.0	275.0	278.0	279.0	285.0
83106F2	002	172.0	186.0	206.0	221.0	222.0	224.0	235.0	245.0	248.0	252.0	261.0	262.0
83106F2	003	168.0	180.0	197.0	208.0	209.0	206.0	215.0	220.0	225.0	219.0	227.0	230.0
83106F2	004	168.0	188.0	202.0	210.0	213.0	207.0	218.0	225.0	230.0	228.0	236.0	234.0
83106F2	005	178.0	190.0	197.0	221.0	241.0	245.0	261.0	249.0	272.0	273.0	274.0	278.0
83106F2	006	177.0	191.0	194.0	223.0	226.0	235.0	238.0	251.0	249.0	258.0	253.0	267.0
83106F2	007	181.0	201.0	208.0	223.0	234.0	250.0	253.0	264.0	266.0	270.0	277.0	286.0
83106F2	008	173.0	182.0	196.0	214.0	213.0	222.0	230.0	238.0	237.0	249.0	251.0	253.0
83106F2	009	175.0	200.0	210.0	227.0	233.0	249.0	257.0	262.0	266.0	276.0	269.0	278.0
83106F2	010	166.0	183.0	191.0	206.0	205.0	202.0	212.0	223.0	228.0	222.0	227.0	234.0
83106F2	011	181.0	199.0	209.0	221.0	235.0	237.0	246.0	257.0	257.0	276.0	277.0	284.0
83106F2	012	164.0	185.0	197.0	207.0	209.0	214.0	223.0	229.0	230.0	237.0	241.0	243.0
83106F2	013	171.0	184.0	203.0	220.0	226.0	243.0	251.0	252.0	250.0	260.0	265.0	268.0
83106F2	014	179.0	193.0	194.0	223.0	224.0	229.0	228.0	245.0	246.0	269.0	278.0	283.0
83106F2	015	169.0	182.0	194.0	217.0	219.0	222.0	219.0	234.0	234.0	245.0	251.0	250.0

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0500 MG/L

ANIMAL	DATE (1983): 13-DEC	20-DEC
	DAY OF STUDY: 83	90
83106F2 001	287.0	283.0
83106F2 002	267.0	270.0
83106F2 003	232.0	217.0
83106F2 004	238.0	234.0
83106F2 005	278.0	287.0
83106F2 006	268.0	276.0
83106F2 007	288.0	294.0
83106F2 008	252.0	257.0
83106F2 009	282.0	282.0
83106F2 010	233.0	230.0
83106F2 011	279.0	280.0
83106F2 012	248.0	249.0
83106F2 013	272.0	272.0
83106F2 014	279.0	293.0
83106F2 015	245.0	254.0

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

ANIMAL	DATE (1983): DAY OF STUDY:	PRE-TEST	27-SEP 6	4-OCT 13	11-OCT 20	18-OCT 27	25-OCT 34	1-NOV 41	8-NOV 48	15-NOV 55	22-NOV 62	29-NOV 69	6-DEC 76
83106F3	001	167.0	171.0	178.0	179.0	175.0	157.0						
83106F3	002	168.0	173.0	181.0	186.0	182.0	182.0	158.0					
83106F3	003	176.0	182.0	208.0	197.0	173.0	194.0						
83106F3	004	180.0	187.0	206.0	220.0	196.0	169.0						
83106F3	005	165.0	165.0	177.0	186.0	172.0	148.0	137.0	150.0	167.0	165.0	180.0	180.0
83106F3	006	176.0	172.0	189.0	203.0	186.0	155.0						
83106F3	007	168.0	173.0	186.0	200.0	198.0	187.0	189.0					
83106F3	008	170.0	169.0	182.0	140.0								
83106F3	009	182.0	192.0	206.0	215.0	194.0	156.0						
83106F3	010	175.0	184.0	201.0	210.0	212.0	221.0	206.0	211.0	220.0	220.0	226.0	221.0
83106F3	011	173.0	186.0	198.0	206.0	155.0	157.0						
83106F3	012	179.0	190.0	203.0	211.0	206.0	178.0						
83106F3	013	179.0	182.0	200.0	213.0	184.0	167.0						
83106F3	014	171.0	186.0	196.0	220.0	203.0	186.0	169.0	154.0	175.0	162.0	163.0	169.0
83106F3	015	171.0	180.0	178.0									

STUDY NUMBER: 83106 INDIVIDUAL BODY WEIGHT DATA (GM)
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

ANIMAL	DATE (1983): 13-DEC	20-DEC
	DAY OF STUDY: 83	90
83106F3 001		
83106F3 002		
83106F3 003		
83106F3 004		
83106F3 005	174.0	149.0
83106F3 006		
83106F3 007		
83106F3 008		
83106F3 009		
83106F3 010	231.0	227.0
83106F3 011		
83106F3 012		
83106F3 013		
83106F3 014		
83106F3 015		

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 10-JAN-84

STUDY NUMBER: 83106 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : NEGATIVE CONTROL SEX: MALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
83106MN 001	21-DEC-83	91	TERMINAL SACRIFICE
83106MN 002	21-DEC-83	91	TERMINAL SACRIFICE
83106MN 003	21-DEC-83	91	TERMINAL SACRIFICE
83106MN 004	21-DEC-83	91	TERMINAL SACRIFICE
83106MN 005	22-DEC-83	92	TERMINAL SACRIFICE
83106MN 006	22-DEC-83	92	TERMINAL SACRIFICE
83106MN 007	21-DEC-83	91	TERMINAL SACRIFICE
83106MN 008	22-DEC-83	92	TERMINAL SACRIFICE
83106MN 009	21-DEC-83	91	TERMINAL SACRIFICE
83106MN 010	22-DEC-83	92	TERMINAL SACRIFICE
83106MN 011	22-DEC-83	92	TERMINAL SACRIFICE
83106MN 012	21-DEC-83	91	TERMINAL SACRIFICE
83106MN 013	22-DEC-83	92	TERMINAL SACRIFICE
83106MN 014	21-DEC-83	91	TERMINAL SACRIFICE
83106MN 015	22-DEC-83	92	TERMINAL SACRIFICE

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0100 MG/L

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
83106M1 001	21-DEC-83	91	TERMINAL SACRIFICE
83106M1 002	21-DEC-83	91	TERMINAL SACRIFICE
83106M1 003	21-DEC-83	91	TERMINAL SACRIFICE
83106M1 004	21-DEC-83	91	TERMINAL SACRIFICE
83106M1 005	22-DEC-83	92	TERMINAL SACRIFICE
83106M1 006	22-DEC-83	92	TERMINAL SACRIFICE
83106M1 007	21-DEC-83	91	TERMINAL SACRIFICE
83106M1 008	22-DEC-83	92	TERMINAL SACRIFICE
83106M1 009	21-DEC-83	91	TERMINAL SACRIFICE
83106M1 010	22-DEC-83	92	TERMINAL SACRIFICE
83106M1 011	22-DEC-83	92	TERMINAL SACRIFICE
83106M1 012	21-DEC-83	91	TERMINAL SACRIFICE
83106M1 013	22-DEC-83	92	TERMINAL SACRIFICE
83106M1 014	21-DEC-83	91	TERMINAL SACRIFICE
83106M1 015	22-DEC-83	92	TERMINAL SACRIFICE

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0500 MG/L

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
83106M2 001	21-DEC-83	91	TERMINAL SACRIFICE
83106M2 002	21-DEC-83	91	TERMINAL SACRIFICE
83106M2 003	21-DEC-83	91	TERMINAL SACRIFICE
83106M2 004	21-DEC-83	91	TERMINAL SACRIFICE
83106M2 005	22-DEC-83	92	TERMINAL SACRIFICE
83106M2 006	22-DEC-83	92	TERMINAL SACRIFICE
83106M2 007	21-DEC-83	91	TERMINAL SACRIFICE
83106M2 008	22-DEC-83	92	TERMINAL SACRIFICE
83106M2 009	21-DEC-83	91	TERMINAL SACRIFICE
83106M2 010	22-DEC-83	92	TERMINAL SACRIFICE
83106M2 011	22-DEC-83	92	TERMINAL SACRIFICE
83106M2 012	21-DEC-83	91	TERMINAL SACRIFICE
83106M2 013	22-DEC-83	92	TERMINAL SACRIFICE
83106M2 014	21-DEC-83	91	TERMINAL SACRIFICE
83106M2 015	22-DEC-83	92	TERMINAL SACRIFICE

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
83106M3 001	3-NOV-83	43	SPONTANEOUS - BODY INTACT
83106M3 002	4-NOV-83	44	SPONTANEOUS - BODY INTACT
83106M3 003	3-NOV-83	43	SPONTANEOUS - BODY INTACT
83106M3 004	20-OCT-83	29	SPONTANEOUS - BODY INTACT
83106M3 005	15-NOV-83	55	SPONTANEOUS - BODY INTACT
83106M3 006	26-NOV-83	66	SPONTANEOUS - BODY INTACT
83106M3 007	14-OCT-83	23	SPONTANEOUS - BODY INTACT
83106M3 008	4-NOV-83	44	SPONTANEOUS - BODY INTACT
83106M3 009	17-NOV-83	57	SPONTANEOUS - BODY INTACT
83106M3 010	20-OCT-83	29	SPONTANEOUS - BODY INTACT
83106M3 011	29-NOV-83	69	SPONTANEOUS - BODY INTACT
83106M3 012	11-OCT-83	20	SACRIFICED IN EXTREMIS
83106M3 013	27-OCT-83	36	SPONTANEOUS - BODY INTACT
83106M3 014	17-OCT-83	26	SPONTANEOUS - BODY INTACT
83106M3 015	3-NOV-83	43	SACRIFICED IN EXTREMIS

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 10-JAN-84

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: FEMALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
83106FN 001	21-DEC-83	91	TERMINAL SACRIFICE
83106FN 002	21-DEC-83	91	TERMINAL SACRIFICE
83106FN 003	21-DEC-83	91	TERMINAL SACRIFICE
83106FN 004	21-DEC-83	91	TERMINAL SACRIFICE
83106FN 005	22-DEC-83	92	TERMINAL SACRIFICE
83106FN 006	22-DEC-83	92	TERMINAL SACRIFICE
83106FN 007	21-DEC-83	91	TERMINAL SACRIFICE
83106FN 008	22-DEC-83	92	TERMINAL SACRIFICE
83106FN 009	21-DEC-83	91	TERMINAL SACRIFICE
83106FN 010	22-DEC-83	92	TERMINAL SACRIFICE
83106FN 011	22-DEC-83	92	TERMINAL SACRIFICE
83106FN 012	21-DEC-83	91	TERMINAL SACRIFICE
83106FN 013	22-DEC-83	92	TERMINAL SACRIFICE
83106FN 014	21-DEC-83	91	TERMINAL SACRIFICE
83106FN 015	22-DEC-83	92	TERMINAL SACRIFICE

STUDY NUMBER: 83106 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0100 MG/L

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
83106F1 001	21-DEC-83	91	TERMINAL SACRIFICE
83106F1 002	21-DEC-83	91	TERMINAL SACRIFICE
83106F1 003	21-DEC-83	91	TERMINAL SACRIFICE
83106F1 004	21-DEC-83	91	TERMINAL SACRIFICE
83106F1 005	22-DEC-83	92	TERMINAL SACRIFICE
83106F1 006	22-DEC-83	92	TERMINAL SACRIFICE
83106F1 007	21-DEC-83	91	TERMINAL SACRIFICE
83106F1 008	22-DEC-83	92	TERMINAL SACRIFICE
83106F1 009	21-DEC-83	91	TERMINAL SACRIFICE
83106F1 010	22-DEC-83	92	TERMINAL SACRIFICE
83106F1 011	22-DEC-83	92	TERMINAL SACRIFICE
83106F1 012	21-DEC-83	91	TERMINAL SACRIFICE
83106F1 013	22-DEC-83	92	TERMINAL SACRIFICE
83106F1 014	21-DEC-83	91	TERMINAL SACRIFICE
83106F1 015	22-DEC-83	92	TERMINAL SACRIFICE

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.0500 MG/L

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
83106F2 001	21-DEC-83	91	TERMINAL SACRIFICE
83106F2 002	21-DEC-83	91	TERMINAL SACRIFICE
83106F2 003	21-DEC-83	91	TERMINAL SACRIFICE
83106F2 004	21-DEC-83	91	TERMINAL SACRIFICE
83106F2 005	22-DEC-83	92	TERMINAL SACRIFICE
83106F2 006	22-DEC-83	92	TERMINAL SACRIFICE
83106F2 007	21-DEC-83	91	TERMINAL SACRIFICE
83106F2 008	22-DEC-83	92	TERMINAL SACRIFICE
83106F2 009	21-DEC-83	91	TERMINAL SACRIFICE
83106F2 010	22-DEC-83	92	TERMINAL SACRIFICE
83106F2 011	22-DEC-83	92	TERMINAL SACRIFICE
83106F2 012	21-DEC-83	91	TERMINAL SACRIFICE
83106F2 013	22-DEC-83	92	TERMINAL SACRIFICE
83106F2 014	21-DEC-83	91	TERMINAL SACRIFICE
83106F2 015	22-DEC-83	92	TERMINAL SACRIFICE

STUDY NUMBER: 83106
DMEH NUMBER: ML83180
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 22-SEP-83

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6 DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 0.2000 MG/L

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
83106F3 001	27-OCT-83	36	SPONTANEOUS - BODY INTACT
83106F3 002	6-NOV-83	46	SPONTANEOUS - BODY INTACT
83106F3 003	1-NOV-83	41	SPONTANEOUS - BODY INTACT
83106F3 004	31-OCT-83	40	SPONTANEOUS - BODY INTACT
83106F3 005	21-DEC-83	91	TERMINAL SACRIFICE
83106F3 006	27-OCT-83	36	SPONTANEOUS - BODY INTACT
83106F3 007	7-NOV-83	47	SPONTANEOUS - BODY INTACT
83106F3 008	15-OCT-83	24	SPONTANEOUS - BODY INTACT
83106F3 009	27-OCT-83	36	SPONTANEOUS - BODY INTACT
83106F3 010	21-DEC-83	91	TERMINAL SACRIFICE
83106F3 011	28-OCT-83	37	SPONTANEOUS - BODY INTACT
83106F3 012	1-NOV-83	41	SPONTANEOUS - BODY INTACT
83106F3 013	28-OCT-83	37	SPONTANEOUS - BODY INTACT
83106F3 014	10-DEC-83	80	SPONTANEOUS - BODY INTACT
83106F3 015	9-OCT-83	18	SPONTANEOUS - BODY INTACT

APPENDIX 4: CLINICAL CHEMISTRY AND PATHOLOGY

STUDY NO.: 830106 *** HEMATOLOGY -- RAW DATA REPORT *** PAGE 1
SCHEDULED PERIOD # 1 REPORTED 12:57 10-JAN-84

ANIMAL NO.	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
830106-NM001	11.3	7.70	14.8	41.8	54.3	19.4	35.7	913.
830106-NM002	9.3	8.68	15.5	45.7	52.7	17.9	34.0	838.
830106-NM003	10.4	8.54	15.4	47.9	55.9	17.9	32.0	768.
830106-NM004	11.3	8.89	16.6	49.8	56.0	18.6	33.2	718.
830106-NM005	17.0	9.63	17.0	54.1	56.0	17.5	31.3	755.
830106-NM006	11.4	8.36	15.2	46.4	55.5	18.1	32.5	796.
830106-NM007	16.4	9.21	17.0	52.7	57.1	18.5	32.3	911.
830106-NM008	12.9	7.84	14.6	44.5	56.7	18.6	32.8	848.
830106-NM009	10.5	8.84	15.0	46.4	52.3	17.0	32.5	829.
830106-NM010	15.7	8.75	15.7	48.0	54.9	18.0	32.8	961.
830106-NM011	11.3	8.61	15.4	47.5	55.1	17.8	32.2	786.
830106-NM012	11.1	8.14	15.4	45.0	55.2	19.0	34.3	829.
830106-NM013	11.4	8.07	16.1	48.0	59.5	19.9	33.5	1023.
830106-NM014	10.4	8.57	15.9	50.4	58.8	18.5	31.5	663.
830106-NM015	12.0	8.18	15.2	46.6	56.7	18.4	32.5	725.
MEAN	12.1	8.53	15.6	47.7	55.8	18.3	32.9	824.
S.D.	2.3	0.51	0.7	3.1	1.9	0.7	1.1	97.
N	15	15	15	15	15	15	15	15
830106-1M001	13.8	9.00	16.4	51.6	57.2	18.2	31.8	748.
830106-1M002	11.4	8.79	15.5	48.4	55.1	17.6	31.9	798.
830106-1M003	10.9	7.59	15.0	42.7	56.2	19.7	35.1	905.
830106-1M004	13.2	8.80	15.7	49.3	55.9	17.8	31.8	843.
830106-1M005	10.2	8.12	15.0	45.5	56.1	18.5	33.0	868.
830106-1M006	10.0	8.55	16.1	48.4	56.5	18.8	33.2	884.
830106-1M007	6.4	9.27	16.4	50.7	54.6	17.7	32.4	791.
830106-1M008	9.1	9.55	17.7	54.3	56.8	18.5	32.6	864.
830106-1M009	8.6	8.14	14.8	43.9	53.8	18.3	33.9	886.
830106-1M010	7.3	8.75	15.9	48.0	54.8	18.2	33.3	1091.
830106-1M011	12.9	8.93	16.8	51.1	57.2	18.7	32.7	713.
830106-1M012	7.9	9.55	16.8	54.3	56.7	17.6	31.0	686.
830106-1M013	13.6	8.91	15.5	47.9	53.7	17.5	32.6	857.
830106-1M014	8.6	9.16	16.8	52.3	57.1	18.4	32.1	741.
830106-1M015	9.5	8.79	16.4	48.2	54.8	18.6	33.9	936.
MEAN	10.2	8.79	16.1	49.1	55.8	18.3	32.8	841.
S.D.	2.3	0.53	0.8	3.4	1.2	0.6	1.0	102.
N	15	15	15	15	15	15	15	15

THIS REPORT GENERATED FROM DATA LOCKED THRU 10-JAN-84

STUDY NO.: 830106 *** HEMATOLOGY -- RAW DATA REPORT *** PAGE 2
SCHEDULED PERIOD # 1 REPORTED 12:57 10-JAN-84

ANIMAL NO.	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
830106-2M001	10.2	9.66	17.5	55.7	57.5	18.1	31.4	798.
830106-2M002	9.6	8.25	15.5	47.5	57.4	18.9	32.8	925.
830106-2M003	11.1	8.14	14.8	45.7	56.1	18.3	32.5	661.
830106-2M004	7.7	8.61	15.2	47.0	54.5	17.7	32.4	977.
830106-2M005	9.6	8.48	15.5	47.0	55.3	18.3	33.1	679.
830106-2M006	11.4	8.84	15.5	48.4	54.6	17.7	32.3	741.
830106-2M007	7.3	8.91	15.5	48.0	53.8	17.4	32.4	746.
830106-2M008	11.6	9.14	16.3	50.2	54.7	17.8	32.5	852.
830106-2M009	7.9	8.73	15.7	50.2	57.5	18.0	31.3	755.
830106-2M010	11.3	9.39	16.3	51.4	54.7	17.4	31.7	846.
830106-2M011	6.1	9.27	16.4	51.8	55.8	17.8	31.8	743.
830106-2M012	5.2	8.82	16.4	50.9	57.8	18.6	32.2	732.
830106-2M013	8.0	9.21	16.1	50.2	54.3	17.3	31.9	916.
830106-2M014	8.2	9.55	16.4	52.1	54.6	17.2	31.5	805.
830106-2M015	7.1	8.50	15.0	48.2	56.7	17.7	31.3	784.
MEAN	8.8	8.90	15.9	49.6	55.7	17.9	32.1	797.
S.D.	2.0	0.46	0.7	2.6	1.4	0.5	0.6	91.
N	15	15	15	15	15	15	15	15
GROUP 3M HAS NO DATA FOR THIS PERIOD.								
830106-NF001	5.7	7.95	15.2	48.6	61.0	19.1	31.3	800.
830106-NF002	4.6	7.87	15.9	49.8	63.2	20.2	31.9	723.
830106-NF003	4.6	9.02	16.4	53.2	58.9	18.2	30.8	775.
830106-NF004	3.6	8.23	16.3	51.3	62.1	19.6	31.6	784.
830106-NF005	7.1	8.38	15.4	49.6	59.2	18.3	30.9	814.
830106-NF006	8.0	8.05	15.4	48.2	59.7	19.1	31.9	941.
830106-NF007	7.5	8.23	15.7	49.1	59.7	19.2	32.1	848.
830106-NF008	5.7	7.36	14.5	46.3	62.9	19.7	31.3	782.
830106-NF009	4.6	8.00	15.7	48.6	60.7	19.7	32.3	718.
830106-NF010	7.0	8.14	15.0	47.1	57.9	18.3	31.6	946.
830106-NF011	5.2	8.27	14.8	47.1	57.0	17.9	31.4	800.
830106-NF012	4.1	7.73	14.8	47.0	60.6	19.1	31.5	796.
830106-NF013	5.0	8.12	15.4	48.8	59.9	18.8	31.4	814.
830106-NF014	10.5	8.64	16.3	51.6	59.7	18.8	31.4	1030.
830106-NF015	4.6	8.82	17.1	53.9	61.0	19.4	31.8	934.
MEAN	5.9	8.19	15.6	49.3	60.2	19.0	31.5	834.
S.D.	1.8	0.42	0.7	2.3	1.7	0.6	0.4	89.
N	15	15	15	15	15	15	15	15

STUDY NO.: 830106 *** HEMATOLOGY -- RAW DATA REPORT *** PAGE 3
SCHEDULED PERIOD # 1 REPORTED 12:57 10-JAN-84

ANIMAL NO.	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
830106-1F001	6.1	8.68	16.1	51.4	59.2	18.6	31.4	979.
830106-1F002	5.0	8.23	15.7	49.5	60.1	19.0	31.6	807.
830106-1F003	5.2	8.29	16.1	52.1	63.0	19.4	30.8	863.
830106-1F004	6.2	8.63	16.1	49.8	57.8	18.6	32.1	780.
830106-1F005	5.0	6.82	13.8	40.0	58.5	20.2	34.5	720.
830106-1F006	6.6	8.32	15.9	47.7	57.2	19.1	33.3	864.
830106-1F007	6.1	9.11	16.6	52.1	57.2	18.2	31.8	788.
830106-1F008	8.4	8.11	15.0	46.3	57.1	18.5	32.4	839.
830106-1F009	8.2	7.43	15.4	43.4	58.3	20.6	35.3	682.
830106-1F010	6.1	8.12	14.5	45.4	55.7	17.9	32.0	868.
830106-1F011	7.3	7.75	15.4	47.7	61.5	19.8	32.2	784.
830106-1F012	6.1	7.59	14.5	46.4	61.0	19.2	31.4	595.
830106-1F013	8.9	8.07	15.0	48.6	60.2	18.7	31.0	905.
830106-1F014	7.1	8.91	15.7	50.2	56.3	17.6	31.1	946.
830106-1F015	4.8	8.70	15.5	48.8	56.0	17.8	31.8	807.
MEAN	6.5	8.18	15.4	48.0	58.6	18.9	32.2	815.
S.D.	1.3	0.60	0.8	3.3	2.2	0.9	1.3	100.
N	15	15	15	15	15	15	15	15
830106-2F001	9.6	7.45	15.2	42.3	56.9	20.5	35.9	845.
830106-2F002	7.0	7.71	15.2	46.8	60.6	19.6	32.3	820.
830106-2F003	8.2	8.29	16.8	49.8	60.2	20.3	33.7	805.
830106-2F004	7.3	8.93	17.9	54.8	61.3	20.0	32.6	934.
830106-2F005	10.0	8.57	16.6	51.8	60.3	19.3	32.0	800.
830106-2F006	5.4	7.61	14.1	44.3	58.1	18.5	31.8	520.
830106-2F007	8.4	7.86	14.6	45.5	57.8	18.6	32.1	739.
830106-2F008	8.6	8.36	16.1	50.7	60.7	19.2	31.5	841.
830106-2F009	6.6	8.23	15.9	49.5	59.9	19.2	32.0	825.
830106-2F010	8.4	7.63	14.1	44.8	58.5	18.4	31.4	677.
830106-2F011	9.3	7.34	14.1	46.3	63.0	19.3	30.7	839.
830106-2F012	5.7	9.59	17.1	55.2	57.5	18.0	31.2	820.
830106-2F013	7.9	8.61	15.4	49.1	57.0	17.9	31.4	791.
830106-2F014	5.5	8.21	15.0	47.0	57.2	18.2	31.9	739.
830106-2F015	7.1	8.52	16.6	52.1	61.3	19.4	31.7	921.
MEAN	7.7	8.19	15.6	48.7	59.4	19.1	32.1	794.
S.D.	1.5	0.61	1.2	3.8	1.9	0.8	1.2	100.
N	15	15	15	15	15	15	15	15

THIS REPORT GENERATED FROM DATA LOCKED THRU 10-JAN-84

STUDY NO.: 830106 *** HEMATOLOGY -- RAW DATA REPORT *** PAGE 4
SCHEDULED PERIOD # 1 REPORTED 12:57 10-JAN-84

ANIMAL NO.	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
830106-3F005	4.6	9.98	18.7	59.6	59.8	18.8	31.3	679.
830106-3F010	11.4	8.89	16.8	53.0	59.6	18.9	31.7	927.
MEAN	8.0	9.44	17.8	56.3	59.7	18.9	31.5	803.
S.D.	4.8	0.77	1.4	4.7	0.1	0.1	0.3	176.
N	2	2	2	2	2	2	2	2

INDIVIDUAL LEUKOCYTE AND RETICULOCYTE DATA
830106 PERIOD 1

ANIMAL IDENT. NUMBER	NEU %	LYM %	MON %	EOS %	RET %
NM001A,B	16	82	2	0	1.6
NM002A	14	83	2	1	1.6
NM003	13	76	11	0	2.3
NM004A,B,C	14	72	13	1	1.8
NM005	5	86	9	0	1.4
NM006D,E	14	76	8	2	2.0
NM007C	11	74	13	2	1.6
NM008A,B	10	81	7	2	2.0
NM009A,C	11	80	5	4	1.7
NM010A,B	20	73	6	1	2.0
NM011A,E	6	88	6	0	2.3
NM012A,B,E	18	72	8	2	2.6
NM013	21	71	6	2	2.2
NM014	15	79	5	1	1.0
NM015A,B	10	83	6	1	1.2
N					15
MEAN					1.82
S.D.					0.44
1M001A,B,C	15	77	8	0	1.8
1M002A	12	75	11	2	2.0
1M003A,B	18	78	2	2	1.6
1M004C	14	70	12	4	1.2
1M005A	26	65	7	2	1.7
1M006A	14	81	5	0	1.0
1M007	21	73	3	3	0.8
1M008	19	71	10	0	1.8
1M009A	21	72	6	1	1.4
1M010A,B	32	63	5	0	1.6
1M011A,C	12	75	13	0	1.3
1M012B	25	59	15	1	1.4
1M013A,D	15	78	6	1	1.2
1M014A	29	61	9	1	1.0
1M015A,C	23	68	6	3	2.2
N					15
MEAN					1.47*
S.D.					0.40

ANIMAL IDENT. NUMBER	NEU %	LYM %	MON %	EOS %	RET %
2M001B	14	80	3	3	1.8
2M002B	10	87	3	0	2.0
2M003A,C,D	16	79	3	2	1.4
2M004A,B	18	71	9	2	1.5
2M005B,C	20	70	9	1	1.9
2M006	17	79	3	1	2.0
2M007A	22	67	11	0	2.0
2M008A,B	12	84	2	2	1.4
2M009B,E	7	85	5	3	1.9
2M010	7	89	4	0	1.8
2M011	20	76	2	2	2.0
2M012A	17	74	7	2	1.4
2M013	19	73	6	2	1.7
2M014	27	68	5	0	1.8
2M015E	11	85	3	1	1.4
N					15
MEAN					1.73
S.D.					0.25

A. SLIGHT POIKILOCYTOSIS. B. SLIGHT POLYCHROMASIA. C. MAST CELLS NOTED.
D. SEVERAL TARGET CELLS NOTED. E. SLIGHT HYPOCHROMASIA.
* SIGNIFICANTLY DIFFERENT, P LESS THAN OR EQUAL TO 0.05, COMPARED TO CONTROLS (TWO-TAILED DUNNETT'S TEST).
NEU(NEUTROPHILS), LYM(LYMPHOCYTES), MON(MONOCYTES), EOS(EOSINOPHILS), RET(RETICULOCYTES)

INDIVIDUAL LEUKOCYTE AND RETICULOCYTE DATA
830106 PERIOD 1

ANIMAL IDENT. NUMBER	NEU %	LYM %	MON %	EOS %	RET %
NF001C	16	66	17	1	1.7
NF002C	16	75	5	4	1.2
NF003	9	84	6	1	2.1
NF004E	21	73	6	1	3.1
NF005E	24	66	10	0	3.3
NF006	11	78	10	1	3.1
NF007C	19	68	7	6	2.5
NF008	11	82	4	3	1.9
NF009	16	75	6	3	1.9
NF010E	18	74	7	1	2.1
NF011A,F	16	75	7	2	1.5
NF012	21	66	7	6	3.3
NF013E	11	81	6	2	1.6
NF014	20	72	3	5	1.5
NF015E	11	79	9	1	3.1
N					15
MEAN					2.26
S.D.					0.74
1F001	19	68	13	0	2.0
1F002	13	82	5	0	1.3
1F003E	19	71	9	1	1.9
1F004	16	71	10	3	2.8
1F005B,E	18	80	1	1	3.0
1F006G	15	82	2	1	1.1
1F007H	21	67	9	3	1.8
1F008	20	73	7	0	1.4
1F009C	20	68	9	3	2.2
1F010	21	72	7	0	2.3
1F011B	8	85	6	1	5.3
1F012	15	75	8	2	3.1
1F013	10	85	4	1	2.1
1F014	22	67	7	4	2.1
1F015	17	77	6	0	1.8
N					15
MEAN					2.28
S.D.					1.02

ANIMAL IDENT. NUMBER	NEU %	LYM %	MON %	EOS %	RET %
2F001	6	89	5	0	0.9
2F002	16	77	5	2	1.4
2F003	10	86	4	0	2.0
2F004	14	80	4	2	1.1
2F005	12	83	4	1	2.6
2F006C	12	82	4	2	4.1
2F007	8	89	2	1	2.1
2F008C	12	84	4	0	1.1
2F009C,E	6	83	8	3	2.8
2F010	12	84	4	0	2.2
2F011	13	80	7	0	1.0
2F012	14	77	6	3	1.3
2F013	16	74	9	1	2.6
2F014	11	89	0	0	1.9
2F015	10	85	4	1	1.3
N					15
MEAN					1.89
S.D.					0.88
3F005	22	68	9	1	2.4
3F010	32	57	10	1	1.8
N					2
MEAN					2.10
S.D.					0.42

A. SLIGHT POIKILOCYTOSIS. B. SLIGHT POLYCHROMASIA. C. MAST CELLS NOTED. E. SLIGHT HYPOCHROMASIA.
F. MODERATE ANISOCYTOSIS. G. ONE MAST CELL NOTED. H. 1 NRBC/ 100 WBC.
NEU(NEUTROPHILS), LYM(LYMPHOCYTES), MON(MONOCYTES), EOS(EOSINOPHILS), RET(RETICULOCYTES)

KDARE1

RESULTS OF KDA BLOOD ANALYSES BY GROUP

STUDY NO. 830106 PERIOD 1

TEST TYPE:	GLU-COSE	BUN	TOT BILI	T PRO-TEIN	ALBU-MIN	ALK PHOS	D-GOT /AST	LDH	D-GPT /ALT	GLOB-ULIN*
TEST DATE:	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983
UNITS:	MG/DL	MG/DL	MG/DL	G/DL	G/DL	IU/L	U/L	IU/L	U/L	G/DL
ANIMAL										
NM001	188.	18.0	0.0#	7.0	3.9	160.	201.	1348.#	20.5	3.1
NM002	87.6	15.2	0.1	6.7	3.8	123.	168.	718.	32.4	2.9
NM003	129.	18.2	0.1	6.4	3.6	216.	231.	1038.	51.1	2.8
NM004	227.	13.5	0.1	7.0	3.9	147.	150.	691.	30.4	3.1
NM005	286.#	14.8	0.1	6.7	3.8	392.##	135.	771.	25.3	2.9
NM006	163.	18.6	0.1	6.5	3.4	230.	132.	774.	31.6	3.1
NM007	175.	13.4	0.1	6.6	3.6	174.	179.	1004.	39.9	3.0
NM008	178.	15.5	0.1	6.2	3.4	156.	146.	807.	20.4	2.8
NM009	204.	15.6	0.0#	6.6	3.6	150.	157.	720.	37.3	3.0
NM010	163.	17.4	0.1	6.5	3.5	157.	233.	785.	63.7#	3.0
NM011	135.	11.7	0.1	6.4	3.5	154.	127.	829.	21.4	2.9
NM012	213.	14.8	0.1	6.3	3.5	147.	142.	683.	29.4	2.8
NM013	176.	15.6	0.1	6.9	3.3	185.	113.	473.	30.1	3.6##
NM014	128.	14.7	0.1	6.5	3.5	176.	142.	1065.	22.0	3.0
NM015	162.	12.2	0.1	6.4	3.4	196.	113.	593.	29.2	3.0
MEAN =	174.	15.3	0.09	6.6	3.6	184.	158.	820.	32.3	3.0
ST. DEV. =	47.4	2.1	0.04	0.24	0.19	64.0	38.1	216.	12.0	0.20

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*GLOBULIN IS DETERMINED BY SUBTRACTION OF ALBUMIN FROM TOTAL PROTEIN
QNS = QUANTITY NOT SUFFICIENT
# = 2 STANDARD DEVIATIONS FROM GROUP MEAN
= 3 OR MORE STANDARD DEVIATIONS FROM GROUP MEAN

KDARE1

RESULTS OF KDA BLOOD ANALYSES BY GROUP

STUDY NO. 830106 PERIOD 1

TEST TYPE:	GLU-COSE	BUN	TOT BILI	T PRO-TEIN	ALBU-MIN	ALK PHOS	D-GOT /AST	LDH	D-GPT /ALT	GLOB-ULIN*
TEST DATE:	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983
UNITS:	MG/DL	MG/DL	MG/DL	G/DL	G/DL	IU/L	U/L	IU/L	U/L	G/DL
ANIMAL										
1M001	237.	15.3	0.1	7.1	3.9	181.	133.	514.	29.9	3.2
1M002	329.	16.1	0.1	6.4	3.5	144.	118.	459.	26.4	2.9
1M003	236.	13.5	0.1	6.5	3.7	173.	138.	809.	30.9	2.8
1M004	242.	11.9	0.1	6.7	3.8	219.	196.#	490.	52.6	2.9
1M005	172.	14.3	0.1	6.4	3.5	156.	168.	679.	35.5	2.9
1M006	237.	13.4	0.1	7.1	3.9	175.	124.	668.	26.3	3.2
1M007	281.	11.2	0.1	6.9	3.7	129.	127.	352.	25.5	3.2
1M008	238.	14.8	0.1	6.9	3.8	215.	112.	400.	29.7	3.1
1M009	290.	12.8	0.1	6.5	3.5	176.	137.	383.	33.4	3.0
1M010	232.	13.6	0.1	6.8	3.7	212.	132.	348.	42.3	3.1
1M011	413.#	14.3	0.1	7.0	3.7	135.	143.	288.	59.8#	3.3
1M012	233.	11.4	0.1	6.5	3.8	107.	74.3	168.	18.0	2.7
1M013	259.	14.1	0.1	6.8	3.6	128.	117.	549.	21.4	3.2
1M014	250.	13.2	0.1	6.7	3.7	157.	97.0	104.	21.0	3.0
1M015	260.	13.1	0.1	6.7	3.6	164.	157.	390.	41.3	3.1
MEAN =	261.	13.5	0.10	6.7	3.7	165.	132.	440.	32.9	3.0
ST. DEV. =	54.3	1.4	0.00	0.24	0.13	33.5	28.9	189.	11.8	0.17
DUNNETT T=	5.03**	-2.74*	1.80	1.91	1.95	-1.12	-1.84	-4.96**	0.09	0.68

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*GLOBULIN IS DETERMINED BY SUBTRACTION OF ALBUMIN FROM TOTAL PROTEIN
QNS = QUANTITY NOT SUFFICIENT
# = 2 STANDARD DEVIATIONS FROM GROUP MEAN
= 3 OR MORE STANDARD DEVIATIONS FROM GROUP MEAN
* = DUNNETT'S T IS SIGNIFICANT AT 0.95 LEVEL
** = DUNNETT'S T IS SIGNIFICANT AT 0.99 LEVEL

RESULTS OF KDA BLOOD ANALYSES BY GROUP

STUDY NO. 830106 PERIOD 1

TEST TYPE:	GLU-COSE	BUN	TOT BILI	T PRO-TEIN	ALBU-MIN	ALK PHOS	D-GOT /AST	LDH	D-GPT /ALT	GLOB-ULIN*
TEST DATE:	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983
UNITS:	MG/DL	MG/DL	MG/DL	G/DL	G/DL	IU/L	U/L	IU/L	U/L	G/DL
ANIMAL										
2M001	220.	14.1	0.1	6.7	3.8	242.	177.	993.	28.9	2.9
2M002	190.	16.4	0.1	6.6	3.5	197.	160.	1054.	28.4	3.1
2M003	258.	15.7	0.1	6.6	3.7	165.	115.	774.	23.0	2.9
2M004	272.	17.3	0.1	6.9	3.9	247.	113.	487.	23.0	3.0
2M005	201.	19.6#	0.1	6.4	3.5	238.	301.#	582.	142.##	2.9
2M006	184.	17.9	0.1	6.3	3.3#	137.	140.	789.	30.6	3.0
2M007	155.	16.3	0.1	6.5	3.6	137.	147.	922.	26.4	2.9
2M008	227.	13.1	0.1	6.5	3.6	173.	115.	391.	38.9	2.9
2M009	195.	17.8	0.1	6.5	3.7	162.	184.	778.	48.7	2.8
2M010	160.	16.7	0.1	6.6	3.6	167.	127.	847.	21.9	3.0
2M011	235.	16.0	0.1	6.3	3.4	202.	126.	693.	28.7	2.9
2M012	182.	14.6	0.1	6.7	3.6	195.	182.	1274.#	27.9	3.1
2M013	232.	15.2	0.1	6.6	3.6	170.	123.	647.	30.6	3.0
2M014	228.	17.4	0.1	6.8	3.7	255.	174.	766.	42.3	3.1
2M015	142.	14.7	0.1	6.4	3.6	222.	196.	832.	54.9	2.8
MEAN =	205.	16.2	0.10	6.6	3.6	194.	159.	789.	39.7	3.0
ST. DEV. =	37.8	1.7	0.00	0.17	0.15	39.4	48.7	222.	29.9	0.10
DUNNETT T=	1.81	1.42	1.80	-0.25	0.46	0.56	0.05	-0.41	1.03	-0.79

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QNS = QUANTITY NOT SUFFICIENT
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= 3 OR MORE STANDARD DEVIATIONS FROM GROUP MEAN
* = DUNNETT'S T IS SIGNIFICANT AT 0.95 LEVEL
** = DUNNETT'S T IS SIGNIFICANT AT 0.99 LEVEL

KDARE1

RESULTS OF KDA BLOOD ANALYSES BY GROUP

STUDY NO. 830106 PERIOD 1

TEST TYPE:	GLU-COSE	BUN	TOT BILI	T PRO-TEIN	ALBU-MIN	ALK PHOS	D-GOT /AST	LDH	D-GPT /ALT	GLOB-ULIN*
TEST DATE:	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983
UNITS:	MG/DL	MG/DL	MG/DL	G/DL	G/DL	IU/L	U/L	IU/L	U/L	G/DL
ANIMAL										
NF001	198.	11.4	0.1	7.5	4.6	63.5	80.7	101.	20.5	2.9
NF002	198.	10.3	0.1	7.3	4.5	45.8	66.4	109.	21.0	2.8
NF003	128.	10.3	0.1	6.7	3.9	165.	162.	520.	22.5	2.8
NF004	128.	15.7	0.1	7.3	4.2	92.5	152.	644.	24.9	3.1
NF005	134.	13.8	0.1	6.6	3.7	173.	154.	465.	27.2	2.9
NF006	229.	13.4	0.1	6.6	3.6	135.	145.	686.	28.2	3.0
NF007	141.	16.3	0.1	6.7	3.9	125.	105.	391.	23.0	2.8
NF008	135.	13.0	0.1	6.9	3.8	120.	119.	280.	28.7	3.1
NF009	171.	11.3	0.1	6.7	4.1	120.	97.7	279.	23.5	2.6
NF010	279.#	13.0	0.1	6.9	3.6	80.3	88.3	369.	15.1#	3.3#
NF011	180.	13.3	0.1	6.8	3.9	85.1	120.	654.	25.8	2.9
NF012	126.	10.7	0.1	6.6	4.0	87.6	108.	555.	25.0	2.6
NF013	137.	15.0	0.1	6.8	3.9	103.	128.	828.	25.8	2.9
NF014	186.	13.7	0.1	6.0#	3.2#	100.	94.9	467.	25.0	2.8
NF015	161.	12.6	0.1	7.2	4.1	93.1	143.	389.	32.6	3.1
MEAN =	169.	12.9	0.10	6.8	3.9	106.	118.	449.	24.6	2.9
ST. DEV. =	44.1	1.9	0.00	0.37	0.35	34.7	29.3	208.	4.1	0.19

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QNS = QUANTITY NOT SUFFICIENT
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= 3 OR MORE STANDARD DEVIATIONS FROM GROUP MEAN

KDARE1

RESULTS OF KDA BLOOD ANALYSES BY GROUP

STUDY NO. 830106 PERIOD 1

TEST TYPE:	GLU-COSE	BUN	TOT BILI	T PRO-TEIN	ALBU-MIN	ALK PHOS	D-GOT /AST	LDH	D-GPT /ALT	GLOB-ULIN*
TEST DATE:	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983
UNITS:	MG/DL	MG/DL	MG/DL	G/DL	G/DL	IU/L	U/L	IU/L	U/L	G/DL
ANIMAL										
1F001	144.	13.5	0.1	6.2	3.7	137.	111.	233.	33.4	2.5#
1F002	161.	11.6	0.1	6.7	3.9	95.7	106.	211.	32.9	2.8
1F003	115.	11.7	0.2#	7.3	4.4	69.9	196.	762.	43.2	2.9
1F004	179.	13.9	0.1	7.4	4.4	74.8	303.##	833.	69.9#	3.0
1F005	187.	14.8	0.1	6.6	3.7	101.	155.	527.	68.6#	2.9
1F006	183.	15.7	0.1	7.5	4.3	89.9	115.	400.	31.6	3.2
1F007	124.	11.5	0.1	7.5	4.4	120.	125.	438.	31.9	3.1
1F008	77.7	12.3	0.1	6.6	3.7	112.	121.	354.	33.5	2.9
1F009	107.	10.4	0.2#	6.3	3.6	90.8	147.	696.	24.5	2.7
1F010	202.	15.9	0.1	6.8	3.9	101.	124.	418.	38.4	2.9
1F011	178.	14.6	0.1	6.8	3.9	78.7	90.5	356.	25.3	2.9
1F012	156.	9.7	0.1	7.4	4.5	69.9	179.	576.	46.7	2.9
1F013	228.	11.6	0.1	6.7	3.8	94.8	95.6	611.	23.8	2.9
1F014	96.9	13.4	0.1	6.9	3.9	84.4	113.	395.	47.7	3.0
1F015	134.	16.2	0.1	6.5	3.8	141.	102.	292.	28.5	2.7
MEAN =	152.	13.1	0.11	6.9	4.0	97.4	139.	473.	38.7	2.9
ST. DEV. =	42.3	2.0	0.04	0.44	0.31	22.2	54.5	189.	14.5	0.17
DUNNETT T=	-1.19	0.20	1.82	0.30	0.56	-0.79	1.50	0.35	3.87**	-0.34

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*GLOBULIN IS DETERMINED BY SUBTRACTION OF ALBUMIN FROM TOTAL PROTEIN
QNS = QUANTITY NOT SUFFICIENT
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= 3 OR MORE STANDARD DEVIATIONS FROM GROUP MEAN
* = DUNNETT'S T IS SIGNIFICANT AT 0.95 LEVEL
** = DUNNETT'S T IS SIGNIFICANT AT 0.99 LEVEL

KDARE1

RESULTS OF KDA BLOOD ANALYSES BY GROUP

STUDY NO. 830106 PERIOD 1

TEST TYPE:	GLU-COSE	BUN	TOT BILI	T PRO-TEIN	ALBU-MIN	ALK PHOS	D-GOT /AST	LDH	D-GPT /ALT	GLOB-ULIN*
TEST DATE:	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983
UNITS:	MG/DL	MG/DL	MG/DL	G/DL	G/DL	IU/L	U/L	IU/L	U/L	G/DL
ANIMAL										
2F001	153.	11.6	0.1	6.3	3.6	95.7	130.	391.	37.8	2.7
2F002	100.	15.2	0.1	6.2	3.5	82.8	101.	340.	25.5	2.7
2F003	71.0	14.0	0.1	6.7	3.9	71.5	98.4	315.	25.0	2.8
2F004	111.	15.3	0.1	6.8	4.0	104.	145.	791.#	28.4	2.8
2F005	116.	14.5	0.1	6.2	3.4	138.	67.7	181.	20.4	2.8
2F006	197.#	15.0	0.1	6.4	3.6	89.9	115.	249.	34.0	2.8
2F007	120.	14.2	0.1	6.0	3.4	97.3	97.7	400.	22.0	2.6
2F008	163.	17.7	0.1	6.6	3.8	130.	103.	123.	26.7	2.8
2F009	110.	17.5	0.1	6.1	3.6	76.4	98.4	208.	23.5	2.5
2F010	112.	17.5	0.1	6.5	3.6	138.	144.	440.	43.3	2.9
2F011	155.	15.2	0.1	6.6	3.7	104.	97.1	513.	19.4	2.9
2F012	107.	17.1	0.1	6.2	3.6	191.#	150.	410.	28.9	2.6
2F013	144.	18.1	0.1	6.1	3.3	114.	163.	384.	36.5	2.8
2F014	100.	12.3	0.1	6.3	3.7	86.0	123.	644.	27.4	2.6
2F015	153.	13.9	0.1	6.7	3.8	127.	127.	258.	40.8	2.9
MEAN =	127.	15.3	0.10	6.4	3.6	110.	117.	376.	29.3	2.7
ST. DEV. =	32.2	2.0	0.00	0.25	0.19	31.2	25.9	176.	7.5	0.12
DUNNETT T=	-2.85*	2.35	0.00	-3.50**	-2.82*	0.35	-0.02	-1.05	1.30	-2.70*

++++++++++++++++++++++++++++++

*GLOBULIN IS DETERMINED BY SUBTRACTION OF ALBUMIN FROM TOTAL PROTEIN
QNS = QUANTITY NOT SUFFICIENT
# = 2 STANDARD DEVIATIONS FROM GROUP MEAN
= 3 OR MORE STANDARD DEVIATIONS FROM GROUP MEAN
* = DUNNETT'S T IS SIGNIFICANT AT 0.95 LEVEL
** = DUNNETT'S T IS SIGNIFICANT AT 0.99 LEVEL

KDARE1

RESULTS OF KDA BLOOD ANALYSES BY GROUP

STUDY NO. 830106 PERIOD 1

TEST TYPE:	GLU-COSE	BUN	TOT BILI	T PRO-TEIN	ALBU-MIN	ALK PHOS	D-GOT /AST	LDH	D-GPT /ALT	GLOB-ULIN*
TEST DATE:	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983	22-DEC 1983
UNITS:	MG/DL	MG/DL	MG/DL	G/DL	G/DL	IU/L	U/L	IU/L	U/L	G/DL
ANIMAL										
3F005	62.7	38.6	0.1	6.9	3.6	242.	230.	291.	72.4	3.3
3F010	98.8	20.6	0.1	6.5	3.3	219.	172.	231.	47.2	3.2
MEAN =	80.8	29.6	0.10	6.7	3.5	231.	201.	261.	59.8	3.3
ST. DEV. =	25.5	12.7	0.00	0.28	0.21	16.3	41.0	42.4	17.8	0.07
DUNNETT T=	-2.95*	8.07**	0.00	-0.52	-2.20	5.60**	2.86*	-1.32	4.70**	2.81*

++++++++++++++++++++++++++++++

*GLOBULIN IS DETERMINED BY SUBTRACTION OF ALBUMIN FROM TOTAL PROTEIN
QNS = QUANTITY NOT SUFFICIENT
# = 2 STANDARD DEVIATIONS FROM GROUP MEAN
= 3 OR MORE STANDARD DEVIATIONS FROM GROUP MEAN
* = DUNNETT'S T IS SIGNIFICANT AT 0.95 LEVEL
** = DUNNETT'S T IS SIGNIFICANT AT 0.99 LEVEL

TABLE
ABSOLUTE NEUTROPHILS AND LYMPHOCYTES VALUES
830106 - PERIOD 1
MALES

ANIMAL IDENT. NUMBER	NEU X1000	LYM X1000	ANIMAL IDENT. NUMBER	NEU X1000	LYM X1000	ANIMAL IDENT. NUMBER	NEU X1000	LYM X1000	ANIMAL IDENT. NUMBER	NEU X1000	LYM X1000
NM001	1.8	9.3	1M001	2.1	10.6	2M001	1.4	8.2			
NM002	1.3	7.7	1M002	1.4	8.6	2M002	1.0	8.4			
NM003	1.4	7.9	1M003	2.0	8.5	2M003	1.8	8.8			
NM004	1.6	8.1	1M004	1.8	9.2	2M004	1.4	5.5			
NM005	0.8	14.6	1M005	2.6	6.6	2M005	1.9	6.7			
NM006	1.6	8.7	1M006	1.4	8.1	2M006	1.9	9.0			
NM007	1.8	12.1	1M007	1.3	4.7	2M007	1.6	4.9			
NM008	1.3	10.4	1M008	1.7	6.5	2M008	1.4	9.7			
NM009	1.2	8.4	1M009	1.8	6.2	2M009	0.6	6.7			
NM010	3.1	11.5	1M010	2.3	4.6	2M010	0.8	10.0			
NM011	0.7	9.9	1M011	1.5	9.7	2M011	1.2	4.6			
NM012	2.0	8.0	1M012	2.0	4.7	2M012	0.9	3.8			
NM013	2.4	8.1	1M013	2.0	10.6	2M013	1.5	5.8			
NM014	1.6	8.2	1M014	2.5	5.2	2M014	2.2	5.6			
NM015	1.2	10.0	1M015	2.2	6.5	2M015	0.8	6.0			
N	15	15	N	15	15	N	15	15			
MEAN	1.59	9.53	MEAN	1.91	7.35**	MEAN	1.36	6.91**			
S.D.	0.60	2.00	S.D.	0.40	2.12	S.D.	0.47	1.96			

FEMALES

NF001	0.9	3.8	1F001	1.2	4.1	2F001	0.6	8.5			
NF002	0.7	3.4	1F002	0.6	4.1	2F002	1.1	5.4			
NF003	0.4	3.9	1F003	1.0	3.7	2F003	0.8	7.0			
NF004	0.8	2.6	1F004	1.0	4.4	2F004	1.0	5.8			
NF005	1.7	4.7	1F005	0.9	4.0	2F005	1.2	8.3	3F005	1.0	3.1
NF006	0.9	6.2	1F006	1.0	5.4	2F006	0.6	4.4			
NF007	1.4	5.1	1F007	1.3	4.1	2F007	0.7	7.5			
NF008	0.6	4.7	1F008	1.7	6.1	2F008	1.0	7.2			
NF009	0.7	3.4	1F009	1.6	5.6	2F009	0.4	5.5			
NF010	1.3	5.2	1F010	1.3	4.4	2F010	1.0	7.0	3F010	3.6	6.5
NF011	0.8	3.9	1F011	0.6	6.2	2F011	1.2	7.4			
NF012	0.9	2.7	1F012	0.9	4.6	2F012	0.8	4.4			
NF013	0.6	4.0	1F013	0.9	7.6	2F013	1.3	5.8			
NF014	2.1	7.6	1F014	1.6	4.8	2F014	0.6	4.9			
NF015	0.5	3.6	1F015	0.8	3.7	2F015	0.7	6.0			
N	15	15	N	15	15	N	15	15	N	2	2
MEAN	0.95	4.32	MEAN	1.09	4.85	MEAN	0.87	6.34**	MEAN	2.30**	4.80
S.D.	0.47	1.32	S.D.	0.35	1.11	S.D.	0.27	1.32	S.D.	1.84	2.40

**. SIGNIFICANTLY DIFFERENT, P LESS THAN OR EQUAL TO 0.01 COMPARED TO CONTROLS (TWO-TAILED DUNNETT'S TEST).

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 001 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	504.0 GM	
ADRENALS	--	0.058 GM	0.012%
HEART	--	1.414 GM	0.281%
KIDNEYS	--	3.538 GM	0.702%
LIVER	--	14.226 GM	2.823%
SPLEEN	--	0.664 GM	0.132%
TESTES	--	5.223 GM	1.036%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106MN 002 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	487.4 GM	
ADRENALS	--	0.052 GM	0.011%
HEART	--	1.569 GM	0.322%
KIDNEYS	--	3.651 GM	0.749%
LIVER	--	14.827 GM	3.042%
SPLEEN	--	0.618 GM	0.127%
TESTES	--	5.810 GM	1.192%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 3
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 003 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	488.0 GM	
HEART	--	1.725 GM	0.353%
KIDNEYS	--	3.322 GM	0.681%
LIVER	--	12.472 GM	2.556%
SPLEEN	--	0.750 GM	0.154%
TESTES	--	6.125 GM	1.255%
ADRENALS	--	0.062 GM	0.013%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 004 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	607.0 GM	
ADRENALS	--	0.062 GM	0.010%
HEART	--	2.065 GM	0.340%
KIDNEYS	--	4.036 GM	0.665%
LIVER	--	16.232 GM	2.674%
SPLEEN	--	0.895 GM	0.147%
TESTES	--	5.933 GM	0.977%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 5
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 005 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	536.0 GM	
ADRENALS	--	0.076 GM	0.014%
HEART	--	1.965 GM	0.367%
KIDNEYS	--	4.203 GM	0.784%
LIVER	--	21.918 GM	4.089%
SPLEEN	--	0.717 GM	0.134%
TESTES	--	6.419 GM	1.198%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 6

P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 006 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	539.0 GM	
ADRENALS	--	0.045 GM	0.008%
HEART	--	1.576 GM	0.292%
KIDNEYS	--	3.099 GM	0.575%
LIVER	--	18.084 GM	3.355%
SPLEEN	--	0.820 GM	0.152%
TESTES	--	4.937 GM	0.916%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 7
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 007 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	471.0 GM	
ADRENALS	--	0.088 GM	0.019%
HEART	--	1.599 GM	0.339%
KIDNEYS	--	3.002 GM	0.637%
LIVER	--	14.466 GM	3.071%
SPLEEN	--	0.639 GM	0.136%
TESTES	--	5.688 GM	1.208%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 8
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 008 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	566.0 GM	
ADRENALS	--	0.064 GM	0.011%
HEART	--	1.838 GM	0.325%
KIDNEYS	--	3.105 GM	0.549%
LIVER	--	14.567 GM	2.574%
SPLEEN	--	0.750 GM	0.133%
TESTES	--	6.326 GM	1.118%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 009 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	480.0 GM	
ADRENALS	--	0.044 GM	0.009%
HEART	--	1.610 GM	0.335%
KIDNEYS	--	3.440 GM	0.717%
LIVER	--	13.754 GM	2.865%
SPLEEN	--	0.826 GM	0.172%
TESTES	--	5.296 GM	1.103%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 10
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 010 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	630.0 GM	
ADRENALS	--	0.068 GM	0.011%
HEART	--	1.865 GM	0.296%
KIDNEYS	--	4.849 GM	0.770%
LIVER	--	24.050 GM	3.817%
SPLEEN	--	0.819 GM	0.130%
TESTES	--	6.604 GM	1.048%

GROSS NECROPSY ALTERATIONS:

LIVER
ABNORMAL COLOR -- PALE YELLOW COLOR, PATCHY, MEDIAL LOBES.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N
PAGE: 11

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 011 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	532.0 GM	
ADRENALS	--	0.077 GM	0.014%
HEART	--	1.663 GM	0.313%
KIDNEYS	--	4.461 GM	0.839%
LIVER	--	21.794 GM	4.097%
SPLEEN	--	0.825 GM	0.155%
TESTES	--	5.604 GM	1.053%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 012 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	512.0 GM	
ADRENALS	--	0.080 GM	0.016%
HEART	--	2.027 GM	0.396%
KIDNEYS	--	3.616 GM	0.706%
LIVER	--	15.516 GM	3.030%
SPLEEN	--	0.758 GM	0.148%
TESTES	--	6.758 GM	1.320%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106MN Ø13 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = Ø

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	474.Ø GM	
ADRENALS	--	Ø.Ø81 GM	Ø.Ø17%
HEART	--	1.434 GM	Ø.3Ø3%
KIDNEYS	--	3.574 GM	Ø.754%
LIVER	--	18.829 GM	3.972%
SPLEEN	--	Ø.641 GM	Ø.135%
TESTES	--	5.892 GM	1.243%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 014 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	521.0 GM	
ADRENALS	--	0.075 GM	0.014%
HEART	--	1.702 GM	0.327%
KIDNEYS	--	3.533 GM	0.678%
LIVER	--	15.438 GM	2.963%
SPLEEN	--	0.700 GM	0.134%
TESTES	--	6.346 GM	1.218%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 15
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106MN 015 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	510.0 GM	
ADRENALS	--	0.063 GM	0.012%
HEART	--	1.666 GM	0.327%
KIDNEYS	--	3.655 GM	0.717%
LIVER	--	14.847 GM	2.911%
SPLEEN	--	0.658 GM	0.129%
TESTES	--	5.602 GM	1.098%

GROSS NECROPSY ALTERATIONS:

LIVER
ABNORMAL COLOR -- PALE YELLOW LOBULAR MARKINGS, MEDIAL LOBES.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 16
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 001 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	520.0 GM	
ADRENALS	--	0.091 GM	0.017%
HEART	--	1.866 GM	0.359%
KIDNEYS	--	3.660 GM	0.704%
LIVER	--	16.174 GM	3.110%
SPLEEN	--	0.883 GM	0.170%
TESTES	--	6.179 GM	1.188%

GROSS NECROPSY ALTERATIONS:

PITUITARY
NOTE: PITUITARY LOST AT NECROPSY

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 002 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	545.0 GM	
ADRENALS	--	0.053 GM	0.010%
HEART	--	1.624 GM	0.298%
KIDNEYS	--	3.470 GM	0.637%
LIVER	--	17.622 GM	3.233%
SPLEEN	--	0.751 GM	0.138%
TESTES	--	5.505 GM	1.010%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 18
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 003 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	557.0 GM	
ADRENALS	--	0.075 GM	0.013%
HEART	--	1.586 GM	0.285%
KIDNEYS	--	3.670 GM	0.659%
LIVER	--	16.893 GM	3.033%
SPLEEN	--	0.915 GM	0.164%
TESTES	--	5.734 GM	1.029%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 004 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	538.0 GM	
ADRENALS	--	0.050 GM	0.009%
HEART	--	1.691 GM	0.314%
KIDNEYS	--	3.808 GM	0.708%
LIVER	--	16.359 GM	3.041%
SPLEEN	--	0.750 GM	0.139%
TESTES	--	5.325 GM	0.990%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 20
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 005 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	538.0 GM	
ADRENALS	--	0.076 GM	0.014%
HEART	--	1.764 GM	0.328%
KIDNEYS	--	3.679 GM	0.684%
LIVER	--	15.871 GM	2.950%
SPLEEN	--	0.730 GM	0.136%
TESTES	--	5.925 GM	1.101%

GROSS NECROPSY ALTERATIONS:

THYMUS
ABNORMAL COLOR -- PATCHY RED AREAS.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 21
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 006 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	557.0 GM	
ADRENALS	--	0.060 GM	0.011%
HEART	--	1.719 GM	0.309%
KIDNEYS	--	3.595 GM	0.645%
LIVER	--	15.881 GM	2.851%
SPLEEN	--	0.755 GM	0.136%
TESTES	--	5.683 GM	1.020%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 22
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 007 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	429.0 GM	
ADRENALS	--	0.064 GM	0.015%
HEART	--	1.349 GM	0.314%
KIDNEYS	--	3.125 GM	0.728%
LIVER	--	11.480 GM	2.676%
SPLEEN	--	0.666 GM	0.155%
TESTES	--	5.830 GM	1.359%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 23
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 008 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	470.0 GM	
ADRENALS	--	0.079 GM	0.017%
HEART	--	1.590 GM	0.338%
KIDNEYS	--	3.405 GM	0.724%
LIVER	--	12.739 GM	2.710%
SPLEEN	--	0.616 GM	0.131%
TESTES	--	5.557 GM	1.182%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 24
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 009 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	533.0 GM	
ADRENALS	--	0.075 GM	0.014%
HEART	--	1.728 GM	0.324%
KIDNEYS	--	3.565 GM	0.669%
LIVER	--	14.757 GM	2.769%
SPLEEN	--	0.846 GM	0.159%
TESTES	--	6.101 GM	1.145%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 25
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 010 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	512.0 GM	
ADRENALS	--	0.082 GM	0.016%
HEART	--	1.615 GM	0.315%
KIDNEYS	--	3.294 GM	0.643%
LIVER	--	15.873 GM	3.100%
SPLEEN	--	0.789 GM	0.154%
TESTES	--	5.600 GM	1.094%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 26
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 011 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	543.0 GM	
ADRENALS	--	0.070 GM	0.013%
HEART	--	2.058 GM	0.379%
KIDNEYS	--	3.589 GM	0.661%
LIVER	--	20.173 GM	3.715%
SPLEEN	--	0.797 GM	0.147%
TESTES	--	5.467 GM	1.007%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 27
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 012 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	553.0 GM	
ADRENALS	--	0.083 GM	0.015%
HEART	--	1.610 GM	0.291%
KIDNEYS	--	3.256 GM	0.589%
LIVER	--	15.785 GM	2.854%
SPLEEN	--	0.673 GM	0.122%
TESTES	--	6.713 GM	1.214%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 013 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	633.0 GM	
ADRENALS	--	0.081 GM	0.013%
HEART	--	1.893 GM	0.299%
KIDNEYS	--	4.379 GM	0.692%
LIVER	--	27.815 GM	4.394%
SPLEEN	--	0.898 GM	0.142%
TESTES	--	6.234 GM	0.985%

GROSS NECROPSY ALTERATIONS:

LIVER
ABNORMAL COLOR -- PATCHY YELLOW AND RED COLORATION, ALL LOBES.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106M1 014 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	525.0 GM	
ADRENALS	--	0.077 GM	0.015%
HEART	--	1.620 GM	0.309%
KIDNEYS	--	3.731 GM	0.711%
LIVER	--	16.276 GM	3.100%
SPLEEN	--	0.718 GM	0.137%
TESTES	--	5.269 GM	1.004%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106M1 015 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	502.0 GM	
ADRENALS	--	0.070 GM	0.014%
HEART	--	1.644 GM	0.327%
KIDNEYS	--	3.460 GM	0.689%
LIVER	--	17.781 GM	3.542%
SPLEEN	--	0.710 GM	0.141%
TESTES	--	5.820 GM	1.159%

GROSS NECROPSY ALTERATIONS:

LIVER
ABNORMAL COLOR -- DEEP RED WITH PALE YELLOW MOTTLING.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 31
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 001 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	434.0 GM	
ADRENALS	--	0.039 GM	0.009%
HEART	--	1.568 GM	0.361%
KIDNEYS	--	3.208 GM	0.739%
LIVER	--	12.688 GM	2.924%
SPLEEN	--	0.749 GM	0.173%
TESTES	--	5.451 GM	1.256%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 32
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 002 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	495.0 GM	
ADRENALS	--	0.058 GM	0.012%
HEART	--	1.643 GM	0.332%
KIDNEYS	--	3.473 GM	0.702%
LIVER	--	14.755 GM	2.981%
SPLEEN	--	0.766 GM	0.155%
TESTES	--	5.642 GM	1.140%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 33
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 003 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	448.0 GM	
ADRENALS	--	0.050 GM	0.011%
HEART	--	1.433 GM	0.320%
KIDNEYS	--	3.090 GM	0.690%
LIVER	--	12.723 GM	2.840%
SPLEEN	--	0.670 GM	0.150%
TESTES	--	5.041 GM	1.125%

GROSS NECROPSY ALTERATIONS:

N O N E.

ANIMAL NO: 83106M2 004 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	477.0 GM	
ADRENALS	--	0.045 GM	0.009%
HEART	--	1.513 GM	0.317%
KIDNEYS	--	3.015 GM	0.632%
LIVER	--	14.702 GM	3.082%
SPLEEN	--	0.707 GM	0.148%
TESTES	--	5.121 GM	1.074%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 35
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 005 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	458.0 GM	
ADRENALS	--	0.066 GM	0.014%
HEART	--	1.495 GM	0.326%
KIDNEYS	--	3.806 GM	0.831%
LIVER	--	13.233 GM	2.889%
SPLEEN	--	0.675 GM	0.147%
TESTES	--	5.703 GM	1.245%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106

***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106M2 006 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	538.0 GM	
ADRENALS	--	0.076 GM	0.014%
HEART	--	1.935 GM	0.360%
KIDNEYS	--	4.021 GM	0.747%
LIVER	--	20.803 GM	3.867%
SPLEEN	--	0.812 GM	0.151%
TESTES	--	5.888 GM	1.094%

GROSS NECROPSY ALTERATIONS:

KIDNEYS
CYST(S) --

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 37
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 007 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	486.0 GM	
ADRENALS	--	0.075 GM	0.015%
HEART	--	1.558 GM	0.321%
KIDNEYS	--	3.149 GM	0.648%
LIVER	--	12.717 GM	2.617%
SPLEEN	--	0.825 GM	0.170%
TESTES	--	6.915 GM	1.423%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 38
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 008 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	476.0 GM	
ADRENALS	--	0.063 GM	0.013%
HEART	--	1.498 GM	0.315%
KIDNEYS	--	3.200 GM	0.672%
LIVER	--	14.020 GM	2.945%
SPLEEN	--	0.758 GM	0.159%
TESTES	--	6.354 GM	1.335%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 39
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 009 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	471.0 GM	
ADRENALS	--	0.048 GM	0.010%
HEART	--	1.708 GM	0.363%
KIDNEYS	--	3.663 GM	0.778%
LIVER	--	13.233 GM	2.810%
SPLEEN	--	0.667 GM	0.142%
TESTES	--	5.438 GM	1.155%

GROSS NECROPSY ALTERATIONS:

KIDNEYS
DILATED PELVIS (HYDRONEPHROSIS) -- RT., MOD.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
PATHOLOGY SECTION

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106M2 010 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	452.0 GM	
ADRENALS	--	0.082 GM	0.018%
HEART	--	1.409 GM	0.312%
KIDNEYS	--	2.729 GM	0.604%
LIVER	--	12.141 GM	2.686%
SPLEEN	--	0.858 GM	0.190%
TESTES	--	5.793 GM	1.282%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 41
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 011 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	449.0 GM	
ADRENALS	--	0.056 GM	0.012%
HEART	--	1.465 GM	0.326%
KIDNEYS	--	2.969 GM	0.661%
LIVER	--	12.415 GM	2.765%
SPLEEN	--	0.582 GM	0.130%
TESTES	--	6.009 GM	1.338%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 42
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 012 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	438.0 GM	
ADRENALS	--	0.042 GM	0.010%
HEART	--	1.346 GM	0.307%
KIDNEYS	--	2.983 GM	0.681%
LIVER	--	12.549 GM	2.865%
SPLEEN	--	0.570 GM	0.130%
TESTES	--	5.212 GM	1.190%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 43
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 013 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	445.0 GM	
ADRENALS	--	0.056 GM	0.013%
HEART	--	1.530 GM	0.344%
KIDNEYS	--	2.793 GM	0.628%
LIVER	--	12.738 GM	2.862%
SPLEEN	--	0.637 GM	0.143%
TESTES	--	5.748 GM	1.292%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 014 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	406.0 GM	
ADRENALS	--	0.066 GM	0.016%
HEART	--	1.386 GM	0.341%
KIDNEYS	--	3.093 GM	0.762%
LIVER	--	11.271 GM	2.776%
SPLEEN	--	0.600 GM	0.148%
TESTES	--	5.405 GM	1.331%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 45
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M2 015 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT	--	516.0 GM	
ADRENALS	--	0.068 GM	0.013%
HEART	--	1.479 GM	0.287%
KIDNEYS	--	3.335 GM	0.646%
LIVER	--	15.304 GM	2.966%
SPLEEN	--	0.728 GM	0.141%
TESTES	--	5.680 GM	1.101%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 46
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 001 DATE OF NECROPSY: 3-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 3

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

EYES
CORNEAL OPACITY --

LIVER
ABNORMAL COLOR -- DARK RED, ALL LOBES

LUNG
ABNORMAL CONSISTENCY -- SPONGY

SPLEEN
SMALL --

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 47
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 002 DATE OF NECROPSY: 4-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 4

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

EYES
CORNEAL OPACITY --

LYMPH NODE
CONGESTED -- MESENTERIC

LUNG
ABNORMAL CONSISTENCY -- SPONGY

STOMACH
FOCI -- PIN POINT BLACK SPOTS, ENTIRE STOMACH.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 48
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 003 DATE OF NECROPSY: 3-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 3

PROSECTOR : (MSBOYD)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LUNG
ABNORMAL CONSISTENCY -- SPONGY
CONGESTED/RED --

STOMACH
ULCERATED --

TESTES
ABNORMAL COLOR -- RED (CONGESTED), BILATERAL

ANIMAL NO: 83106M3 004 DATE OF NECROPSY: 20-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 1

PROSECTOR : (MCARR)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

CECUM
DISTENDED WITH GAS --

COLON
IMPACTED --

DUODENUM
ABNORMAL CONTENT -- BROWN, RED SUBSTANCE

ILEUM
DISTENDED WITH GAS --

JEJUNUM
ABNORMAL CONTENT -- BROWN, RED SUBSTANCE
FLACCID --

LUNG
ABNORMAL CONSISTENCY -- SPONGY
ABNORMAL COLOR -- GREY COLORATION.
CONGESTED/RED --

STOMACH
DISTENDED WITH GAS --

GI TRACT
NOTE: ENTIRE TRACT SAVED.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 50
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 005 DATE OF NECROPSY: 15-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 6

PROSECTOR : (MCARR)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

DUODENUM
ABNORMAL CONTENT -- RED/BROWN CONTENT

ILEUM
ABNORMAL CONTENT -- RED/BROWN CONTENT

JEJUNUM
ABNORMAL CONTENT -- RED/BROWN CONTENT

LIVER
ABNORMAL COLOR -- BLACK

LUNG
ABNORMAL CONSISTENCY -- SPONGY
CONGESTED/RED --

SKELETAL MUSCLE
ATROPHIC --

SPLEEN
SMALL -- 3X6MM.

GI TRACT
DISTENDED WITH GAS --
FLACCID --

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 51
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 006 DATE OF NECROPSY: 26-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 6

PROSECTOR : (MCARR)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LUNG
ABNORMAL COLOR -- GRAY
ABNORMAL CONSISTENCY -- SPONGY

SPLEEN
SMALL -- 3X6MM.

GI TRACT
DISTENDED WITH GAS --

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 52
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 007 DATE OF NECROPSY: 14-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 8

PROSECTOR : (RJHILL)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LYMPH NODE
NOTE: MESENTERIC NODE INDISTINGUISHABLE DUE TO AUTOLYSIS

LUNG
ABNORMAL CONSISTENCY -- FIRM.
CONGESTED/RED -- MOTTLED

PITUITARY
NOTE: DESTROYED AT NECROPSY.

GROSS CONDITION
AUTOLYSIS -- WHOLE BODY.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 53
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 008 DATE OF NECROPSY: 4-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 8

PROSECTOR : (RJHILL)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LUNG
ABNORMAL COLOR -- MOTTLED, SLIGHT.

SEMINAL VESICLES
ATROPHY / SMALL -- 1/4 NORMAL SIZE.

GROSS CONDITION
AUTOLYSIS -- PARTIAL.

GI TRACT
DISTENDED WITH GAS --

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 54
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 009 DATE OF NECROPSY: 17-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 6

PROSECTOR : (MCARR)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

DUODENUM
ABNORMAL CONTENT -- RED/BROWN SUBSTANCE.

EYES
CONGESTED --

JEJUNUM
ABNORMAL CONTENT -- RED/BROWN SUBSTANCE.

GI TRACT
DISTENDED WITH GAS --

ANIMAL NO: 83106M3 010 DATE OF NECROPSY: 20-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 8

PROSECTOR : (MCARR)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

SPLEEN
SMALL -- 1.5X.4CM.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 56
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 011 DATE OF NECROPSY: 29-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 6

PROSECTOR : (MCARR)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

EYES
CORNEAL OPACITY -- BILATERAL

LIVER
ABNORMAL COLOR -- BLACK

LUNG
ABNORMAL COLOR -- GRAY
ABNORMAL CONSISTENCY -- SPONGY
INCOMPLETE COLLAPSE --

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 57
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 012 DATE OF NECROPSY: 11-OCT-83

ANIMAL STATUS CODE: M HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

ADRENALS
CONGESTED -- BILATERAL

SPLEEN
SMALL -- 1.5X.5CM.

STOMACH
ULCERATED -- NONGLANDULAR AREA, MILD

GI TRACT
DISTENDED WITH GAS --

ANIMAL NO: 83106M3 013 DATE OF NECROPSY: 27-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 8

PROSECTOR : (MCARR)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

NOSE/TURBINATES
ABNORMAL DISCHARGE -- PORPHYRIN DISCHARGE, EXTERNAL NARES.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 59
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 014 DATE OF NECROPSY: 17-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 12

PROSECTOR : (MCARR)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

GROSS CONDITION
AUTOLYSIS --

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106M3 015 DATE OF NECROPSY: 3-NOV-83

ANIMAL STATUS CODE: M HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

DUODENUM
HEMORRHAGE -- LUMEN

LUNG
ABNORMAL CONSISTENCY -- SPONGY
INCOMPLETE COLLAPSE --

SPLEEN
SMALL -- 0.5X0.2 CM.

GI TRACT
DISTENDED WITH GAS --

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 61
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 001 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	265.0 GM	
ADRENALS	--	0.071 GM	0.027%
HEART	--	1.009 GM	0.381%
KIDNEYS	--	2.056 GM	0.776%
LIVER	--	7.700 GM	2.906%
SPLEEN	--	0.437 GM	0.165%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 62
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 002 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	280.0 GM	
ADRENALS	--	0.099 GM	0.035%
HEART	--	1.106 GM	0.395%
KIDNEYS	--	1.852 GM	0.661%
LIVER	--	8.851 GM	3.161%
SPLEEN	--	0.395 GM	0.141%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 63
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 003 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	284.0 GM	
ADRENALS	--	0.092 GM	0.032%
HEART	--	1.075 GM	0.379%
KIDNEYS	--	1.987 GM	0.700%
LIVER	--	7.400 GM	2.606%
SPLEEN	--	0.466 GM	0.164%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 004 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	231.0 GM	
ADRENALS	--	0.071 GM	0.031%
HEART	--	0.768 GM	0.332%
KIDNEYS	--	1.745 GM	0.755%
LIVER	--	6.533 GM	2.828%
SPLEEN	--	0.335 GM	0.145%

GROSS NECROPSY ALTERATIONS:

UTERUS
HYDROMETRA -- MILD,BILATERAL

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 65
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 005 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	254.0 GM	
ADRENALS	--	0.065 GM	0.026%
HEART	--	0.811 GM	0.319%
KIDNEYS	--	1.648 GM	0.649%
LIVER	--	6.710 GM	2.642%
SPLEEN	--	0.359 GM	0.141%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 66
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 006 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	289.0 GM	
ADRENALS	--	0.070 GM	0.024%
HEART	--	0.965 GM	0.334%
KIDNEYS	--	1.941 GM	0.672%
LIVER	--	7.705 GM	2.666%
SPLEEN	--	0.521 GM	0.180%

GROSS NECROPSY ALTERATIONS:

UTERUS
HYDROMETRA -- MILD,BILATERAL

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106FN 007 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	274.0 GM	
ADRENALS	--	0.088 GM	0.032%
HEART	--	0.921 GM	0.336%
KIDNEYS	--	2.099 GM	0.766%
LIVER	--	7.611 GM	2.778%
SPLEEN	--	0.499 GM	0.182%

GROSS NECROPSY ALTERATIONS:

KIDNEYS
DILATED PELVIS (HYDRONEPHROSIS) -- MODERATE,BILATERAL

LIVER
ABNORMAL COLOR -- DIFFUSELY LIGHT TAN

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
PATHOLOGY SECTION

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106FN 008 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	316.0 GM	
ADRENALS	--	0.080 GM	0.025%
HEART	--	1.081 GM	0.342%
KIDNEYS	--	2.075 GM	0.657%
LIVER	--	8.814 GM	2.789%
SPLEEN	--	0.511 GM	0.162%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 69
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 009 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	290.0 GM	
ADRENALS	--	0.082 GM	0.028%
HEART	--	1.000 GM	0.345%
KIDNEYS	--	1.721 GM	0.593%
LIVER	--	9.250 GM	3.190%
SPLEEN	--	0.404 GM	0.139%

GROSS NECROPSY ALTERATIONS:

UTERUS
HYDROMETRA -- BILATERAL,MILD

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 70
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 010 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	286.0 GM	
ADRENALS	--	0.091 GM	0.032%
HEART	--	1.026 GM	0.359%
KIDNEYS	--	2.225 GM	0.778%
LIVER	--	9.256 GM	3.236%
SPLEEN	--	0.624 GM	0.218%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 71
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 011 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	295.0 GM	
ADRENALS	--	0.051 GM	0.017%
HEART	--	0.949 GM	0.322%
KIDNEYS	--	1.853 GM	0.628%
LIVER	--	8.264 GM	2.801%
SPLEEN	--	0.541 GM	0.183%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 72
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 012 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	268.0 GM	
ADRENALS	--	0.076 GM	0.028%
HEART	--	0.920 GM	0.343%
KIDNEYS	--	2.269 GM	0.847%
LIVER	--	9.989 GM	3.727%
SPLEEN	--	0.451 GM	0.168%

GROSS NECROPSY ALTERATIONS:

KIDNEYS
DILATED PELVIS (HYDRONEPHROSIS) -- BILATERAL,SEVERE

LIVER
ABNORMAL COLOR -- TAN MOTTLING

UTERUS
HYDROMETRA -- MILD,BILATERAL

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106FN Ø13 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = Ø

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	262.Ø GM	
ADRENALS	--	Ø.Ø74 GM	Ø.Ø28%
HEART	--	Ø.861 GM	Ø.329%
KIDNEYS	--	2.119 GM	Ø.8Ø9%
LIVER	--	1Ø.Ø82 GM	3.848%
SPLEEN	--	Ø.423 GM	Ø.161%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 74
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106FN 014 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	271.0 GM	
ADRENALS	--	0.053 GM	0.020%
HEART	--	0.878 GM	0.324%
KIDNEYS	--	1.644 GM	0.607%
LIVER	--	6.908 GM	2.549%
SPLEEN	--	0.587 GM	0.217%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106FN Ø15 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = Ø

PROSECTOR : (CLGETM)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	258.Ø GM	
ADRENALS	--	Ø.Ø29 GM	Ø.Ø11%
HEART	--	Ø.838 GM	Ø.325%
KIDNEYS	--	1.958 GM	Ø.759%
LIVER	--	8.951 GM	3.469%
SPLEEN	--	Ø.418 GM	Ø.162%

GROSS NECROPSY ALTERATIONS:

UTERUS
HYDROMETRA -- MILD,BILATERAL

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106F1 001 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	281.0 GM	
ADRENALS	--	0.080 GM	0.028%
HEART	--	0.920 GM	0.327%
KIDNEYS	--	1.767 GM	0.629%
LIVER	--	8.706 GM	3.098%
SPLEEN	--	0.501 GM	0.178%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106F1 002 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	243.0 GM	
ADRENALS	--	0.065 GM	0.027%
HEART	--	0.806 GM	0.332%
KIDNEYS	--	1.548 GM	0.637%
LIVER	--	6.124 GM	2.520%
SPLEEN	--	0.460 GM	0.189%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 003 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	231.0 GM	
ADRENALS	--	0.067 GM	0.029%
HEART	--	0.793 GM	0.343%
KIDNEYS	--	1.598 GM	0.692%
LIVER	--	6.616 GM	2.864%
SPLEEN	--	0.461 GM	0.200%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 004 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	297.0 GM	
ADRENALS	--	0.069 GM	0.023%
HEART	--	0.898 GM	0.302%
KIDNEYS	--	1.706 GM	0.574%
LIVER	--	8.951 GM	3.014%
SPLEEN	--	0.476 GM	0.160%

GROSS NECROPSY ALTERATIONS:

UTERUS
HYDROMETRA -- BILATERAL,MILD

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 80
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 005 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	316.0 GM	
ADRENALS	--	0.100 GM	0.032%
HEART	--	1.201 GM	0.380%
KIDNEYS	--	2.191 GM	0.693%
LIVER	--	13.010 GM	4.117%
SPLEEN	--	0.524 GM	0.166%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 81
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 006 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	232.0 GM	
ADRENALS	--	0.072 GM	0.031%
HEART	--	0.760 GM	0.328%
KIDNEYS	--	1.589 GM	0.685%
LIVER	--	8.841 GM	3.811%
SPLEEN	--	0.391 GM	0.169%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 007 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	275.0 GM	
ADRENALS	--	0.098 GM	0.035%
HEART	--	1.061 GM	0.386%
KIDNEYS	--	1.925 GM	0.700%
LIVER	--	7.726 GM	2.809%
SPLEEN	--	0.526 GM	0.191%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 83
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 008 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	239.0 GM	
ADRENALS	--	0.100 GM	0.042%
HEART	--	0.925 GM	0.387%
KIDNEYS	--	1.921 GM	0.804%
LIVER	--	10.203 GM	4.269%
SPLEEN	--	0.416 GM	0.174%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106F1 009 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	279.0 GM	
ADRENALS	--	0.092 GM	0.033%
HEART	--	0.886 GM	0.318%
KIDNEYS	--	1.913 GM	0.686%
LIVER	--	7.644 GM	2.740%
SPLEEN	--	0.601 GM	0.215%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 010 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	280.0 GM	
ADRENALS	--	0.080 GM	0.029%
HEART	--	0.968 GM	0.346%
KIDNEYS	--	2.041 GM	0.729%
LIVER	--	8.423 GM	3.008%
SPLEEN	--	0.503 GM	0.180%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 011 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = -0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	284.0 GM	
ADRENALS	--	0.098 GM	0.035%
HEART	--	1.147 GM	0.404%
KIDNEYS	--	2.213 GM	0.779%
LIVER	--	13.121 GM	4.620%
SPLEEN	--	0.606 GM	0.213%

GROSS NECROPSY ALTERATIONS:

UTERUS
HYDROMETRA -- MILD,BILATERAL

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 012 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	289.0 GM	
ADRENALS	--	0.086 GM	0.030%
HEART	--	0.891 GM	0.308%
KIDNEYS	--	2.007 GM	0.694%
LIVER	--	8.565 GM	2.964%
SPLEEN	--	0.474 GM	0.164%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106F1 013 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	306.0 GM	
ADRENALS	--	0.079 GM	0.026%
HEART	--	0.957 GM	0.313%
KIDNEYS	--	1.940 GM	0.634%
LIVER	--	8.948 GM	2.924%
SPLEEN	--	0.529 GM	0.173%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106F1 014 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	256.0 GM	
ADRENALS	--	0.076 GM	0.030%
HEART	--	0.824 GM	0.322%
KIDNEYS	--	1.921 GM	0.750%
LIVER	--	9.671 GM	3.778%
SPLEEN	--	0.597 GM	0.233%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F1 015 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	265.0 GM	
ADRENALS	--	0.057 GM	0.022%
HEART	--	1.047 GM	0.395%
KIDNEYS	--	1.904 GM	0.718%
LIVER	--	7.620 GM	2.875%
SPLEEN	--	0.367 GM	0.138%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 91
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 001 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	267.0 GM	
ADRENALS	--	0.084 GM	0.031%
HEART	--	0.919 GM	0.344%
KIDNEYS	--	1.930 GM	0.723%
LIVER	--	8.641 GM	3.236%
SPLEEN	--	0.411 GM	0.154%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 002 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	250.0 GM	
ADRENALS	--	0.093 GM	0.037%
HEART	--	0.833 GM	0.333%
KIDNEYS	--	1.783 GM	0.713%
LIVER	--	6.922 GM	2.769%
SPLEEN	--	0.527 GM	0.211%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 93
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 003 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	207.0 GM	
ADRENALS	--	0.096 GM	0.046%
HEART	--	0.865 GM	0.418%
KIDNEYS	--	1.544 GM	0.746%
LIVER	--	10.199 GM	4.927%
SPLEEN	--	0.419 GM	0.202%

GROSS NECROPSY ALTERATIONS:

LIVER
ABNORMAL COLOR -- MOTTLED YELLOW-TAN

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 94
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 004 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	216.0 GM	
ADRENALS	--	0.070 GM	0.032%
HEART	--	0.781 GM	0.362%
KIDNEYS	--	1.566 GM	0.725%
LIVER	--	6.042 GM	2.797%
SPLEEN	--	0.460 GM	0.213%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106F2 005 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)

ORGAN WTS. BY: (TVWILS)

PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	270.0 GM	
ADRENALS	--	0.078 GM	0.029%
HEART	--	0.980 GM	0.363%
KIDNEYS	--	1.862 GM	0.690%
LIVER	--	7.773 GM	2.879%
SPLEEN	--	0.565 GM	0.209%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106F2 006 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	254.0 GM	
ADRENALS	--	0.097 GM	0.038%
HEART	--	0.952 GM	0.375%
KIDNEYS	--	1.918 GM	0.755%
LIVER	--	7.820 GM	3.079%
SPLEEN	--	0.421 GM	0.166%

GROSS NECROPSY ALTERATIONS:

UTERUS
HYDROMETRA -- MILD,BILATERAL

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106F2 007 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	270.0 GM	
ADRENALS	--	0.107 GM	0.040%
HEART	--	0.914 GM	0.339%
KIDNEYS	--	2.010 GM	0.744%
LIVER	--	8.068 GM	2.988%
SPLEEN	--	0.511 GM	0.189%

GROSS NECROPSY ALTERATIONS:

N O N E.

ANIMAL NO: 83106F2 008 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	238.0 GM	
ADRENALS	--	0.064 GM	0.027%
HEART	--	0.966 GM	0.406%
KIDNEYS	--	1.685 GM	0.708%
LIVER	--	7.016 GM	2.948%
SPLEEN	--	0.523 GM	0.220%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 009 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	262.0 GM	
ADRENALS	--	0.080 GM	0.031%
HEART	--	0.964 GM	0.368%
KIDNEYS	--	1.869 GM	0.713%
LIVER	--	7.205 GM	2.750%
SPLEEN	--	0.487 GM	0.186%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 100
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 010 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	213.0 GM	
ADRENALS	--	0.076 GM	0.036%
HEART	--	0.744 GM	0.349%
KIDNEYS	--	1.657 GM	0.778%
LIVER	--	6.463 GM	3.034%
SPLEEN	--	0.432 GM	0.203%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 101
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 011 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	263.0 GM	
ADRENALS	--	0.081 GM	0.031%
HEART	--	0.851 GM	0.324%
KIDNEYS	--	1.630 GM	0.620%
LIVER	--	7.109 GM	2.703%
SPLEEN	--	0.463 GM	0.176%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 012 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	229.0 GM	
ADRENALS	--	0.101 GM	0.044%
HEART	--	0.933 GM	0.407%
KIDNEYS	--	2.276 GM	0.994%
LIVER	--	10.437 GM	4.558%
SPLEEN	--	0.485 GM	0.212%

GROSS NECROPSY ALTERATIONS:

LIVER
ABNORMAL COLOR -- YELLOW-TAN MOTTLING

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 103
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 013 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (CLGETM)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	250.0 GM	
ADRENALS	--	0.082 GM	0.033%
HEART	--	0.962 GM	0.385%
KIDNEYS	--	1.808 GM	0.723%
LIVER	--	6.874 GM	2.750%
SPLEEN	--	0.507 GM	0.203%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 104
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 014 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	271.0 GM	
ADRENALS	--	0.087 GM	0.032%
HEART	--	0.847 GM	0.313%
KIDNEYS	--	1.902 GM	0.702%
LIVER	--	10.897 GM	4.021%
SPLEEN	--	0.489 GM	0.180%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F2 015 DATE OF NECROPSY: 22-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (RJHILL)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	233.0 GM	
ADRENALS	--	0.116 GM	0.050%
HEART	--	0.938 GM	0.403%
KIDNEYS	--	2.037 GM	0.874%
LIVER	--	7.099 GM	3.047%
SPLEEN	--	0.400 GM	0.172%

GROSS NECROPSY ALTERATIONS:

N O N E.

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N
PAGE: 106

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 001 DATE OF NECROPSY: 27-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM NOT RECORDED

PROSECTOR : (CLGETM)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

EYES
CORNEAL OPACITY -- BILATERAL

LUNG
CONGESTED/RED -- ACCESSORY LOBE

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 002 DATE OF NECROPSY: 6-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 13

PROSECTOR : (MCARR)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

GI TRACT
DISTENDED WITH GAS --

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 108
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 003 DATE OF NECROPSY: 1-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 10

PROSECTOR : (RJHILL)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LUNG
CONGESTED/RED --

GI TRACT
DISTENDED WITH GAS -- SEVERE.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 004 DATE OF NECROPSY: 31-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 12

PROSECTOR : (MCARR)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LUNG
FOCUS(I) -- 3 MM DIAM., RT. CAUDAL LOBE.

NOSE/TURBINATES
ABNORMAL DISCHARGE -- PORPHYRIA

GI TRACT
DISTENDED WITH GAS --

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 005 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MSBOYD)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	143.0 GM	
ADRENALS	--	0.043 GM	0.030%
HEART	--	0.637 GM	0.445%
KIDNEYS	--	1.281 GM	0.896%
LIVER	--	4.264 GM	2.982%
SPLEEN	--	0.211 GM	0.148%

GROSS NECROPSY ALTERATIONS:

N O N E.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 006 DATE OF NECROPSY: 27-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 7

PROSECTOR : (MCARR)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

KIDNEYS
DILATED PELVIS (HYDRONEPHROSIS) -- RIGHT. (LESION DETECTED AT TISSUE TRIMMING)

LUNG
INCOMPLETE COLLAPSE --
ABNORMAL COLOR -- GRAY.
ABNORMAL CONSISTENCY -- SPONGY

NOSE/TURBINATES
ABNORMAL DISCHARGE -- PORPHYRIN, EXTERNAL NARES.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 112
PATHOLOGY SECTION
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 007 DATE OF NECROPSY: 7-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 5

PROSECTOR : (CLGETM)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LUNG
ABNORMAL CONSISTENCY -- SPONGY
CONGESTED/RED --

UTERUS
ABNORMAL COLOR -- DARK

GI TRACT
DISTENDED WITH GAS --

ANIMAL NO: 83106F3 008 DATE OF NECROPSY: 15-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 1

PROSECTOR : (MCARR)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

ADRENALS
ENLARGED -- 1.6X NORMAL.
CONGESTED --

CECUM
GAS FILLED --

COLON
IMPACTED -- FECAL MATERIAL, SUSPECT BLOCKAGE.

DUODENUM
ABNORMAL CONTENT -- SOFT, BLACK.

EYES
CORNEAL OPACITY -- BILATERAL.

ILEUM
GAS FILLED --

JEJUNUM
ABNORMAL CONTENT -- SOFT, BLACK.

KIDNEYS
DILATED PELVIS (HYDRONEPHROSIS) -- RT., MILD.

LIVER
FOCI -- 1X5MM. DIAM., RT. MEDIAL LOBE, VENT. SURFACE, WHITE.

SKIN
ABNORMAL COLOR -- YELLOW

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N
PAGE: 114

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 008 DATE OF NECROPSY: 15-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 1

PROSECTOR : (MCARR)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

SKELETAL MUSCLE
ATROPHIC -- MILD

STOMACH
ABNORMAL CONTENT -- SOFT, BLACK.
EROSIONS -- (LESIONS DETECTED AT TISSUE TRIMMING).

GROSS CONDITION
EMACIATION -- NO VISIBLE BODY FAT

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 009 DATE OF NECROPSY: 27-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 5

PROSECTOR : (MCARR)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LUNG
INCOMPLETE COLLAPSE --
ABNORMAL COLOR -- GRAY (NOT VISIBLE AFTER FORMALIN INFLATION).
ABNORMAL CONSISTENCY -- SPONGY

NOSE/TURBINATES
ABNORMAL DISCHARGE -- PORPHYRIN EXCRETION, EXTERNAL NARES.

STOMACH
EROSIONS -- (LESIONS DETECTED AT TISSUE TRIMMING).

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 116
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 010 DATE OF NECROPSY: 21-DEC-83

ANIMAL STATUS CODE: S HOURS POST MORTEM = 0

PROSECTOR : (MCARR)
ORGAN WTS. BY: (TVWILS)
PATHOLOGIST : (WERIBE)

WEIGHTS:

TERMINAL BODY WEIGHT	--	201.0 GM	
ADRENALS	--	0.068 GM	0.034%
HEART	--	0.802 GM	0.399%
KIDNEYS	--	1.642 GM	0.817%
LIVER	--	7.104 GM	3.534%
SPLEEN	--	0.408 GM	0.203%

GROSS NECROPSY ALTERATIONS:

GI TRACT
DISTENDED WITH GAS --

THIS REPORT GENERATED FROM DATA LOCKED THRU 7-JAN-87

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 Ø11 DATE OF NECROPSY: 28-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 5

PROSECTOR : (MCARR)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

NOSE/TURBINATES
ENCRUSTED --
ABNORMAL COLOR -- RED.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
PATHOLOGY SECTION

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE

ANIMAL NO: 83106F3 012 DATE OF NECROPSY: 1-NOV-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 12

PROSECTOR : (MCARR)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

NOSE/TURBINATES
ABNORMAL DISCHARGE -- PORPHYRIA

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 013 DATE OF NECROPSY: 28-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 1

PROSECTOR : (RJHILL)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

COLON
BLOOD IN LUMEN -- SMALL AMOUNT

GI TRACT
DISTENDED WITH GAS -- SEVERE
NOTE: GUT APPEARED TO BE AUTOLYZED BUT ANIMAL WAS APPARENTLY
DEAD ONLY ABOUT 15 MINUTES.

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB *****
P A T H O L O G Y S E C T I O N

STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE
PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 014 DATE OF NECROPSY: 10-DEC-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 4

PROSECTOR : (MSBOYD)

ORGAN WTS. BY: ( )

PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LUNG
CONGESTED/RED --

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 121
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

ANIMAL NO: 83106F3 015 DATE OF NECROPSY: 9-OCT-83

ANIMAL STATUS CODE: D HOURS POST MORTEM = 3

PROSECTOR : (PMGRUE)
ORGAN WTS. BY: ( )
PATHOLOGIST : (DCTHAK)

WEIGHTS:

TERMINAL BODY WEIGHT -- NOT RECORDED

GROSS NECROPSY ALTERATIONS:

LUNG
CONGESTED/RED --

SKIN AND HAIR
STAINED -- RED, NOSE, MOUTH, UROGENITAL REGION.

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 10-JAN-84

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** TERMINAL BODY WEIGHTS ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES PERIODS: 13-DEC-83: 3-JAN-84

	M A L E S			
	MN	M1	M2	M3
1	504.0	520.0	434.0	NA
2	487.4	545.0	495.0	NA
3	488.0	557.0	448.0	NA
4	607.0	538.0	477.0	NA
5	536.0	538.0	458.0	NA
6	539.0	557.0	538.0	NA
7	471.0	429.0	486.0	NA
8	566.0	470.0	476.0	NA
9	480.0	533.0	471.0	NA
10	630.0	512.0	452.0	NA
11	532.0	543.0	449.0	NA
12	512.0	553.0	438.0	NA
13	474.0	633.0	445.0	NA
14	521.0	525.0	406.0	NA
15	510.0	502.0	516.0	NA
MEAN	523.827	530.333	465.933	0.000
S.E.	12.140	11.580	8.699	0.000
(N)	15	15	15	0

ANALYSIS OF VARIANCE: F = 10.56, P = 0.0002

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
M1	6.5067	0.422	2.29	2.94
M2	-57.8933**	-3.752	2.29	2.94

NOTES: AN 'E' FOLLOWING A WEIGHT INDICATES THAT IT HAS BEEN EXCLUDED FROM SUMMARY STATISTICS

'NA' INDICATES ANIMAL NOT IN OBSERVED GROUP
'NW' INDICATES NO WEIGHT AVAILABLE FOR ANIMAL
'* ' INDICATES MEAN STATISTICALLY DIFFERENT FROM CONTROL (P LESS THAN OR EQUAL TO 0.05)
'**' INDICATES MEAN STATISTICALLY DIFFERENT FROM CONTROL (P LESS THAN OR EQUAL TO 0.01)

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 10-JAN-84

STUDY NO: 83106 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 2
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: RAT SUBSTANCE: 2,6 DIETHYLPHENYL AZOMETHINE PRINTED: 4-FEB-87

** TERMINAL BODY WEIGHTS ** (WEIGHTS IN GRAMS)
SELECTION CRITERIA: SCHEDULED SACRIFICES PERIODS: 13-DEC-83: 3-JAN-84

	FEMALES			
	FN	F1	F2	F3
1	265.0	281.0	267.0	NA
2	280.0	243.0	250.0	NA
3	284.0	231.0	207.0	NA
4	231.0	297.0	216.0	NA
5	254.0	316.0	270.0	143.0
6	289.0	232.0	254.0	NA
7	274.0	275.0	270.0	NA
8	316.0	239.0	238.0	NA
9	290.0	279.0	262.0	NA
10	286.0	280.0	213.0	201.0
11	295.0	284.0	263.0	NA
12	268.0	289.0	229.0	NA
13	262.0	306.0	250.0	NA
14	271.0	256.0	271.0	NA
15	258.0	265.0	233.0	NA
MEAN	274.867	271.533	246.200	172.000
S.E.	5.223	6.854	5.728	29.000
(N)	15	15	15	2

ANALYSIS OF VARIANCE: F = 14.03, P = 0.0000

DUNNETT'S TEST

GROUP	DIFF. FROM CONTROL	CALCULATED T-VALUES	CRITICAL VALUES .05	.01
F1	-3.3333	-0.385	2.43	3.08
F2	-28.6667**	-3.311	2.43	3.08
F3	-102.8667**	-5.764	2.43	3.08

NOTES: AN 'E' FOLLOWING A WEIGHT INDICATES THAT IT HAS BEEN EXCLUDED FROM SUMMARY STATISTICS

'NA' INDICATES ANIMAL NOT IN OBSERVED GROUP
'NW' INDICATES NO WEIGHT AVAILABLE FOR ANIMAL
'* ' INDICATES MEAN STATISTICALLY DIFFERENT FROM CONTROL (P LESS THAN OR EQUAL TO 0.05)
'**' INDICATES MEAN STATISTICALLY DIFFERENT FROM CONTROL (P LESS THAN OR EQUAL TO 0.01)

IR-84-040

MAC TOXICOLOGY
JAN 2 8 1985

International Research
and Development Corporation
MATTAWAN, MICHIGAN, U.S.A. 49071 TELEPHONE (616) 668-3336

SPONSOR: Monsanto Company

TEST ARTICLE: 2,6-Diethylphenylazomethine

SUBJECT: Teratology Study in Rats (IR-84-040)

DATE OF SUBMISSION: January 25, 1985

401-271

"credence through research"

Monsanto

Azomethine

FROM (NAME—LOCATION—PHONE) Dept. of Medicine & Environmental Health — ~~R.C.Dirks /G2WD/8818~~

DATE : February 22, 1985

SUBJECT : 2,6-Diethylphenylazomethine: Teratology Study in Rats

REFERENCE : IR-84-040; IRDC No. 401-271

TO : R. W. Street /C2SC

CC. E.E. Debus /C2SC
B.W. Eley /C2SB
T.W. Fuhremann
R.L. Harness /C2NA
R.C. Peck /G2WB
L.A. Suba /C2SC
S.F. Dirks /G2WF
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The accompanying report contains the results of the referenced study with 2,6-diethylphenylazomethine (azomethine). Quality assurance reviews were conducted by International Research and Development Corporation (IRDC). A review of the data and an evaluation of the conclusions presented in this report are summarized below.

Methods

Azomethine (Lot No. stg 2-23-84; purity 99.5%) was administered in corn oil by stomach tube to groups of 25 mated Sprague-Dawley female rats on days six through 15 of gestation. Dose levels were 0 (vehicle control) 15, 75 and 250 mg/kg/day at a constant dosing volume of 5 ml/kg.

The animals were observed twice daily for mortality and overt clinical signs of toxicity. During the treatment period (days six through 15 of gestation) each animal was given a more detailed physical examination daily. Individual body weights were recorded on gestation days 0, 6, 9, 12, 16 and 20.

On gestation day 20, all animals were killed and the ovaries and uteri were exposed by abdominal incision. The number and location of viable fetuses, early and late resorptions, number of implantations and the number of corpora lutea were recorded. The fetuses were then removed and the abdominal and thoracic cavities examined for gross signs of toxicity.

AA040865

All fetuses were individually weighed and examined for external malformations. Approximately one-half the fetuses were examined for soft tissue malformations and the other half were examined for skeletal malformations and variations.

Results

All control and treated animals survived until termination of the study. The only clinical sign of toxicity possibly related to treatment was "excessive salivation" in the high-dose group.

Body weight gain was decreased approximately 15% and 39% in the mid- and high-dose animals respectively, during the treatment period. Body weights and body weight gains of the low-dose group were comparable to the control group.

A slightly increased incidence of kidney hydronephrosis was noted in the mid- and high-dose dams during the gross necropsy examinations. However, the changes were not dose related and since this is a common spontaneous lesion was not considered to be a result of azomethine administration.

The uterine examinations did not reveal any azomethine-related changes in the reproductive parameters examined. There was an apparent dose-related increase in the group mean preimplantation loss in the mid- and high-dose groups, but the values were well within the laboratory's historical control range.

There were only four malformations observed in the study. All of these were found in three litters of the control group. The number of developmental variations was greater than malformations, but none were considered to be related to azomethine administration. Apparent increases in the numbers of fetuses and litters with greater than 13 ribs, fewer than 13 ribs, and sternebrae unossified were found to be within historical control ranges.

Conclusion

The oral administration of 2,6-diethylphenyl-azomethine to pregnant rats at dosages of 0, 15, 75 and 250 mg/kg/day on days 6-15 of gestation resulted in minor clinical signs of toxicity in the high-dose group and substantial decreases in body weight gain in the mid- and high-dose groups. No indication of a teratogenic response was observed at any dosage level. The teratogenic no effect level was considered to be 250 mg/kg/day, the highest dosage level tested.

Richard C Dirks

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I. QUALITY ASSURANCE STATEMENT

Study Title: Teratology Study in Rats (IR-84-040)

Test Article: 2,6-Diethylphenylazomethine

The conduct of this study has been subjected to periodic inspections. The dates of inspection and the dates that findings were reported to management and the Study Director are listed in Appendix A.

This reort has been reviewed by the International Research and Development Corporation Quality Assurance Department in accordance with the United States Environmental Protection Agency Good Laboratory Practice Regulations of May 2, 1984.

Approved And Submitted By: Patrick E. Traster, B.S. Director of Quality Assurance

1/23/89
Date

401-271

II. SYNOPSIS

Mated Charles River COBS® CD® rats consecutively assigned to one control and three treatment groups of 25 animals each were used to determine the teratogenic potential of 2,6-Diethylphenylazomethine. Dosage levels of 15, 75 and 250 mg/kg/day were administered orally by gavage as a single daily dose on days 6 through 15 of gestation at a dosage volume of 5 ml/kg. The control group received the vehicle only, corn oil, on a comparable regimen. Cesarean sections were performed on all surviving females on gestation day 20 and the fetuses were removed for teratologic evaluation.

There was a slight decrease in maternal weight gain over the entire gestation period (gestation days 0-20) and a slight increase in the occurrence of excessive salivation in the high-dose group relative to that in the control group. A dose-related decrease in maternal weight gain during treatment was noted in the mid and high-dose groups in comparison to the control value.

There were no adverse dose-related effects on maternal survival, necropsy findings, Cesarean section observations or the incidence of fetal malformations and developmental variations in the treatment groups when compared to those in the control group.

When administered orally by gavage to Charles River COBS® CD® rats at dose levels of 250 mg/kg/day or less, 2,6-Diethylphenylazomethine did not induce a teratogenic effect.

III. INTRODUCTION

A. OBJECTIVE

The objective of this study was to determine the teratogenic potential of the test article in rats in accordance with Series 83-3 of the Environmental Protection Agency Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals, issued November, 1982.

B. TEST ARTICLE IDENTIFICATION

The test article[a] was received from Monsanto Company, Muscatine, Iowa on March 2, 1984 as indicated below:

Label				Description
Monsanto ANALYTICAL LABORATORY				clear amber liquid
DEPT. NO. LASSO III	JOB NO.			
DATE 2-23-84	TIME RECEIVED 1300			
MATERIAL Azo				
CAR NO. Stg #	TANK NO. 200	BATCH NO.	LOT NO.	
SAMPLED BY don yager				
REMARKS assay: Form .08 Dea. .3 Azo 99.5				

C. VEHICLE CONTROL ARTICLE IDENTIFICATION

The vehicle control article, corn oil, was received from Best Foods, CPC International, Inc., General Offices,

[a]The Sponsor has indicated the lot number to be STG2-23-84

Englewood Cliffs, New Jersey on February 9, 1984 (vehicle control # 0529VC) and March 12, 1984 (vehicle control #0540VC). Specific label and descriptive information is recorded in the IRDC vehicle control article log book and is available on request.

IV. METHODS AND PROCEDURES

This study was conducted in accordance with the protocol as approved by the Sponsor and in compliance with the Standard Operating Procedures of International Research and Development Corporation (IRDC). Procedures pertinent to this study are described herein.

A. EXPERIMENTAL DESIGN

1. Animal Receipt and Maintenance

One hundred thirty-one untreated, 70-day old, virgin female Charles River COBS® CD® rats were received from the Charles River Breeding Laboratories, Inc., Portage, Michigan on April 2, 1984. Upon receipt, the animals were assigned temporary animal numbers and housed individually in suspended wire-mesh cages.

During the 28-day acclimation period, the animals were provided with basal laboratory diet of Purina® Certified Rodent Chow® #5002 and tap water available ad libitum and were carefully observed for changes in appearance and behavior.

The basal laboratory diet, Purina® Certified Rodent Chow® #5002, was analyzed by the manufacturer for the presence of pesticides, heavy metals and aflatoxins; each diet-lot used was recorded. The drinking water at IRDC is analyzed quarterly for the presence of pesticides, heavy metals and coliforms. The results of these analyses are

stored in the IRDC Archives at Mattawan, Michigan and are available upon request.

Throughout the study, all animals were housed in an environmentally controlled room. Temperature ranged between 22°C and 25°C and humidity ranged between 24% and 55%. The humidity was below the protocol specified lower limit of 35% on five occasions. Fluorescent lighting provided illumination 12 hours per day. The rats were housed individually in suspended wire-mesh cages from receipt until sacrifice except during mating. Nesting material was not provided since the dams were sacrificed prior to delivery. The rats were identified by cage, group and individually by a Monel® metal ear-tag bearing its animal number. The individual animal number plus the IRDC study number comprised a unique identification number for each animal. The rats were approximately 14 weeks old at the time of mating and weighed between 210 and 285 g on gestation day 0. Two females were slightly underweight at study initiation.

Mating was initiated on April 30, 1984 and the last Cesarean section was performed on May 24, 1984.

2. Rationale for Selection of Species and Strain

The rat is an acceptable model for teratology studies. This laboratory has historical control data on the incidence of fetal malformations and variations in this

strain from this source. This strain is susceptible to known teratogenic agents.

3. Mating

At the end of the acclimation period, all animals were weighed and subjected to a detailed physical examination. At this time, animals considered suitable for study were cohabitated with stock males utilized exclusively for this purpose.

One female and one male rat of the same strain and source were placed together for mating. The occurrence of copulation was determined by daily inspection for a copulatory plug or vaginal smear for sperm. The day evidence of mating was detected was designated day 0 of gestation and the female was returned to an individual cage, assigned a permanent animal number and properly identified by ear-tag.

4. Organization of Test Groups

Mated females were consecutively assigned in a block design to one control and three treatment groups consisting of 25 rats each by the following procedure. The order in which the mated females were assigned corresponded to the day the copulatory plug was observed and the order in which the animal appeared on the breeding record. The first mated female on the breeding record was assigned to the first group, the second mated female assigned to the second group, and all remaining animals were assigned in this manner until

the required number of mated females had been placed into each group.

B. TEST ARTICLE ADMINISTRATION

Individual daily total volumes of test material administered are presented in Appendix B.

The selected route of administration was oral since this was a convenient and acceptable route of administration for materials of this type. Dose levels were selected on the basis of a previously conducted range-finding study.

The appropriate amount of 2,6-Diethylphenylazomethine for each group was dissolved daily in the vehicle, corn oil, and shaken by hand to ensure dissolution. The test article was prepared at concentrations to permit the administration of dose levels of 15, 75 and 250 mg/kg/day at a dosage volume of 5 ml/kg.

The test article was administered as a single daily dose on days 6 through 15 of gestation. Test article administration was accomplished by intragastric intubation using 3 cc disposable plastic syringes and 16 gauge, 3 inch long curved stainless steel dosing needles. Dosing began approximately 2 1/2 to 3 hours after initiation of the illuminated phase of the photoperiod. The control group received the vehicle only on a comparable regimen at a volume of 5 ml/kg. Individual dosages were determined from the most recently recorded individual body weights.

C. MATERNAL OBSERVATIONS

1. Appearance and Behavior

Prior to and following treatment, the females were observed twice daily for mortality and overt changes in appearance and behavior. They were observed twice daily for mortality and once daily for clinical signs of toxicity on days 6 through 15 of gestation.

2. Body Weights

Individual maternal body weights were recorded on gestation days 0, 6, 9, 12, 16 and 20.

3. Cesarean Section Observations

On gestation day 20, all surviving females were sacrificed by carbon dioxide inhalation. Immediately following sacrifice, the uterus and ovaries were exposed by an abdominal incision. The number and location of viable and nonviable fetuses, early and late resorptions and the number of total implantations and corpora lutea were recorded. The uterus was then excised and the fetuses removed. The abdominal and thoracic cavities and organs of the dams were examined for grossly evident morphological changes and the carcasses discarded. Maternal tissues were preserved in 10% neutral buffered formalin for histopathological examination as deemed necessary by the gross findings. Uteri from females that appeared nongravid were opened and placed in 10% ammonium sulfide solution for detection of implantation[1].

D. FETAL MORPHOLOGICAL OBSERVATIONS

Fetuses were individually weighed, sexed, tagged and examined for external malformations and variations, including the palate and eyes. Approximately one-half of the fetuses were placed in Bouin's solution for subsequent soft tissue examination using the Wilson[2] razor-blade sectioning technique. The remaining one-half of the fetuses were eviscerated, fixed in alcohol, macerated with potassium hydroxide, stained with Alizarin Red S and cleared with glycerin by a method similar to that described by Dawson[3] for subsequent skeletal examination. Fetal findings were classified as malformations or developmental variations.

E. STATISTICAL ANALYSIS

All statistical analyses compared the treatment groups with the control group, with the level of significance at $p<0.05$ and $p<0.01$. All means were accompanied by standard deviations.

Male to female fetal sex ratios and the proportions of litters with malformations were compared using the Chi-square test criterion with Yates' correction for 2 x 2 contingency tables and/or Fisher's exact probability test as described by Siegel[4] to judge significance of differences.

The proportions of resorbed and dead fetuses and postimplantation losses were compared by the Mann-Whitney U-test as described by Siegel[4] and Weil[5] to judge significance of differences.

Mean numbers of corpora lutea, total implantations, live fetuses and mean fetal body weights were compared by analysis of variance (one-way classification), Bartlett's test for homogeneity of variances and the appropriate t-test (for equal or unequal variances) as described by Steel and Torrie[6] using Dunnett's multiple comparison tables[7] to judge significance of differences.

F. DATA RETENTION

All preservable specimens, raw data, a sample of the test article and copies of the final report are retained in the International Research and Development Corporation Archives in Mattawan, Michigan.

V. RESULTS

A. MATERNAL OBSERVATIONS

1. Appearance and Behavior

Individual antemortem and necropsy observations are presented in Table 1.

Survival was 100% in the control and treatment groups. Excessive salivation was present in a few high-dose (250 mg/kg/day) rats but was not observed in the rats in the control, low-dose (15 mg/kg/day) or mid-dose (75 mg/kg/day) groups. Incidental antemortem observations noted in control and/or treated females included: scabbing or hair loss on the limbs and abdomen, dried blood around the eyes, nose and/or forelimbs and malaligned upper incisors.

Necropsy findings present as single instances and/or not occurring in a dose-related pattern in control and/or treated rats included hydronephrosis, distended ureter, congested lungs, smaller than normal kidney, and multiple clear fluid-filled cysts on the surface of the spleen. The organs with the latter two findings were preserved for possible histopathological examination, but at the discretion of the Study Director, this examination was not conducted.

2. Body Weights

A summary of maternal body weights and body weight change is presented in Table 2 and individual body weights

are presented in Table 3.

A dose-related decrease in maternal weight gain in the mid and high-dose groups over the entire treatment period (gestation days 6-15) was observed. The reduced weight gain observed over the entire treatment period was attributed to a weight gain reduction and a weight loss observed over gestation days 6-9 in the mid and high-dose groups, respectively. No similar reductions occurred in the low-dose group during these intervals. During the post-treatment interval (gestation days 16-20) the weight gain in the treatment groups was comparable to that of the control group. A slight reduction in maternal weight gain was noted in the high-dose group over the entire gestation period (gestation days 0-20), while the values in the control, low and mid-dose groups were similar over this interval.

3. Cesarean Section Observations

A summary of maternal Cesarean section observations is presented in Table 4. Individual observations are presented in Table 5 and historical control values are presented in Appendix C.

There were no dose-related or statistically significant differences in the mean numbers of viable fetuses, postimplantation losses, implantations, corpora lutea, fetal body weights, or in the fetal sex distribution in the treated groups when compared to the control values.

B. FETAL MORPHOLOGICAL OBSERVATIONS

A summary of all external, visceral and skeletal fetal malformations is presented in Table 6 and individual

malformation data are presented in Table 7. Developmental variations are summarized in Table 8, individual data are presented in Table 9 and historical control data is presented in Appendix C.

There were no findings indicative of a test article related effect on fetal morphology at 250 mg/kg/day or less. The only malformations observed were in the control group. Microphthalmia, folded retina and sternoschisis were seen in one, two and one fetus(es), respectively, in three control litters. No malformations were noted in fetuses from the treated groups. Similarly, no test article related differences were observed in the incidence of developmental variations. An increase in the incidence of unossified 5th and/or 6th sternebrae was noted in the low and mid-dose groups in relation to the control, however, this was not considered meaningful as a similar increase was not seen in the high-dose group.

VI. SIGNATURES

Prepared By: _____ 1/10/85
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Director of Toxicology Division

401-271

VII. DISCUSSION AND CONCLUSION

Survival was 100% in the control and treatment groups.

Excessive salivation and a slight inhibition of maternal weight gain over the entire gestation period (gestation days 0-20) were observed in the high-dose (250 mg/kg/day) group. A dose-related reduction in maternal weight gain over the entire treatment period (gestation days 6-15) occurred in the mid (75 mg/kg/day) and high-dose groups relative to the control value. There were no treatment-related differences in appearance and behavior in the low (15 mg/kg/day) and mid-dose groups or in weight gain in the low-dose group in comparison to those of the control group.

No adverse dose-related differences in necropsy findings, Cesarean section observations or the incidence of fetal malformations and developmental variations occurred in the treatment groups when compared to those of the control group.

When administered orally by gavage to Charles River COBS® CD® rats at dose-levels of 250 mg/kg/day or less, 2,6-Diethylphenylazomethine did not induce a teratogenic effect.

To the best of my knowledge, there were no significant deviations from the Good Laboratory Practice Regulations which affected the quality or integrity of the study. This study was conducted in conformance with the Good Laboratory

Practice Regulations. This report accurately reflects the raw data obtained during the performance of the study.

Michael F. Kenel

1/9/85

Michael F. Kenel, Ph.D.
Staff Toxicologist, Reproduction
and Teratology
Study Director

Date

401-271

VIII. REFERENCES

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7. Dunnett, C. W. (1964). New tables for multiple comparisons with a control. Biometrics, 20: 482-491.

Table 1. Individual Antemortem and Necropsy Observations

Dosage Level, Dam Number	Gestation Day	Antemortem Observations	Day of Sacrifice	Necropsy Observations
0 mg/kg/day (Control):				
57882	6-15	No visible abnormalities	20	No gross lesions
57883	6-15	No visible abnormalities	20	No gross lesions
57884	6-15	No visible abnormalities	20	No gross lesions
57885	6-15	No visible abnormalities	20	No gross lesions
57886	6-15	No visible abnormalities	20	No gross lesions
57887	6-13 14-15	No visible abnormalities Hair loss, both forelimbs	20	No gross lesions
57888	6-15	No visible abnormalities	20	No gross lesions
57889	6-15	No visible abnormalities	20	No gross lesions
57890	6-15	No visible abnormalities	20	No gross lesions
57891	6-15	No visible abnormalities	20	No gross lesions
57892	6-15	No visible abnormalities	20	No gross lesions
57893	6 7-15	No visible abnormalities Hair loss, lower ventral abdomen	20	Spleen[a]: multiple 1 mm in diameter to 1 mm x 3 mm fluid-filled cysts, surface, clear
57894	6-15	No visible abnormalities	20	No gross lesions
57895	6-15	No visible abnormalities	20	No gross lesions
57896	6-15	No visible abnormalities	20	No gross lesions
57897	6-15	No visible abnormalities	20	No gross lesions
57898	6-15	No visible abnormalities	20	No gross lesions

[a]Saved in formalin

Table 1. Cont. Individual Antemortem and Necropsy Observations

Test Article, Dosage Level, Dam Number	Gestation Day	Antemortem Observations	Day of Sacrifice	Necropsy Observations
0 mg/kg/day (Control) (Cont.):				
57899	6-15	No visible abnormalities	20	No gross lesions
57900	6-15	No visible abnormalities	20	No gross lesions
57901	6-15	No visible abnormalities	20	No gross lesions
57902	6-15	No visible abnormalities	20	No gross lesions
57903	6-15	No visible abnormalities	20	No gross lesions
57904	6-15	No visible abnormalities	20	No gross lesions
57905	6-15	No visible abnormalities	20	No gross lesions
57906	6-15	No visible abnormalities	20	No gross lesions
2,6-Diethylphenylazomethine, 15 mg/kg/day:				
57907	6-15	No visible abnormalities	20	No gross lesions
57908	6-15	No visible abnormalities	20	No gross lesions
57909	6-15	No visible abnormalities	20	Lung: congested, all lobes, moderate Uterus[b]: nongravid
57910	6-15	No visible abnormalities	20	No gross lesions
57911	6-15	No visible abnormalities	20	No gross lesions
57912	6-15	No visible abnormalities	20	No gross lesions
57913	6-12 13-15	No visible abnormalities Hair loss, both forelimbs	20	No gross lesions
57914	6-15	No visible abnormalities	20	No gross lesions
57915	6-15	No visible abnormalities	20	No gross lesions

[b]Confirmed by ammonium sulfide test

Table 1. Cont. Individual Antemortem and Necropsy Observations

Test Article, Dosage Level, Dam Number	Gestation Day	Antemortem Observations	Day of Sacrifice	Necropsy Observations
2,6-Diethylphenylazomethine, 15 mg/kg/day (Cont.):				
57916	6 7-15	No visible abnormalities Hair loss, both forelimbs	20	No gross lesions
57917	6-15	No visible abnormalities	20	No gross lesions
57918	6 7-15 9-15 12-15 15	No visible abnormalities Hair loss, left hindlimb Hair loss, right hindlimb Hair loss, right and left bilateral abdomen Hair loss, ventral abdomen Scabbing, left hindlimb	20	No gross lesions
57919	6-15	No visible abnormalities	20	No gross lesions
57920	6-15	No visible abnormalities	20	No gross lesions
57921	6-15	No visible abnormalities	20	No gross lesions
57922	6-15	No visible abnormalities	20	No gross lesions
57923	6-15	Hair loss, both forelimbs	20	No gross lesions
57924	6-15	No visible abnormalities	20	No gross lesions
57925	6-15	No visible abnormalities	20	No gross lesions
57926	6-14 15	No visible abnormalities Material discharged from vagina, red, wet	20	No gross lesions
57927	6-15	No visible abnormalities	20	No gross lesions
57928	6-15	No visible abnormalities	20	No gross lesions
57929	6-15	No visible abnormalities	20	No gross lesions

Table 1. Cont. Individual Antemortem and Necropsy Observations

Test Article, Dosage Level, Dam Number	Gestation Day	Antemortem Observations	Day of Sacrifice	Necropsy Observations
2,6-Diethylphenylazomethine, 15 mg/kg/day (Cont.):				
57930	6-15	No visible abnormalities	20	No gross lesions
57931	6-15	No visible abnormalities	20	No gross lesions
2,6-Diethylphenylazomethine, 75 mg/kg/day:				
57932	6-15	No visible abnormalities	20	No gross lesions
57933	6-15	No visible abnormalities	20	No gross lesions
57934	6-15	No visible abnormalities	20	No gross lesions
57935	6-15	No visible abnormalities	20	No gross lesions
57936	6-15	No visible abnormalities	20	Kidney[a]; small in size, approximately 3 mm in diameter, left
57937	6-15	No visible abnormalities	20	No gross lesions
57938	6-15	No visible abnormalities	20	No gross lesions
57939	6-15	Hair loss, both forelimbs	20	No gross lesions
57940	6-15	No visible abnormalities	20	No gross lesions
57941	6-15	No visible abnormalities	20	No gross lesions
57942	6-15	No visible abnormalities	20	No gross lesions
57943	6-15	No visible abnormalities	20	No gross lesions
57944	6-15	No visible abnormalities	20	No gross lesions
57945	6-7 8-15	Hair loss, left forelimb No visible abnormalities	20	No gross lesions

[a]Saved in formalin

Table 1. Cont. Individual Antemortem and Necropsy Observations

Test Article, Dosage Level, Dam Number	Gestation Day	Antemortem Observations	Day of Sacrifice	Necropsy Observations
2,6-Diethylphenylazomethine, 75 mg/kg/day (Cont.):				
57946	6-15	No visible abnormalities	20	Ureters: distended, bilateral, slight Kidney: hydronephrosis, left, moderate
57947	6-15	No visible abnormalities	20	No gross lesions
57948	6-15	No visible abnormalities	20	No gross lesions
57949	6 7-15 13-15	No visible abnormalities Matter around right eye, black, dry Malaligned upper incisors Hair loss, left hindlimb	20	No gross lesions
57950	6-15	No visible abnormalities	20	Kidney: hydronephrosis, right, slight
57951	6-15	No visible abnormalities	20	No gross lesions
57952	6-15	No visible abnormalities	20	No gross lesions
57953	6-13 14-15 15	No visible abnormalities Hair loss, right forelimb Hair loss, left forelimb	20	No gross lesions
57954	6-15	No visible abnormalities	20	Kidneys: hydronephrosis, left, slight and right, moderate to severe
57955	6-15	No visible abnormalities	20	No gross lesions
57956	6-15	No visible abnormalities	20	No gross lesions
2,6-Diethylphenylazomethine, 250 mg/kg/day:				
57957	6-15	No visible abnormalities	20	No gross lesions
57958	6-12 13-15	No visible abnormalities Excessive salivation	20	No gross lesions

Table 1. Cont. Individual Antemortem and Necropsy Observations

Test Article, Dosage Level, Dam Number	Gestation Day	Antemortem Observations	Day of Sacrifice	Necropsy Observations
2,6-Diethylphenylazomethine, 250 mg/kg/day (Cont.):				
57959	6-15	No visible abnormalities	20	No gross lesions Uterus[b]: nongravid
57960	6-15	No visible abnormalities	20	No gross lesions
57961	6-8,12-15 9-11	No visible abnormalities Matter around nose, both eyes and both forelimbs, black, dry	20	No gross lesions
57962	6-15	No visible abnormalities	20	No gross lesions
57963	6-15	No visible abnormalities	20	No gross lesions Uterus[b]: nongravid
57964	6-13 14-15	No visible abnormalities Excessive salivation	20	No gross lesions Uterus[b]: nongravid
57965	6-15	No visible abnormalities	20	No gross lesions
57966	6-15	No visible abnormalities	20	No gross lesions
57967	6-15	Hair loss, both forelimbs	20	No gross lesions
57968	6-15	No visible abnormalities	20	No gross lesions
57969	6-13 14-15	No visible abnormalities Excessive salivation	20	No gross lesions
57970	6-10 11-15	No visible abnormalities Hair loss, both hindlimbs	20	No gross lesions
57971	6-14 15	No visible abnormalities Excessive salivation	20	No gross lesions

[b]Confirmed by ammonium sulfide test

Table 1. Cont. Individual Antemortem and Necropsy Observations

Test Article, Dosage Level, Dam Number	Gestation Day	Antemortem Observations	Day of Sacrifice	Necropsy Observations
2,6-Diethylphenylazomethine, 250 mg/kg/day (Cont.):				
57972	6-12	No visible abnormalities	20	Kidney: hydronephrosis, right, slight
	13-15	Hair loss, both hindlimbs and left lateral abdomen		
	15	Hair loss, right lateral abdomen		
57973	6-13	No visible abnormalities	20	No gross lesions
57974	6-13	No visible abnormalities	20	No gross lesions
57975	6-15	No visible abnormalities	20	No gross lesions
57976	6-7	No visible abnormalities	20	No gross lesions
	8-15	Hair loss, both hindlimbs		
	10-15	Hair loss, right lateral abdomen		
	12-15	Excessive salivation		
	14-15	Scabbing, right lateral abdomen		
	15	Hair loss, left lateral abdomen		
57977	6-15	No visible abnormalities	20	No gross lesions
57978	6-15	No visible abnormalities	20	No gross lesions
57979	6-15	No visible abnormalities	20	No gross lesions
57980	6-15	No visible abnormalities	20	No gross lesions
57981	6-15	No visible abnormalities	20	No gross lesions

Table 2. Summary of Maternal Body Weights and Body Weight Changes

	Group Mean Maternal Body Weights (grams)							
	2,6-Diethylphenylazomethine (mg/kg/day)							
	0 (Control)		15		75		250	
Day of Gestation	Mean	±S.D.	Mean	±S.D.	Mean	±S.D.	Mean	±S.D.
0	245	10.0	245	18.2	249	15.5	244	13.8
6	278	12.7	276	21.2	283	16.9	277	13.3
9	286	13.7	284	22.5	283	20.6	271	16.1
12	299	16.1	297	22.9	297	23.0	282	16.0
16	323	16.1	322	25.7	322	22.5	305	17.8
20	387	19.2	382	28.9	386	25.4	371	25.4
Days of Gestation	**Group Mean Maternal Body Weight Change (grams)[a]**							
0 to 6	33	6.9	31	6.1	34	6.5	33	5.2
6 to 9	8	4.0	8	4.1	1	6.9	- 6	7.7
9 to 12	13	5.1	13	4.7	14	4.8	12	6.9
12 to 16	24	5.2	25	6.0	25	4.4	23	8.9
16 to 20	64	7.9	60	8.1	64	7.6	66	10.6
6 to 15[b]	46	6.3	46	8.9	39	8.9	28	8.1
0 to 20	142	13.4	137	16.4	137	15.2	127	17.0

a - Values represent the mean of the individual changes in maternal body weight for these intervals
b - Day 16 weights were utilized to reflect the entire 10-day treatment regimen
S.D. - Standard deviation

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Table 3. Individual and Group Mean Maternal Body Weights (grams)

Test Article, Dosage Level, Dam Number	Day of Gestation					
	0	6	9	12	16	20
0 mg/kg/day (Control):						
57882	217	246	254	266	288	342
57883	240	274	283	294	326	400
57884	241	283	296	308	337	399
57885	245	278	278	294	321	383
57886	238	268	279	287	315	367
57887	240	268	276	274	308	363
57888	235	272	280	285	315	374
57889	239	275	284	294	319	386
57890	230	265	269	277	307	370
57891	250	292	302	315	344	402
57892	250	289	294	313	342	402
57893	248	282	289	307	322	380
57894	239	277	278	292	313	388
57895	252	295	299	316	338	407
57896	241	272	279	296	312	394
57897	257	293	303	314	337	414
57898	255	289	300	317	339	409
57899	260	292	301	315	336	389
57900	249	265	276	288	313	368
57901	245	260	268	279	304	362
57902	236	262	273	289	307	373
57903	260	292	301	324	351	419
57904	255	293	310	322	345	408
57905	252	281	292	307	332	395
57906	240	276	276	293	307	372
Mean	245	278	286	299	323	387
±S.D.	10.0	12.7	13.7	16.1	16.1	19.2
2,6-Diethylphenylazomethine, 15 mg/kg/day:						
57907	228	259	259	269	293	342
57908	252	290	302	320	351	410
57909[a]	237	271	279	275	276	285
57910	269	299	312	317	351	411
57911	252	284	290	308	334	407
57912	248	294	299	315	356	411
57913	213	249	257	269	294	336
57914	247	277	282	303	329	380
57915	240	268	278	282	314	377
57916	285	320	329	334	356	415
57917	232	258	262	281	304	359
57918	236	264	267	281	303	357
57919	242	271	276	292	315	378
57920	210	236	249	261	289	353
57921	264	306	314	330	357	434
57922	251	279	283	294	312	362
57923	256	284	294	309	333	407
57924	255	281	292	300	316	375
57925	264	304	311	330	353	412
57926	215	240	246	258	275	344
57927	236	268	271	282	306	364
57928	247	274	290	302	326	388
57929	264	297	311	329	358	420
57930	238	256	264	278	292	350
57931	232	264	268	284	304	365
Mean	245	276	284	297	322	382
±S.D.	18.2	21.2	22.5	22.9	25.7	28.9

[a]Nongravid, not included in calculation of mean
S.D. - Standard deviation

Table 3. Cont. Individual and Group Mean Maternal Body Weights (grams)

Test Article, Dosage Level, Dam Number	Day of Gestation 0	6	9	12	16	20
2,6-Diethylphenylazomethine, 75 mg/kg/day:						
57932	236	258	256	264	290	348
57933	260	288	286	305	330	393
57934	240	265	260	270	300	359
57935	239	273	269	283	315	390
57936	242	283	282	298	315	370
57937	229	263	260	278	302	364
57938	246	281	282	296	317	376
57939	262	313	308	328	359	438
57940	248	279	282	289	318	381
57941	230	268	269	286	317	383
57942	256	293	296	308	331	402
57943	244	275	276	285	310	361
57944	233	271	272	279	306	369
57945	265	296	310	327	350	422
57946	246	286	289	307	332	394
57947	282	313	322	336	364	432
57948	277	309	317	328	355	425
57949	243	270	245	247	276	353
57950	231	260	264	276	301	364
57951	267	309	313	333	351	416
57952	266	290	291	300	329	397
57953	261	295	295	310	338	401
57954	245	274	279	293	312	378
57955	225	265	264	284	303	360
57956	262	296	300	318	338	385
Mean	249	283	283	297	322	386
±S.D.	15.5	16.9	20.6	23.0	22.5	25.4
2,6-Diethylphenylazomethine, 250 mg/kg/day:						
57957	219	254	258	262	288	335
57958	227	260	253	264	287	361
57959[a]	249	273	265	258	262	268
57960	252	296	298	293	336	418
57961	242	266	254	268	298	349
57962	218	252	249	263	282	341
57963[a]	238	247	235	243	255	257
57964[a]	235	253	240	251	255	264
57965	255	284	275	285	308	375
57966	240	284	278	288	312	374
57967	243	276	260	285	300	366
57968	224	263	252	254	284	348
57969	267	299	299	310	336	414
57970	251	281	266	275	318	401
57971	267	293	299	302	328	400
57972	244	272	258	272	279	325
57973	257	286	287	304	316	385
57974	244	280	275	287	305	365
57975	242	280	270	283	294	366
57976	257	293	280	303	327	405
57977	235	267	265	278	296	368
57978	256	284	287	301	321	382
57979	232	262	256	264	282	344
57980	242	279	278	294	314	365
57981	246	280	256	277	306	372
Mean	244	277	271	282	305	371
±S.D.	13.8	13.3	16.1	16.0	17.8	25.4

[a]Nongravid, not included in calculation of mean
S.D. - Standard deviation

Table 5. Individual and Group Mean Maternal and Fetal Observations at Cesarean Section

Dosage Level, Dam Number	Fetuses: Viable No.	Fetuses: Viable %	Fetuses: Nonviable No.	Resorptions: Late No.	Resorptions: Early No.	Post-Implantation Loss No.	Total Implantations No.	Corpora Lutea No.	Fetal Sex Distribution: Male	Fetal Sex Distribution: Female	Mean Fetal Body Weight Grams
0 mg/kg/day (Control):											
57882	13	92.9	0	0	1	1	14	15	6	7	3.4
57883	15	100.0	0	0	0	0	15	15	6	9	3.5
57884	13	81.3	0	0	3	3	16	17	6	7	3.6
57885	14	82.4	0	0	3	3	17	18	10	4	3.6
57886	14	93.3	0	0	1	1	15	15	6	8	3.5
57887	11	78.6	0	0	3	3	14	14	6	5	3.4
57888	12	100.0	0	0	0	0	12	12	7	5	3.8
57889	13	86.7	0	0	2	2	15	17	10	3	4.0
57890	13	100.0	0	0	0	0	13	14	9	4	3.7
57891	15	93.8	0	0	1	1	16	16	9	6	3.8
57892	14	93.3	0	0	1	1	15	15	11	3	3.6
57893	14	93.3	0	0	1	1	15	18	5	9	3.2
57894	16	100.0	0	0	0	0	16	16	7	9	3.2
57895	16	100.0	0	0	0	0	16	16	11	5	3.6
57896	17	100.0	0	0	0	0	17	18	7	10	3.4
57897	14	93.3	0	0	1	1	15	15	8	6	3.7
57898	16	94.1	0	0	1	1	17	18	8	8	3.4
57899	13	92.9	0	0	1	1	14	15	7	6	3.0
57900	13	92.9	0	0	1	1	14	14	5	8	3.0
57901	13	92.9	0	0	1	1	14	14	6	7	2.9
57902	14	100.0	0	0	0	0	14	15	6	8	3.4
57903	16	100.0	0	0	0	0	16	17	8	8	3.5
57904	12	100.0	0	0	0	0	12	16	5	7	3.4
57905	15	100.0	0	0	0	0	15	15	5	10	3.4
57906	14	93.3	0	0	1	1	15	15	8	6	3.2
Total	350	94.1	0	0	22	22	372	390	182	168	-
Mean	14.0	-	0.0	0.0	0.9	0.9	14.9	15.6	-	-	3.4
±S.D.	1.47	-	0.00	0.00	0.97	0.97	1.36	1.53	-	-	0.26

- - Not applicable
S.D. - Standard deviation

Table 5. Cont. Individual and Group Mean Maternal and Fetal Observations at Cesarean Section

Test Article, Dosage Level, Dam Number	Fetuses: Viable No.	Fetuses: Viable %	Fetuses: Nonviable No.	Resorptions: Late No.	Resorptions: Early No.	Post-implantation Loss No.	Total Implantations No.	Corpora Lutea No.	Fetal Sex Distribution: Male	Fetal Sex Distribution: Female	Mean Fetal Body Weight Grams
2,6-Diethylphenylazomethine, 15 mg/kg/day:											
57907	12	92.3	0	0	1	1	13	13	5	7	3.5
57908	13	81.3	0	0	3	3	16	16	4	9	3.4
57909	Nongravid										
57910	15	88.2	0	0	2	2	17	17	5	10	3.9
57911	16	100.0	0	0	0	0	16	16	5	11	3.5
57912	12	92.3	0	0	1	1	13	15	9	3	3.6
57913	10	66.7	0	0	5	5	15	15	3	7	3.2
57914	11	84.6	0	0	2	2	13	14	6	5	3.7
57915	12	100.0	0	0	0	0	12	14	5	7	3.7
57916	15	93.8	0	0	1	1	16	20	7	8	3.1
57917	12	92.3	0	0	1	1	13	14	3	9	2.6
57918	14	100.0	0	0	0	0	14	14	9	5	3.6
57919	14	100.0	0	0	0	0	14	14	6	8	3.6
57920	15	100.0	0	0	0	0	15	15	10	5	3.3
57921	17	100.0	0	0	0	0	17	19	6	11	3.7
57922	13	92.9	0	0	1	1	14	16	8	5	3.5
57923	15	93.8	0	0	1	1	16	18	7	8	3.8
57924	14	100.0	0	0	0	0	14	15	8	6	3.3
57925	14	93.3	0	0	1	1	15	15	6	8	2.9
57926	13	92.9	0	0	1	1	14	14	6	7	3.1
57927	13	92.9	0	0	1	1	14	14	4	9	3.1
57928	15	93.8	0	0	1	1	16	18	7	8	3.4
57929	14	93.3	0	1	0	1	15	15	6	8	3.3
57930	14	93.3	0	0	1	1	15	16	8	6	3.2
57931	14	100.0	0	0	0	0	14	14	5	9	3.5
Total	327	93.2	0	1	23	24	351	371	148	179	-
Mean	13.6	-	0.0	0.0	1.0	1.0	14.6	15.5	-	-	3.4
±S.D.	1.61	-	0.00	0.20	1.16	1.14	1.35	1.79	-	-	0.30

- - Not applicable
S.D. - Standard deviation

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Table 5. Cont. Individual and Group Mean Maternal and Fetal Observations at Cesarean Section

Test Article, Dosage Level, Dam Number	Fetuses: Viable No.	Fetuses: Viable %	Fetuses: Nonviable No.	Resorptions: Late No.	Resorptions: Early No.	Post-implantation Loss No.	Total Implantations No.	Corpora Lutea No.	Fetal Sex Distribution: Male	Fetal Sex Distribution: Female	Mean Fetal Body Weight Grams
2,6-Diethylphenylazomethine, 75 mg/kg/day:											
57932	13	100.0	0	0	0	0	13	14	8	5	3.2
57933	13	92.9	0	0	1	1	14	15	5	8	3.3
57934	13	81.3	0	1	2	3	16	17	5	8	3.3
57935	15	100.0	0	0	0	0	15	18	10	5	3.5
57936	12	85.7	0	0	2	2	14	20	7	5	3.0
57937	15	93.8	0	0	1	1	16	16	7	8	3.1
57938	13	86.7	0	0	2	2	15	15	6	7	3.5
57939	18	100.0	0	0	0	0	18	18	12	6	3.6
57940	13	92.9	0	0	1	1	14	14	8	5	3.4
57941	18	100.0	0	0	0	0	18	19	10	8	3.1
57942	15	93.8	0	1	0	1	16	17	8	7	3.2
57943	14	100.0	0	0	0	0	14	16	8	6	3.2
57944	13	100.0	0	0	0	0	13	13	7	6	3.3
57945	17	100.0	0	0	0	0	17	18	4	13	3.0
57946	13	100.0	0	0	0	0	13	16	4	9	3.6
57947	17	100.0	0	0	0	0	17	17	8	9	3.3
57948	17	94.4	0	0	1	1	18	18	7	10	3.1
57949	14	100.0	0	0	0	0	14	16	8	6	3.4
57950	12	85.7	0	0	2	2	14	14	9	3	3.2
57951	15	93.8	0	0	1	1	16	16	5	10	3.6
57952	14	93.3	0	0	1	1	15	15	8	6	3.5
57953	15	100.0	0	0	0	0	15	19	6	9	3.5
57954	12	92.3	0	0	1	1	13	15	5	7	3.6
57955	12	75.0	0	0	4	4	16	16	6	6	3.2
57956	10	90.9	0	0	1	1	11	13	7	3	3.4
Total	353	94.1	0	2	20	22	375	405	178	175	-
Mean	14.1	-	0.0	0.1	0.8	0.9	15.0	16.2	-	-	3.3
±S.D.	2.07	-	0.00	0.28	1.00	1.05	1.80	1.89	-	-	0.19

- - Not applicable
S.D. - Standard deviation

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Table 5. Cont. Individual and Group Mean Maternal and Fetal Observations at Cesarean Section

Test Article, Dosage Level, Dam Number	Fetuses: Viable No.	Fetuses: Viable %	Fetuses: Nonviable No.	Resorptions: Late No.	Resorptions: Early No.	Post-implantation Loss No.	Total Implantations No.	Corpora Lutea No.	Fetal Sex Distribution: Male	Fetal Sex Distribution: Female	Mean Fetal Body Weight Grams
2,6-Diethylphenylazomethine, 250 mg/kg/day:											
57957	9	100.0	0	0	0	0	9	14	6	3	3.0
57958	14	100.0	0	0	0	0	14	15	8	6	3.6
57959	Nongravid										
57960	16	100.0	0	0	0	0	16	18	7	9	3.3
57961	12	85.7	0	0	2	2	14	17	7	5	3.4
57962	11	84.6	0	0	2	2	13	14	4	7	3.8
57963	Nongravid										
57964	Nongravid										
57965	14	87.5	0	0	2	2	16	17	4	10	3.3
57966	13	100.0	0	0	0	0	13	15	7	6	3.2
57967	14	87.5	0	0	2	2	16	17	5	9	3.5
57968	13	100.0	0	0	0	0	13	13	9	4	3.2
57969	16	100.0	0	0	0	0	16	16	6	10	3.6
57970	16	100.0	0	0	0	0	16	16	10	6	3.2
57971	15	100.0	0	0	0	0	15	17	10	5	3.7
57972	8	80.0	0	0	2	2	10	17	2	6	3.2
57973	14	100.0	0	0	0	0	14	15	8	6	3.3
57974	11	84.6	0	0	2	2	13	13	5	6	3.5
57975	15	93.8	0	0	1	1	16	21	8	7	2.7
57976	16	100.0	0	0	0	0	16	19	5	11	3.6
57977	14	93.3	0	0	1	1	15	16	9	5	3.2
57978	14	87.5	0	0	2	2	16	17	7	7	3.8
57979	13	100.0	0	0	0	0	13	13	9	4	3.3
57980	13	92.9	0	0	1	1	14	17	8	5	3.4
57981	14	93.3	0	0	1	1	15	15	9	5	3.2
Total	295	94.2	0	0	18	18	313	352	153	142	-
Mean	15.4	-	0.0	0.0	0.8	0.8	14.2	16.0	-	-	3.4
±S.D.	2.15	-	0.00	0.00	0.91	0.91	1.95	2.00	-	-	0.26

- - Not applicable
S.D. - Standard deviation

TABLE 6. Summary of the Incidence of Fetal Malformations

	2,6-Diethylphenylazomethine (mg/kg/day)			
Dosage Levels	0 (Control)	15	75	250
No. of litters examined:	25	24	25	22
No. of fetuses examined externally:	350	327	353	295
No. of fetuses examined viscerally:	176	165	176	147
No. of fetuses examined skeletally:	174	162	177	148
Malformations observed:	No. of fetuses (No. of litters)			
Microphthalmia:	1 (1)			
Folded retina:	2 (1)			
Sternoschisis:	1 (1)			
Total fetuses (litters) with malformations:	4 (3)	0 (0)	0 (0)	0 (0)

Values from the treated groups, specified to be tested in the report, did not differ significantly from the control group, $P > 0.05$

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TABLE 7. Individual Fetal Malformations

Dosage Level, Dam Number	No. of Fetuses Examined Externally	No. of Fetuses Examined Viscerally	No. of Fetuses Examined Skeletally	No. of Fetuses with Malformations	Fetus Number	Description of Malformation
0 mg/kg/day (Control):						
57882	13	6	7	0		No malformations observed
57883	15	8	7	0		No malformations observed
57884	13	6	7	0		No malformations observed
57885	14	7	7	0		No malformations observed
57886	14	7	7	0		No malformations observed
57887	11	6	5	0		No malformations observed
57888	12	6	6	0		No malformations observed
57889	13	7	6	0		No malformations observed
57890	13	6	7	0		No malformations observed
57891	15	8	7	2	3,11	Folded retina: left eye
57892	14	7	7	0		No malformations observed
57893	14	7	7	0		No malformations observed
57894	16	8	8	1	12	Microphthalmia: right eye less that 1/4 normal size
57895	16	8	8	0		No malformations observed
57896	17	8	9	0		No malformations observed
57897	14	7	7	1	3	Sternoschisis: sternebrae #1, #2 and #3 malformed, misshapen, separated by opening in sternal cartillage
57898	16	8	8	0		No malformations observed
57899	13	7	6	0		No malformations observed
57900	13	6	7	0		No malformations observed
57901	13	7	6	0		No malformations observed
57902	14	7	7	0		No malformations observed
57903	16	8	8	0		No malformations observed
57904	12	6	6	0		No malformations observed
57905	15	8	7	0		No malformations observed
57906	14	7	7	0		No malformations observed
Total	350	176	174	4		

TABLE 7. Cont. Individual Fetal Malformations

Test Article, Dosage Level, Dam Number	No. of Fetuses Examined Externally	No. of Fetuses Examined Viscerally	No. of Fetuses Examined Skeletally	No. of Fetuses with Malformations	Fetus Number	Description of Malformation
2,6-Diethylphenylazomethine, 15 mg/kg/day:						
57907	12	6	6	0		No malformations observed
57908	13	7	6	0		No malformations observed
57910	15	8	7	0		No malformations observed
57911	16	8	8	0		No malformations observed
57912	12	6	6	0		No malformations observed
57913	10	5	5	0		No malformations observed
57914	11	6	5	0		No malformations observed
57915	12	6	6	0		No malformations observed
57916	15	8	7	0		No malformations observed
57917	12	6	6	0		No malformations observed
57918	14	7	7	0		No malformations observed
57919	14	7	7	0		No malformations observed
57920	15	7	8	0		No malformations observed
57921	17	9	8	0		No malformations observed
57922	13	6	7	0		No malformations observed
57923	15	8	7	0		No malformations observed
57924	14	7	7	0		No malformations observed
57925	14	7	7	0		No malformations observed
57926	13	6	7	0		No malformations observed
57927	13	7	6	0		No malformations observed
57928	15	7	8	0		No malformations observed
57929	14	7	7	0		No malformations observed
57930	14	7	7	0		No malformations observed
57931	14	7	7	0		No malformations observed
Total	327	165	162	0		

TABLE 7. Cont.

Individual Fetal Malformations

Test Article, Dosage Level, Dam Number	No. of Fetuses Examined Externally	No. of Fetuses Examined Viscerally	No. of Fetuses Examined Skeletally	No. of Fetuses with Malformations	Fetus Number	Description of Malformation
2,6-Diethylphenylazomethine, 75 mg/kg/day:						
57932	13	6	7	0		No malformations observed
57933	13	7	6	0		No malformations observed
57934	13	6	7	0		No malformations observed
57935	15	8	7	0		No malformations observed
57936	12	6	6	0		No malformations observed
57937	15	8	7	0		No malformations observed
57938	13	6	7	0		No malformations observed
57939	18	9	9	0		No malformations observed
57940	13	6	7	0		No malformations observed
57941	18	9	9	0		No malformations observed
57942	15	8	7	0		No malformations observed
57943	14	7	7	0		No malformations observed
57944	13	7	6	0		No malformations observed
57945	17	9	8	0		No malformations observed
57946	13	6	7	0		No malformations observed
57947	17	9	8	0		No malformations observed
57948	17	8	9	0		No malformations observed
57949	14	7	7	0		No malformations observed
57950	12	5	7	0		No malformations observed
57951	15	8	7	0		No malformations observed
57952	14	7	7	0		No malformations observed
57953	15	7	8	0		No malformations observed
57954	12	6	6	0		No malformations observed
57955	12	6	6	0		No malformations observed
57956	10	5	5	0		No malformations observed
Total	353	176	177	0		

TABLE 8. Summary of the Incidence of Fetal Developmental Variations

Dosage Levels	2,6-Diethylphenylazomethine (mg/kg/day)			
	0 (Control)	15	75	250
No. of litters examined:	25	24	25	22
No. of fetuses examined externally:	350	327	353	295
No. of fetuses examined viscerally:	176	165	176	147
No. of fetuses examined skeletally:	174	162	177	148
Developmental Variations Observed	**No. of fetuses (No. of litters)**			
Greater than normal (13 pairs) ribs:	11 (7)	5 (5)	15 (9)	18 (11)
Fewer than normal (13 pairs) ribs:		1 (1)	1 (1)	2 (2)
7th cervical rib:			1 (1)	
Hyoid unossified:	5 (4)	4 (3)	(4) (4)	2 (1)
Sternebrae #5 and/or #6 unossified	22 (12)	38 (15)	41 (17)	19 (9)
Other sternebra(e) unossified			2 (2)	2 (2)
Misaligned sternebra(e):	5 (5)	3 (3)	6 (5)	4 (4)
Skull reduced in ossification:	2 (2)			1 (1)
Pubic bone unossified:				1 (1)
Major vessel variations:			1 (1)	
Renal papillae not developed and/or distended ureter(s):	3 (2)	1 (1)	1 (1)	5 (3)
Total fetuses (litters) with variations:	46 (19)	48 (18)	64 (21)	46 (18)

TABLE 9. Individual Fetal Variations

Dosage Level, Dam Number	No. of Fetuses Examined Externally	No. of Fetuses Examined Viscerally	No. of Fetuses Examined Skeletally	No. of Fetuses with Variations	Fetus Number	Description of Variations
0 mg/kg/day (Control):						
57882	13	6	7	3	1,10	Sternebra #5 unossified
					8	Skull reduced in ossification: right squamosal
57883	15	8	7	0		No variations observed
57884	13	6	7	3	9,14	Distended ureter: left
					10	Hyoid unossified
57885	14	7	7	0		No variations observed
57886	14	7	7	2	9,11	Sternebra #5 unossified
57887	11	6	5	2	8,10	Sternebra #5 unossified
57888	12	6	6	4	1	Hyoid unossified
					5,7,9	Greater than normal (13 pairs) ribs
					5	Misaligned sternebra: #5
57889	13	7	6	1	5	Sternebra #5 unossified
57890	13	6	7	1	5	Greater than normal (13 pairs) ribs
57891	15	8	7	0		No variations observed
57892	14	7	7	1	1	Greater than normal (13 pairs) ribs
57893	14	7	7	3	5,15	Hyoid unossified
					7	Sternebra #5 unossified
57894	16	8	8	1	9	Misaligned sternebra: #4
57895	16	8	8	2	2,10	Sternebrae #5 and/or #6 unossified
57896	17	8	9	0		No variations observed
57897	14	7	7	0		No variations observed
57898	16	8	8	1	16	Sternebrae #5 and #6 unossified
57899	13	7	6	2	2	Sternebra #5 unossified
					11	Greater than normal (13 pairs) ribs
57900	13	6	7	6	1,3,7,9	Sternebra #5 unossified
					5	Greater than normal (13 pairs) ribs
					12	Skull reduced in ossification: right jugal
57901	13	7	6	6	3,7,9,11	Sternebra #5 unossified
					5	Misaligned sternebra: #4
					6	Renal papilla not developed and distended ureter: left
					9	Hyoid unossified
57902	14	7	7	2	3	Greater than normal (13 pairs) ribs
					5	Misaligned sternebra: #5
57903	16	8	8	1	6	Sternebra #5 unossified
57904	12	6	6	2	1	Sternebra #5 unossified
					11	Misaligned sternebrae: #2 and #4
57905	15	8	7	3	6,10,14	Greater than normal (13 pairs) ribs
57906	14	7	7	0		No variations observed
Total	350	176	174	46		

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TABLE 9. Cont.

Individual Fetal Variations

Test Article, Dosage Level, Dam Number	No. of Fetuses Examined Externally	No. of Fetuses Examined Viscerally	No. of Fetuses Examined Skeletally	No. of Fetuses with Variations	Fetus Number	Description of Variations
2,6-Diethylphenylazomethine, 15 mg/kg/day:						
57907	12	6	6	1	12	Distended ureter: left
57908	13	7	6	0		No variations observed
57910	15	8	7	0		No variations observed
57911	16	8	8	2	1	Misaligned sternebra: #5
					3	Sternebra #6 unossified
57912	12	6	6	1	12	Hyoid unossified
						Sternebra #6 unossified
57913	10	5	5	5	3,8	Hyoids unossified
					6,8,10,14	Sternebrae #5 and/or #6 unossified
57914	11	6	5	1	6	Greater than normal (13 pairs) ribs
57915	12	6	6	0		No variations observed
57916	15	8	7	6	2,4,8,10	
					12,14	Sternebra #5 unossified
					4	Fewer than normal (13 pairs) ribs
					12	Hyoid unossified
57917	12	6	6	6	2,4,6,8	
					10,12	Sternebra #5 and/or #6 unossified
57918	14	7	7	2	6,8	Sternebra #5 unossified
57919	14	7	7	0		No variations observed
57920	15	7	8	1	15	Sternebra #5 unossified
57921	17	9	8	0		No variations observed
57922	13	6	7	1	3	Greater than normal (13 pairs) ribs
57923	15	8	7	3	5,7,11	Sternebra #5 unossified
57924	14	7	7	4	3,9,13	Sternebra #5 unossified
					5	Greater than normal (13 pairs) ribs
57925	14	7	7	2	7	Sternebra #5 unossified
					13	Greater than normal (13 pairs) ribs
57926	13	6	7	2	1,6	Sternebra #5 unossified
57927	13	7	6	2	5,7	Sternebrae #5 and/or #6 unossified
57928	15	7	8	4	1,13,16	Sternebra #5 unossified
					7	Misaligned Sternebra: #2
57929	14	7	7	2	2,13	Sternebra #5 unossified
57930	14	7	7	0		No variations observed
57931	14	7	7	3	6	Misaligned sternebrae: #3 and #4
					10	Sternebra #5 unossified
					14	Greater than normal (13 pairs) ribs
Total	327	165	162	48		

TABLE 9. Cont.

Individual Fetal Variations

Test Article, Dosage Level, Dam Number	No. of Fetuses Examined Externally	No. of Fetuses Examined Viscerally	No. of Fetuses Examined Skeletally	No. of Fetuses with Variations	Fetus Number	Description of Variations
2,6-Diethylphenylazomethine, 75 mg/kg/day:						
57932	13	6	7	3	3	Greater than normal (13 pairs) ribs
					7,11	Sternebra #5 unossified
57935	13	7	6	3	5,9	Sternebra #5 unossified
					8	Distended ureter: left
57934	13	6	7	2	6	Greater than normal (13 pairs) ribs
					13	Sternebra #5 unossified
57935	15	8	7	0		No variations observed
57936	12	6	6	5	3,5,9,11	Sternebrae #5 and/or #6 unossified
					3	Misaligned sternebra: #4
					14	Major vessel variation: no innominate; right subclavian arises from the aortic arch
57937	15	8	7	4	2,5,11	Sternebra #5 unossified
					15	Greater than normal (13 pairs) ribs
57938	13	6	7	2	2	Greater than normal (13 pairs) ribs
					14	Hyoid unossified
						Sternebra #5 unossified
57939	18	9	9	0		No variations observed
57940	13	6	7	1	3	Sternebra #5 unossified
57941	18	9	9	7	4,8,12,18	Greater than normal (13 pairs) ribs
					6,8,10,16	Sternebra #5 unossified
					16	Other sternebra unossified: #2
57942	15	8	7	3	5	Misaligned sternebrae: #3 and #4
					9	Misaligned sternebra: #4
					15	Sternebra #5 unossified
57943	14	7	7	1	5	Misaligned sternebra: #4
57944	13	7	6	2	4	Sternebra #5 unossified
					12	Misaligned sternebra: #5
57945	17	9	8	5	2,10,12	
					14,16	Sternebra #5 unossified
57946	13	6	7	1	7	Greater than normal (13 pairs) ribs
57947	17	9	8	2	4,6	Greater than normal (13 pairs) ribs
57948	17	8	9	6	1,8,10	
					12,16	Sternebrae #5 and/or #6 unossified
					4	Misaligned sternebra: #4
					12	Hyoid unossified
						Greater than normal (13 pairs) ribs
57949	14	7	7	4	1,11,13	Greater than normal (13 pairs) ribs
					5	Sternebrae #5 and #6 unossified

TABLE 9. Cont.

Individual Fetal Variations

Test Article, Dosage Level, Dam Number	No. of Fetuses Examined Externally	No. of Fetuses Examined Viscerally	No. of Fetuses Examined Skeletally	No. of Fetuses with Variations	Fetus Number	Description of Variations
2,6-Diethylphenylazomethine, 75 mg/kg/day (Cont.):						
57950	12	5	7	5	2,6,8	
					11,13	Sternebrae #5 and/or #6 unossified
					6	Other sternebra unossified: #2
57951	15	8	7	1	6	Sternebra #5 unossified
57952	14	7	7	1	14	7th cervical rib: left
57953	15	7	8	0		No variations observed
57954	12	6	6	0		No variations observed
57955	12	6	6	4	1,5,12	Sternebra #5 unossified
					5	Fewer than normal (13 pairs) ribs
					7	Hyoid unossified
57956	10	5	5	2	7	Sternebra #5 unossified
					11	Hyoid unossified
Total	353	176	177	64		

TABLE 9. Cont.

Individual Fetal Variations [1]

Test Article, Dosage Level, Dam Number	No. of Fetuses Examined Externally	No. of Fetuses Examined Viscerally	No. of Fetuses Examined Skeletally	No. of Fetuses with Variations	Fetus Number	Description of Variations
2,6-Diethylphenylazomethine, 250 mg/kg/day:						
57957	9	4	5	2	1,5	Sternebra #5 unossified
					1	Pubic bone unossified: bilateral
57958	14	7	7	0		No variations observed
57960	16	8	8	1	14	Greater than normal (13 pairs) ribs Sternebrae #5 and #6 unossified Other sternebrae unossified: #1 and #2
57961	12	6	6	1	5	Greater than normal (13 pairs) ribs
57962	11	6	5	4	5	Distended ureter: bilateral
					8,12	Greater than normal (13 pairs) ribs
					11	Distended ureter: left
57965	14	7	7	4	5	Misaligned sternebra: #4
					7,9,15	Sternebra #5 unossified
					15	Skull reduced in ossification: supraoccipital
57966	13	6	7	3	1,3,13	Greater than normal (13 pairs) ribs
					1	Misaligned sternebra: #4
57967	14	7	7	3	2,14	Greater than normal (13 pairs) ribs
					5	Fewer than normal (13 pairs) ribs
57968	13	6	7	3	3,7,11	Sternebra #5 unossified
57969	16	8	8	1	2	Sternebrae #5 and/or #6 unossified Other sternebra unossified: #2
57970	16	8	8	0		No variations observed
57971	15	8	7	0		No variations observed
57972	8	4	4	1	3	Greater than normal (13 pairs) ribs Sternebra #5 unossified
57973	14	7	7	0		No variations observed
57974	11	5	6	4	1,8	Greater than normal (13 pairs) ribs
					7	Distended ureter: bilateral
					9	Distended ureter: left
57975	15	8	7	4	2,7	Hyoid unossified
					9,15	Greater than normal (13 pairs) ribs
57976	16	8	8	2	1,5	Sternebra #5 unossified
57977	14	7	7	6	2,8,13,15	Sternebra #5 unossified
					6	Fewer than normal (13 pairs) ribs
					14	Renal papillae not developed and distended ureter: kidney, bilateral; ureter, left
57978	14	7	7	2	3	Misaligned sternebra: #5
					8	Greater than normal (13 pairs) ribs
57979	13	7	6	2	4,10	Greater than normal (13 pairs) ribs
57980	13	6	7	2	3,14	Sternebra #5 unossified
57981	14	7	7	1	9	Greater than normal (13 pairs) ribs Misaligned sternebra: #4
Total	295	147	148	46		

APPENDIX A

Quality Assurance Inspections

Quality Assurance Inspections

Dates of Inspections	Dates of Reports to Management	Dates of Reports to Study Director
4/19/84	11/02/84	11/02/84
4/30/84	1/14/85	1/14/85
5/01/84		
5/07/84		
5/11/84		
5/21/84		
9/17/84		
9/18/84		
11/02/84		
1/14/85		
1/23/85		

APPENDIX B

Individual Volume of Test Material Administered

Individual Daily Total Volume of Test Material Administered

Test Article, Dosage Level, Animal Number	Volume of Test Material Administered (ml) Day of Gestation									
	6	7	8	9	10	11	12	13	14	15
0 mg/kg/day (Control):										
57882	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57883	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57884	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57885	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57886	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57887	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57888	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57889	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57890	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57891	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57892	1.4	1.4	1.4	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57893	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57894	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57895	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57896	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57897	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57898	1.4	1.4	1.4	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57899	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57900	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57901	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57902	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57903	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57904	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6
57905	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57906	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
2,6-Diethylphenylazomethine, 15 mg/kg/day:										
57907	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57908	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57909	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57910	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6
57911	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57912	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57913	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57914	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57915	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57916	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7
57917	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57918	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57919	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57920	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3
57921	1.5	1.5	1.5	1.6	1.6	1.6	1.7	1.7	1.7	1.7
57922	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57923	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57924	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57925	1.5	1.5	1.5	1.6	1.6	1.6	1.7	1.7	1.7	1.7
57926	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3
57927	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57928	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57929	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6
57930	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57931	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4

Individual Daily Total Volume of Test Material Administered

Test Article, Dosage Level, Animal Number	Volume of Test Material Administered (ml) Day of Gestation 6	7	8	9	10	11	12	13	14	15
2,6-Diethylphenylazomethine, 75 mg/kg/day:										
57932	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57933	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57934	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57935	1.4	1.4	1.4	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57936	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57937	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57938	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57939	1.6	1.6	1.6	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57940	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57941	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57942	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57943	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57944	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57945	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6
57946	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57947	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7
57948	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6
57949	1.4	1.4	1.4	1.2	1.2	1.2	1.2	1.2	1.2	1.2
57950	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57951	1.5	1.5	1.5	1.6	1.6	1.6	1.7	1.7	1.7	1.7
57952	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57953	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57954	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57955	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57956	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
2,6-Diethylphenylazomethine, 250 mg/kg/day:										
57957	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57958	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57959	1.4	1.4	1.4	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57960	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57961	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57962	1.3	1.3	1.3	1.2	1.2	1.2	1.3	1.3	1.3	1.3
57963	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
57964	1.3	1.3	1.3	1.2	1.2	1.2	1.3	1.3	1.3	1.3
57965	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57966	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57967	1.4	1.4	1.4	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57968	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57969	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6
57970	1.4	1.4	1.4	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57971	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
57972	1.4	1.4	1.4	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57973	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57974	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57975	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
57976	1.5	1.5	1.5	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57977	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
57978	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57979	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
57980	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5
57981	1.4	1.4	1.4	1.3	1.3	1.3	1.4	1.4	1.4	1.4

APPENDIX C

Historical Control Data

IRDC Historical Control Data - Charles River COBS® CD® Rats

Summary of Maternal and Fetal Observations at Cesarean Section

No. of animals in the historical control:	685
No. of animals that died:	1
No. of animals that delivered:	1
No. of animals examined at Cesarean section:	683
No. nongravid:	49
No. gravid:	634
No. of dams with resorptions only:	2
No. of dams with live fetuses:	632
No. of live fetuses/dam:	13.3[11.4-14.7]
No. of late resorptions/dam:	0.0[0.0-0.1]
No. of early resorptions/dam:	0.9[0.5-1.6]
No. of postimplantation losses/dam:	0.9[0.5-1.6]
No. of implantations/dam:	14.2[12.5-15.4]
No. of corpora lutea/dam:	15.9[14.1-17.2]
Fetal sex ratio[a]: Male:Female	4164:4280
%Male:%Female	49.3:50.7
Range - %Male	45.6-55.8
%Female	44.2:54.4
Mean fetal body weight (g):	3.4[2.9-3.6]

[ ] - Range of mean
[a]Sex of one fetus inadvertently not recorded
The historical control data compiled March 24, 1984 includes data from studies terminating June, 1982 to February, 1984.

IRDC Historical Control Data - Charles River COBS® CD® Rats

Summary of the Incidence of Malformations and of Developmental Variations

No. of litters examined:	632
Total no. of fetuses examined externally:	8445
Total no. of fetuses examined skeletally:	4768[a]
Total no. of fetuses examined viscerally:	3676

Malformations Observed	No. Fetuses (Litters)	[Range of Fetuses % ([litters %)]
Dome-shaped head:	1 (1)	[0.0(0.0)-0.3(4.2)]
Ablepharia:	1 (1)	[0.0(0.0)-0.3(4.2)]
Anophthalmia:	4 (4)	[0.0(0.0)-0.7(5.6)]
Microphthalmia:	15 (15)	[0.0(0.0)-2.8(13.0)]
Nares absent:	2 (2)	[0.0(0.0)-0.4(5.6)]
Aglossia:	1 (1)	[0.0(0.0)-0.3(4.2)]
Microglossia:	2 (2)	[0.0(0.0)-0.3(4.0)]
Macroglossia:	3 (2)	[0.0(0.0)-0.6(4.2)]
Cleft lip:	3 (3)	[0.0(0.0)-0.4(5.6)]
Cleft palate:	6 (6)	[0.0(0.0)-0.8(11.1)]
Mandibular agnathia:	2 (2)	[0.0(0.0)-0.3(4.2)]
Mandibular micrognathia:	4 (4)	[0.0(0.0)-0.6(8.0)]
Micromelia:	1 (1)	[0.0(0.0)-0.4(4.8)]
Carpal/tarsal flexure:	1 (1)	[0.0(0.0)-0.3(4.0)]
Omphalocele:	5 (5)	[0.0(0.0)-0.9(8.3)]
Edema:	1 (1)	[0.0(0.0)-0.4(5.9)]
Bent tail:	3 (2)	[0.0(0.0)-0.6(5.6)]
Thread-like tail with small or no anus:	2 (2)	[0.0(0.0)-1.3(11.1)]
No tail with small anal opening:	2 (2)	[0.0(0.0)-0.3(4.2)]
Hydrocephaly:	1 (1)	[0.0(0.0)-0.6(2.4)]
Folded retina:	1 (1)	[0.0(0.0)-0.8(5.6)]
Interventricular septal defect:	1 (1)	[0.0(0.0)-0.6(4.0)]
Situs inversus:	1 (1)	[0.0(0.0)-0.9(4.0)]
Diaphragmatic hernia:	1 (1)	[0.0(0.0)-0.6(4.2)]
Malformed skull bones:	2 (2)	[0.0(0.0)-0.6(4.2)]
Fused skull bones:	2 (1)	[0.0(0.0)-1.1(4.2)]
Malformed scapula:	3 (3)	[0.0(0.0)-1.2(8.7)]
Extra site of ossification in vertebrae:	1 (1)	[0.0(0.0)-0.5(4.2)]
Vertebral anomalies with or without associated rib anomalies:	2 (2)	[0.0(0.0)-0.6(4.8)]
Costal cartilage anomaly:	1 (1)	[0.0(0.0)-0.7(5.6)]
Malformed ribs:	2 (2)	[0.0(0.0)-1.2(5.6)]
Forked ribs:	1 (1)	[0.0(0.0)-0.6(4.0)]
Bent ribs:	12 (12)	[0.0(0.0)-1.4(10.3)]
Extra rib:	1 (1)	[0.0(0.0)-0.6(4.0)]
Sternoschisis:	2 (2)	[0.0(0.0)-0.8(5.6)]
Fused sternebrae:	3 (2)	[0.0(0.0)-1.1(4.2)]
Extra site of ossification:	2 (2)	[0.0(0.0)-1.2(8.7)]

[a]One fetus lost during processing

IRDC Historical Control Data - Charles River COBS® CD® Rats

Summary of the Incidence of Malformations and of Developmental Variations

Developmental Variations Observed	No. Fetuses (Litters)	[Range of Fetuses % (Litters %)]
27 presacral vertebrae:	5 (5)	[0.0(0.0)-1.1(8.0)]
25 presacral vertebrae:	15 (13)	[0.0(0.0)-2.8(11.1)]
Greater than normal (13 pairs) ribs:	196 (121)	[0.0(0.0)-17.5(50.0)]
Fewer than normal (13 pairs) ribs:	109 (74)	[0.0(0.0)-9.8(34.8)]
7TH cervical rib(s):	29 (23)	[0.0(0.0)-3.5(14.3)]
Hyoid unossified:	87 (48)	[0.0(0.0)-6.8(32.0)]
Sternebrae #5 and/or #6 unossified:	1,012 (362)	[3.4(16.0)-68.8(95.2)]
Other sternebrae unossified:	35 (27)	[0.0(0.0)-2.7(20.0)]
Entire sternum unossified:	2 (2)	[0.0(0.0)-0.6(4.0)]
Sternebrae misaligned:	29 (27)	[0.0(0.0)-2.8(17.4)]
Skull reduced in ossification:	49 (43)	[0.0(0.0)-4.2(22.2)]
Vertebrae reduced in ossification:	17 (14)	[0.0(0.0)-1.7(9.5)]
Pubic bone unossified:	7 (6)	[0.0(0.0)-1.1(5.6)]
Ischium reduced in ossification:	1 (1)	[0.0(0.0)-0.6(4.0)]
Major vessel variations:	5 (5)	[0.0(0.0)-1.4(5.3)]
Renal papillae not developed and/or distended ureter:	164 (108)	[0.0(0.0)-14.9(36.4)]

APPENDIX D

Personnel Involved in the Study

The following list of people were responsible for the supervision of various phases of this study:

Dale Aldridge, B.S.	Unit Supervisor, Report Writing, Reproduction and Teratology
Stephen Allen, B.S.	Unit Supervisor, Test Material Control
Carol Bajo	Group Supervisor, Reproduction and Teratology
Ann Borton, B.S.	Unit Supervisor, Reproduction and Teratology
Dixie K. Bushee, B.S.	Unit Supervisor, Test Material Control
Mark W. Griggs, B.S.	Group Supervisor, Test Material Control
Michael F. Kenel, Ph.D.	Staff Toxicologist, Reproduction and Teratology Study Director
Kathryn A. Laughlin, B.S.	Report Writer, Reproduction and Teratology
James L. Schardein, M.S.	Assistant Director, Toxicology Division and Director of Reproduction and Teratology
Colleen A. Schwartz	Assistant to the Director, Reproduction and Teratology
Yolanta Sochanek, B.S.	Unit Supervisor, Reproduction and Teratology
Roger D. Terry, B.S.	Group Supervisor, Reproduction and Teratology
Patrick E. Traster, B.S.	Director of Laboratory Services
R. John Weaver, M.S.	Director of Statistics

401-271

Monsanto

DEPARTMENT OF [illegible]INE & ENVIRONMENTAL HEALTH
[illegible]MPLE SUBMISSION
STUDY NO. IR-84-039 J 040

PLEASE TYPE OR PRINT Teratology - Rats

I. SAMPLE IDENTIFICATION

PRODUCT NAME(S)	CHEMICAL NAME	
Azomethine	Benzeneamine,2,6-diethyl N-methylene	
CP NO.	CHEM. ABSTRACTS REG. NO.	LOT OR I.D. NO., NOTE BOOK REF.
34781	35203-08-8	stg 2-23-84
SAMPLE SIZE	PURITY	SAMPLE DISPOSITION
1 liter	99.5%	☒ DISCARD ☐ RETURN ☐ HOLD, NOTIFY BEFORE DISCARDING

II. CHEMICAL AND PHYSICAL PROPERTIES

STRUCTURAL FORMULA (COMPOSITION OF MIXTURE)

CONFIDENTIAL

EMPIRICAL FORMULA	MOLECULAR WEIGHT	COLOR/PHYSICAL STATE
$C_{11}H_{15}N$	161.24	light yellow liquid

MELTING POINT	BOILING POINT	VAPOR PRESSURE	SPECIFIC GRAVITY
		4×10^{-3} psia at 100°F	

SOLUBILITY: WATER	ORGANIC SOLVENTS (SPECIFY)	OTHER
insoluble	acetone, chloroform	

PHYSICAL/CHEMICAL HAZARDS

☐ FLAMMABLE ☐ UNSTABLE TO LIGHT ☐ POLYMERIZES READILY ☒ NO SPECIAL PRECAUTIONS
☐ EXPLOSIVE ☐ UNSTABLE TO HEAT ☐ HYGROSCOPIC ☐ OTHER (SPECIFY)
☐ OXIDIZER ☐ UNSTABLE TO WATER ☐ REACTS WITH _____

OTHER PROPERTIES, SPECIAL REQUIREMENTS (SPECIFY)
Stable

III. TOXICITY INFORMATION

ORAL LD_{50} 1490 mg/kg
DERMAL LD_{50} _____
EYE IRRITATION 44.5/110
SKIN IRRITATION 1.8/8.0
SINGLE VAPOR INHALATION .83 mg/L (nominal) 6 hr, no mortality

____ NO INFORMATION AVAILABLE
____ SEE ATTACHMENT
____ OTHER (SPECIFY)

IV. DOCUMENTATION

COMPOSITION & PURITY
☐ STATED ABOVE
☐ SEE ATTACHMENT
☒ STAFF TOXICOLOGY FILE

METHOD OF SYNTHESIS
☐ SEE ATTACHMENT
☐ STAFF TOXICOLOGY FILE
☒ OPERATING CO. FILE

SUBMITTED BY: (Name, Location, Phone No., Date)	DMEH CONTACT: (Name, Location, Phone No., Date)
Lydia A. Suba - C2SL - 4-3095 3/15/84	~~T. J. Long - G2WD - 4-8851~~ R.C. Dicks 4-8818 3/15/84

V. EHL USE

STUDY NUMBER(S)	SUBSTANCE IDENTIFICATION CODE

WHITE COPY—LABORATORY COPY; YELLOW COPY—DMEH FILE COPY; PINK COPY—REQUESTOR'S COPY

3-3078 (REV. 1/80)

MASTER FILE
PROJECT NO. AB-84-386

ANALYTICAL BIO-CHEMISTRY LABORATORIES INC
P.O. Box 1097 • Columbia, MO 65205
Shipping Address: 7200 East ABC Lane, Columbia, MO 65202
314/474-8579 • Telex 82¹ 814 • Answer Back (ABCLAB UD

3-5-85

Static Acute Toxicity Report
#32235

Acute Toxicity of Azomethine to Daphnia magna

Monsanto Number AB-84-386

Submitted To:

Monsanto Chemical Company
Attn: Dr. Joel Kronenberg
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167

February 28, 1985

Submitted By: Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P. O. Box 1097
Columbia, Missouri 65205
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Prepared By:

Alan D. Forbis 3/1/85
Alan D. Forbis Date
Aquatic Biologist III/Study Director

Lori Georgie by AF 3/1/85
Lori Georgie Date
Biologist I

David Burgess 3/1/85
David Burgess Date
Biologist II

Approved By:

Carl M. Thompson 3-1-85
Carl M. Thompson Date
Supervisor, Aquatic Toxicology

Kevin F. Yount 3/1/85
Kevin F. Yount Date
Quality Assurance Officer

Michael Williams (CT) 3-1-85
Michael Williams, Ph.D. Date
Group Leader, Animal Toxicology

/gsl

Monsanto

FROM (NAME—LOCATION—PHONE) Dept. of Medicine & Environmental Health

DATE : July 29, 1985

CP 84781

SUBJECT : 2,6-Diethylphenyl Azomethine Acute Aquatic Toxicity Study - Daphnia magna (AB-84-386; ABC #32235)

REFERENCE :

TO : L.A. Suba
C2SC

cc. E.E. Debus - C2SC
S.F. Dirks
T.W. Fuhremann
R.L. Harness - C2SB
R.W. Street - C2SC
Toxdata

The results of the referenced acute static aquatic toxicity study with 2,6-diethylphenyl azomethine (lot 116-200, 99.2% pure) are summarized below. The study and quality assurance reviews were conducted by Analytical Bio-Chemistry Laboratories, Inc.

LC50 (mg/l)	
24 hr	48 hr
41	35

The 48 hr no observable adverse effect level (NOEL) was 5.6 mg/l.

The water temperature, dissolved oxygen concentration, pH and ammonia concentration were within acceptable limits throughout the study.

On the basis of this test, 2,6-diethylphenyl azomethine is considered to be slightly toxic to Daphnia magna.

Joel Kronenberg

Joel M. Kronenberg, PhD
Senior Product Toxicologist
Monsanto Company
Department of Medicine and
Environmental Health

dlj

SUMMARY

The acute toxicity of Azomethine to Daphnia magna was assessed using the methods outlined by the Committee on Methods for Toxicity Tests with Aquatic Organisms. Water quality parameters of temperature, dissolved oxygen and pH were measured at the termination of the test and were within acceptable limits.

The results of the 48 hour static Daphnia magna toxicity study are summarized below. All reported values were based upon nominal concentrations.

Compound	48-hour LC_{50} (95% C.I.)
Azomethine	35 (18-56) mg/l

The no effect level observed for Azomethine was 5.6 mg/l after 48 hours, which was based on the lack of mortality and abnormal effects.

INTRODUCTION

This definitive static bioassay was performed by the Aquatic Toxicology Division of Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri, for Monsanto Chemical Company, from February 25 to February 27, 1985. The purpose of this test was to determine the 24 and 48 hour LC_{50} levels for Azomethine to Daphnia magna. The study was performed using ABC Protocol #7806 as approved by Dr. Richard C. Dirks, Monsanto Chemical Company, on October 10, 1984.

METHODS AND MATERIALS

The procedures for static bioassay, as described in Methods of Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians (1) and Standard Methods for Examination of Water and Wastewater (2), were used in this experiment. The Daphnia magna used in the test were cultured at the ABC facilities. The adult Daphnia were fed algae (Selenastrum capricornutum) at least every three days prior to testing and supplemented with a suspension of tetramin/cerophyl. The daphnids were identified to species using the taxonomic key presented by Pennak (3).

The static Daphnia bioassay was conducted in 250 ml glass beakers containing 200 ml of ABC aged well water with the chemical characteristics listed in Table 1. These vessels were kept at 20 (±2.0) °C in a temperature controlled area. The lighting was maintained at 50-70 footcandles on a 16 hour daylight photoperiod with 30 minute simulated dawn and dusk periods.

An initial range finding experiment was conducted using 10 Daphnia each in exposure concentrations of 0.1, 1, 10 and 100 mg/l. From this information, five concentrations in duplicate of the test compound with ten Daphnia (first instar less than 24 hours old) per beaker were selected for the definitive bioassay. These concentrations were a logarithmic series ranging from 5.6 to 56 mg/l and included a control and solvent control. All concentrations were observed once every 24 hours for mortality and abnormal effects such as surfacing, clumping of the daphnids together and daphnids lying on the bottom of test chambers.

The Azomethine (2,6-diethylphenyl) test compound was received on February 18, 1985, as a yellow liquid and was stored at room temperature. Sample purity was not specified. Test concentrations were prepared based on total compound. All standard weights and dilutions can be found in the Appendix. Acetone was used in the preparation of all working stock solutions. The solvent control received an aliquot (0.56 ml) of acetone equivalent to that of the highest test concentration.

The 24 and 48-hour LC_{50} values and corresponding 95% confidence limits were determined by an LC_{50} computer program developed by Stephan et al. (4). This program calculated the LC_{50} statistic and its 95 percent confidence limits using the binomial, moving average angle and

probit methods because no one method is appropriate for all possible sets of data. The method of calculation selected was that which gave the narrowest confidence limits for each separate analysis.

RESULTS

Table 2 presents the predicted LC_{50} values and 95% confidence intervals for Azomethine. The 24 and 48-hour LC_{50} values for Azomethine were 41 and 35 mg/l. All results were based on the nominal concentrations of 5.6, 10, 18, 32 and 56 mg/l. The no-effect concentration based on the lack of mortality and abnormal effects was 5.6 mg/l after 48 hours. The abnormal effects of mortality, surfacing, clumping, quiescence and daphnids lying on the bottom were observed in the 10, 18, 32 and 56 mg/l test concentrations.

Table 3 presents the mortality rate and water quality parameters measured during the test. The dissolved oxygen concentrations ranged between 7.6 and 8.1 mg/l. These values represented 83 and 88 percent saturation at 20°C, respectively, and were considered adequate for testing (1). The pH values of the treated chambers were consistent with the control and ranged from 8.2 to 8.6.

The study was conducted following the intent of the Good Laboratory Practice Regulations (5) and the final report was reviewed by Analytical Bio-Chemistry Laboratories' Quality Assurance Unit. All original raw data was provided to Monsanto Chemical Company, with a copy retained at Analytical Bio-Chemistry Laboratories.

TABLE 1

Chemical Characteristics of Well Water Used by
ABC's Aquatic Toxicology Division

Parameter	Concentration
Temperature	15-20°C[b]
Dissolved Oxygen[a]	9.2-10.2 ppm[b]
pH	7.8-8.3[b]
Hardness ($CaCO_3$)	225-275 ppm[b]
Alkalinity ($CaCO_3$)	325-375 ppm[b]
Conductivity	700 µmhos/cm
NH_3-N	0.60 ppm
NO_3-NO_2-N	0.20 ppm
Ortho-Phosphate	0.10 ppm
Aluminum	<0.010 ppm
Arsenic	<0.0005 ppm
Cadmium	<0.002 ppm
Chromium	<0.006 ppm
Cobalt	<0.003 ppm
Copper	<0.002 ppm
Iron	<0.004 ppm
Lead	0.017 ppm
Mercury	0.0008 ppm
Nickel	<0.013 ppm
Silver	<0.0004 ppm
Zinc	0.001 ppm
Measured organophosphorus pesticides	c
Measured organochlorine pesticides plus PCB's	c

[a]After aeration.

[b]Represents seasonal variation, with the monthly range not exceeding 10%.

[c]See report appendix for individual analyses.

TABLE 2

Acute Toxicity of Azomethine
to Daphnia magna[a]

Compound	LC_{50} (mg/l) 24 hours	48 hours
Azomethine	41(3) (34-50)[b]	35(1) (18-56)

[a]Bioassay conducted at 20°C (±2.0).

[b]95% confidence limits.

The 48-hour no-effect concentration was 5.6 mg/l, based on the lack of mortality and abnormal effects.

All values were rounded to two significant figures following ABC S.O.P. #8.7.

LC_{50} calculated using:

(1) Binomial Method

(2) Moving Average Method

(3) Probit Method

TABLE 3

Mortality Rates and Water Quality Measurements During the Acute Toxicity Test of Azomethine to Daphnia magna

Concentration (mg/1)	Percent Mortality Hours		Water Quality					
			0 Hours			48 Hours		
	24 hr	48 hr	Temp. °C	D.O.[a] mg/1	pH[b]	Temp. °C	D.O.[a] mg/1	pH[b]
Control	0	0	20	8.0	8.2	20	8.1	8.5
Solvent Control	0	0						
5.6	0	0				20	8.0	8.6
10	0	0						
18	0	0				20	8.0	8.6
32	35	35						
56	75	100				20	7.6	8.5

[a] Dissolved oxygen concentrations - Dissolved Oxygen System (YSI Model 54).

[b] pH - pH Probe (Corning Model 476182) used with a Corning Model 125 pH and mV meter.

NOTE: Dissolved oxygen saturation at the test temperature of 20°C is 9.2 mg/1.

LITERATURE CITED

(1) Methods of Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. Stephan, C. E. Chairman. 1975. Committee on Methods for Toxicity Tests with Aquatic Organisms. U.S. EPA, Ecol. Res. Ser. 660/3-75009.

(2) American Public Health Association. 1980. Standard Methods for the Examination of Water and Wastewater. 15th ed. Washington, DC. 1134 p.

(3) Pennak, R. W. 1978. Freshwater Invertebrates of the United States. John Wiley and Sons, New York, 2nd ed. 803 p.

(4) Stephan, C. E., K. A. Busch, R. Smith, J. Burke and R. W. Andrews. 1978. A computer program for calculating an LC_{50}. U. S. Environmental Protection Agency, Duluth, Minnesota, pre-publication manuscript, August, 1978.

(5) (a) U.S. Food and Drug Administration. 1978. Nonclinical Laboratory Studies, Good Laboratory Practice Regulations (21 CFR, Part 58). Federal Register, Vol. 43, No. 247:59986-60025.

(b) U.S. Environmental Protection Agency. 1983. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160). Federal Register, Vol. 48, No. 230:53946-53969.

(c) U.S. Environmental Protection Agency. 1983. Toxic Substances Control; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 792). Federal Register, Vol. 48; No. 230:53922-53944.

(d) Organization for Economic Cooperation and Development. 1981. OECD Guidelines for Testing of Chemicals, Principles of Good Laboratory Practice Annex 2, C(81) 30(Final):7-28.

Quality Assurance Statement for final report #32235 entitled, "Acute Toxicity of Azomethine to Daphnia magna," for Dr. Joel Kronenberg, Monsanto Chemical Company, St. Louis, Missouri.

In accordance with ABC Laboratories intent that all studies conducted at our facilities are designed and function in conformance with good laboratory practice regulations and the protocols for individual laboratory studies, an inspection of the final report for Azomethine was conducted and found to be in acceptable form by a member of our Quality Assurance Unit. Recording of day 0 water quality parameters were observed on February 25, 1985. No deviations were noted. A final inspection of all data and records on February 28, 1985 indicates that the report submitted to you is an accurate reflection of the study as it was conducted by ABC Laboratories.

Should you have any questions relating to the information provided in this statement or the function of our Quality Assurance Unit, please contact the Quality Assurance Unit at your convenience.

Kevin F. Yount 3/1/85

Kevin F. Yount Date
Quality Assurance Officer

Study Compliance Statement for ABC report #32235 entitled, "Acute Toxicity of Azomethine to Daphnia magna," for Dr. Joel Kronenberg, Monsanto Chemical Company, St. Louis, Missouri.

In accordance with ABC Laboratories' intent that all aquatic toxicity tests conducted by our facility follow good laboratory practices, ABC's study director for the above test herein confirms that the study was conducted in compliance with the U.S. E.P.A. Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160).

All original raw data was sent to Monsanto Chemical Company, with a copy retained at Analytical Bio-Chemistry Laboratories.

Alan D. Forbis 3/1/85

Alan D. Forbis Date
ABC Study Director

APPENDIX - RAW DATA

Note: Some of the records which appear in this raw data appendix have been provided as photocopies of original records on file at ABC. This has been done by necessity for certain data which are used commonly in several studies at ABC. Such records include reference toxicity test data, standard solution preparations, organism culture logs, and well water chemical screen results.

DAPHNIA ACUTE TOXICITY BIOASSAY

☑ Definitive ☐ Preliminary

Test Material: AZOMETHINE
Study No.: 32235
Protocol No.: 7806
ABC Study Director: A. Forbis

Lab Form No.: 67

Analytical Bio-Chemistry Labs
7200 ABC Lane
P. O. Box 1097
Columbia, Missouri 65205

Test Species: ☑ Daphnia magna ☐ _____ (Lot #85-B-1)
Dilution Water: ☐ Recon. ☑ Well No./Vessel: 10
Date Initiated: 2/25/85 (2:55pm) Date Terminated: 2/27/85

Test Conc. mg/l (ppm)		Mortality and Behavioral Observations					
		24 hour		48 hour			
		Dead	Obs.	Dead	Obs.	Dead	Obs.
Control	A	0	N	C	N		
	B	0	N	C	N		
SOL CONTROL	A	0	N	C	N		
	B	0	N	C	N		
5.6	A	0	N	C	N		
	B	0	N	C	N		
10	A	0	3 SUR 1 N LOB	C	2 SUR 8 N		
	B	0	6 SUR +N	C	3 SUR 7 N		
18	A	0	8 SUR 2 OB	C	3 SUR 7 OB		
	B	0	2 SUR 8 OB	C	2 SUR 8 OB		
32	A	4	6 SUR/C/Q	4	1 SUR 5 OB		
	B	3	7 SUR/C/Q	3	4 SUR 3 OB		
56	A	7	3 SUR/C/Q	10	—		
	B	8	2 SUR/C/Q	10	—		
Observer Date		LO 2/26/85 (2:30pm)		DB 2/27/85 (1:40pm)			

Remarks: N=Normal, LOE=Loss of Equilibrium, SUR=Surfacing, C=Clumping of Daphnia, OB=On Bottom, Q=Quiescent

Prepared By: Lori Georgie Date: 2/25/85
Checked By: Mark Budgen Date: 2/28/85

STUDY # 032235 pg 001 of 0035

DAPHNID STUDY WATER QUALITY

Test Material: AZOMETHINE

Study No.: 32235

Protocol No.: 7806

ABC Study Director: A FORBIS

Lab Form No.: 63

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65201

	WATER QUALITY												
	Control			Low			Middle			High			
Study Day	Temp. [a] °C	D.O. [b] mg/l	pH [c]	Temp. °C	D.O. mg/l	pH	Temp. °C	D.O. mg/l	pH	Temp. °C	D.O. mg/l	pH	Prepared By
0	20	8.0	8.2										LG 2/25/85
2	20	8.1	8.5	20	8.0	8.6	20	8.0	8.6	20	7.6	8.5	DB 2/27/85

[a] Temperature - Monitored using a mercury thermometer.

[b] Dissolved oxygen concentrations - Dissolved Oxygen Probe (YSI Dissolved Oxygen System Model 54.

[c] pH - pH Probe (Corning Model 476182) used with a Corning Model 125 pH with mV meter.

Prepared By: David Bunzen Date: 2/20/85

Checked By: Lori Georgia Date: 2/27/85

Remarks:

DAPHNIA ACUTE TOXICITY BIOASSAY

☐ Definitive ☑ Preliminary

Test Material: AZOMETHINE

Study No.: 32235

Protocol No.: 7806

ABC Study Director: A. FORRIS

Lab Form No.: 67

Analytical Bio-Chemistry Labs
7200 ABC Lane
P. O. Box 1097
Columbia, Missouri 65205

Test Species: ☑ Daphnia magna ☐ _____ (Lot # —)

Dilution Water: ☐ Recon. ☑ Well No./Vessel: 10

Date Initiated: 2/20/85 Date Terminated: 2/22/85

Test Conc. mg/l (ppm)	Mortality and Behavioral Observations					
	24 hour		48 hour			
	Dead	Obs.	Dead	Obs.	Dead	Obs.
~~Control~~						
C 1	0	N	0	N		
1 C	0	N	0	N		
1C	0	N	0	4 ERR 6N		
1CC	10	—	10	—		
Observer Date	2/21/85 LG		DB 2/22/85			

Remarks: N=Normal, LOE=Loss of Equilibrium, SUR=Surfacing, C=Clumping of Daphnia, OB=On Bottom, Q=Quiescent

Prepared By: Mark Burger Date: 2/20/85

Checked By: Lori Gorgie Date: 2/27/85

COMPOUND PREPARATIONS

Test Material: AZOMETHINE
Study No.: 32235
Protocol No.: 7806
Lot No.: — Purity: — %
ABC Study Director: A. FORBIS

Lab Form No.: 27
Analytical Bio-Chemistry Lab
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Preparation of Concentrated Working Standard

Date 2/20/85 Prepared By: Vinod Bungra
Final Gross Weight 0.200 g
Tare Weight 0.000 g
Net Weight 0.200 g
Adj. Net Weight — g*
*Corrected for purity of primary standard.
Dilution Volume 10 (ACETONE) ml
Concentration 20 mg/ml
Balance calibrated with class C weights:
5.000 g (class C) + 0.000 g (tare) = 5.003 g (final wt.)

Preparation of Preliminary Test Concentrations

Date 2/20/85 Prepared By: Vinod Bungra

	Conc. of Work. Std. (mg/ml)	Aliq. Vol. (ml)	Dilution Vol. (l)	Final Conc. (mg/l)
	20	.001	0.2	0.1
1.	20	.01	0.2	1.0
2.	20	0.1	0.2	10
3.	20	1.0	0.2	100

Preparation of Concentrated Working Standard

Date 2/25/85 Prepared By: Lori Georgi
Final Gross Weight 0.200 g
Tare Weight 0.000 g
Net Weight 0.200 g
Adj. Net Weight — g*
*Corrected for purity of primary standard.
Dilution Volume 10(Acetone) ml
Concentration 20 mg/ml
Balance calibrated with class C weights:
0.500 g (class C) + 0.000 g (tare) = 0.500 g (final wt.)

Preparation of Definitive Test Concentrations

Date 2/25/85 Prepared By: Lori Georgi

	Conc. of Work. Std. (mg/ml)	Aliq. Vol. (ml)	Dilution Vol. (l)	Final Conc. (mg/l)
Control	—	—	—	Control
1.	Acetone	0.56	0.2	Sol Control
2.	20	0.056	0.2	5.6
3.	20	0.10	0.2	10
4.	20	0.18	0.2	18
5.	20	0.32	0.2	32
6.	20	0.56	0.2	56
7.				

Checked By: Vinod Bungra Date: 2/25/85

INVERTEBRATE CULTURE RECORD

Species: Daphnia magna

Lot No.: 85-B-1

Date Initiated: 1/24/85

Lab Form No: 52

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P. O. Box 1097
Columbia, MO 65205

Date	No. Adult Alive	Instar Present	Fed & Changed	Study I.D.	Comments	Obs. By:
1/24	—	~25	✓		300 ml ALGAE 2ml MIDGE FOOD	DB
1/29	25	—	✓		" "	DB
1/31	25	100	✓		" "	DB
2/3	25	150	✓		" "	LG
2/4				32811-120		DB
2/5	25	700	✓		" "	DB
2/7	25	500	✓		" "	LG
2/10	24	~600	✓		" "	PC
2/12	24	700	✓		" "	DB
2/14	24	900	✓		" "	LG
2/17	24	500	✓		" "	LG
2/19	24	900	✓		" "	LG
2/20	24	500	✓		" "	DB
2/21	23	500	✓		" "	LG
2/24	22	703	✓		" "	AF
2/25				32238-140 32235-140		LG

Prepared by: David Burgess Date: 1/24/85

Checked by: Lori Georgie Date: 2/27/85

This is an exact copy of The original document"
By [signature] date 2-25-85

DEFINITIVE CONCENTRATION NOTIFICATION

Firm: Monsanto Chem Co.
Address: 800 N. Lindbergh Blvd.
City/State/Zip: St. Louis, Mo 63167
Phone: (314) 694-8832

Lab Form No.: 186
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, MO 65202

Sponsor's Study Director: Joel Kronenberg *
Person notified: same( ) Other: Diana Jones

Date of Notification: 2/25/85

Notification of preliminary testing results with the following definitive test levels agreed upon:

Test Material	ABC #	Test Species	Test Conc. (mg/l)
AZOMETHINE	32235	Daphnia magna	5.6, 10, 18, 32 + 56

* Note: Joel Kronenberg was assigned as Study Sponsor (Monsanto) to replace Rick Dirks, who signed protocol. This notification made by phone on 2-13-85 in a conversation between Carl Thompson & Joel Kronenberg.

Carl Thompson
2-28-85

Notified By: Lori Georgie Date: 2/25/85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Azomethine

Study No.: 32235

Test Species: Daphnia magna

Exposure Period: 24 hrs

ABC Study Director: A. Forbis

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
56	20	15	75	2.06947
32	20	7	35	13.1588
18	20	0	0	LESS THAN 0.001
10	20	0	0	LESS THAN 0.001
5.6	20	0	0	LESS THAN 0.001

THE BINOMIAL TEST SHOWS THAT 18 AND 56 CAN BE USED AS

STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THIS LIMIT IS >95 PERCENT AN APPROXIMATE LC50 OF 39.3294 PPM IS OBTAINED BY

NONLINEAR INTERPOLATION BETWEEN 32 AND 56

----RESULTS CALCULATED USING THE MOVING AVERAGE METHOD----

SPAN	G	LC50 PPM	95 PERCENT CONFIDENCE LIMITS LOWER	UPPER
2	.109754	39.7248	33.7201	49.4097
1	.604762	39.3294	24.1486	51.14

----------RESULTS CALCULATED USING THE PROBIT METHOD----------

ITERATIONS	G	H	CHI-SQUARE	PROBABILITY
5	.183741	1	1.10939	.774807

SLOPE = 5.64138

95 PERCENT CONFIDENCE LIMITS = 3.2232 AND 8.05956

LC50 = 40.6

95 PERCENT CONFIDENCE LIMITS = 34.312 AND 49.5849

****

Method Reported:

☐ Binomial ☐ Moving Average ☑ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: Lori Georgie Date: 2/27/85

Checked By: [signature] Date: 2/28/85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Azomethine

Study No.: 32235

Test Species: Daphnia magna

Exposure Period: 48 hrs

ABC Study Director: A Forbis

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
56	20	20	100	LESS THAN 0.001
32	20	7	35	13.1588
18	20	0	0	LESS THAN 0.001
10	20	0	0	LESS THAN 0.001
5.6	20	0	0	LESS THAN 0.001

THE BINOMIAL TEST SHOWS THAT 18 AND 56 CAN BE USED AS

STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS BECAUSE
THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THIS LIMIT IS >95 PERCENT
AN APPROXIMATE LC50 OF 35.328 PPM IS OBTAINED BY

NONLINEAR INTERPOLATION BETWEEN 32 AND 56

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING
AVERAGE OR PROBIT METHOD CAN GIVE STATISTICALLY SOUND RESULTS.

****

Method Reported:

☒ Binomial ☐ Moving Average ☐ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: Lori Georgi Date: 2/27/85

Checked By: David Budgen Date: 2/28/85

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65205 • (314) 474-8579

February 10, 1984

ANALYTICAL RESULTS FOR:

Aquatic Division
Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P.O. Box 1097
Columbia, MO 65205

Water Analysis Results

ABC Lab No.	30896-1
Sample I.D.	ABC Deep Well Water
NH_3-N	0.6 mg/l
NO_3-NO_2-N	0.20 mg/l
Total Phosphorus	<0.01 mg/l
Al	<10 µg/l
Co	<3 µg/l
Fe	<4 µg/l
As	<0.5 µg/l
Cd	<2 µg/l
Cr	<6 µg/l
Cu	2 µg/l
Pb	17 µg/l
Hg	0.8 µg/l
Ni	<13 µg/l
Ag	<0.4 µg/l
Zn	1 µg/l

<Indicates less than, if present at all.

Floyd E. Kaiser
Nutritional Group Supervisor

FEK/kkg

Please note that the original data for the analysis reported in this table are in ABC's archives.

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65205 • (314) 474-8579

December 6, 1983

ANALYTICAL RESULTS FOR:

Aquatic Division
Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P. O. Box 1097
Columbia, MO 65205

Analysis of Well Water for Organophosphates

ABC Lab No.	Customer I. D.	Compound	ppb
30637-1	Lab Well Water	Diazinon	<0.055
		Methyl Parathion	<0.14
		Malathion	<0.15
		Ethyl Parathion	<0.15

Stanley Shaffer
Residue Chemist

SS/kg

Please note that the original data for the analysis reported in this table are in ABC's archives.

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65205 • (314) 474-8579

December 6, 1983

ANALYTICAL RESULTS FOR:

Aquatic Division
Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P. O. Box 1097
Columbia, MO 65205

Analysis of Well Water for Nonionic
Chlorinated Hydrocarbon Residue

ABC Lab No.	30637-1
Customer I. D.	Aquatic Well Water
Compound	ppb
αBHC	<0.02
βBHC	<0.02
γBHC	<0.02
δBHC	<0.02
Heptachlor	<0.02
Heptachlor Expoxide	<0.04
αChlordane	<0.04
βChlordane	<0.04
Tech Chlordane	<0.08
Aldrin	<0.02
Dieldrin	<0.05
p,p'-DDE	<0.05
o,p'-DDT	<0.08
p,p'-DDD	<0.08
p,p'-DDT	<0.08
Endrin	<0.08
Methoxychlor	<0.30
Toxaphene	<0.80
Aroclor 1242	<0.80
Aroclor 1016	<0.80
Aroclor 1254	<0.80
Aroclor 1260	<0.80
HCB	<0.01
Mirex	<0.10

<indicates less than, if present at all.

Stanley Shaffer
Residue Chemist

SS/kg

Please note that the original data for the analysis reported in this table are in ABC's archives.

Monsanto

DEPARTMENT OF MEDICINE & ENVIRONMENTAL HEALTH

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone: (314) 694-1000

November 20, 1984

Carl M. Thompson
Aquatic Biologist
ABC Laboratories, Inc.
7200 East ABC Lane
P.O. Box 1097
Columbia, MO 65205

RE: Agreement for Toxicological Studies
Dated as of the 14 day of Sept., 1979;
Acute aquatics Daphnia magna 48-hr. LC50
AB-84-386 Azomethine
AB-84-389 2,6-Diethylaniline
AB-84-392 Iminodiacetic acid
AB-84-395 Glyphosate formulation
LLN 83-06 (STING®)

Dear Mr. Thompson:

This letter is pursuant to the above agreement and authorizes you to commence a toxicological study in October, 1984, in accordance with the enclosed signed protocol, and, in addition, designates Richard C. Dirks, Ph.D. as Monsanto's representative to act for Monsanto in connection with this study. The fee for each study will be ~~$650~~ $700. If you wish to avoid the inconvenience of multiple invoices for this short-term study, you may elect to submit a single invoice for the total cost of the study at the same time that the draft report is sent to Monsanto. The study is to be completed and a final report acceptable to Monsanto submitted within 90 days after the commencement date. We look forward to working with you and encourage you to contact our representative if you have any questions about the protocol or any other aspects of the study.

RDD 11-28-84

Although this study is not intended to be submitted to or reviewed by the United States Environmental Protection Agency, we wish to advise you that the study authorized by this letter must nevertheless be conducted in compliance with the study protocol and the appropriate provisions of FDA (21 CFR Part 58) and EPA FIFRA (40 CFR Part 160) Good Laboratory Practice Regulations.

Please note that except for the fee invoicing option provided above, nothing in this letter or the enclosed protocol in any way modifies or alters the terms and conditions of our Agreement. In the event of any conflict or inconsistency between the enclosed protocol and our Agreement, our Agreement shall govern.

Please indicate your acceptance of this letter of authorization by dating and signing this letter in duplicate in the spaces provided below and return one of the signed duplicates to Dr. Dirks, Monsanto's designated representative for this study.

Sincerely,

F R Johannsen

Frederick R. Johannsen, PhD
Manager Product Toxicology

/jb

enclosure

ACCEPTED AND AGREED TO THIS

28 DAY OF Nov, 1984.

By: Lyle Johnson

Title: Vice President
Lab Operations

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65205
Shipping Address: 7200 East ABC Lane, Columbia, MO 65202
(314) 474-8579 • Telex 821 814 • Answer Back (ABCLAB UD)

ABC LABS
NOV 26 1984
RECEIVED

ABC PROTOCOL NO. 7806
(Revised July 11, 1984)

STATIC BIOASSAY PROCEDURE FOR DETERMINING THE ACUTE TOXICITY OF CHEMICAL SUBSTANCES TO DAPHNIA MAGNA

ABC Study Number 32235

Test Material ~~Azomethine~~ 2,6-diethylphenyl azomethine

AB-54-356

1.0 INTRODUCTION

Aquatic toxicity tests have been used extensively in the assessment of the environmental effects of chemical substances. Indeed, aquatic bioassays are required by federal laws such as the Toxic Substances Control Act (1), FIFRA (2), and the Clean Water Act of 1977 (3). With the testing guidelines for these laws in mind, as well as FDA's Good Laboratory Practice Regulations (4) which complement them, Analytical Bio-Chemistry Laboratories, Inc. has prepared the following protocol. The static bioassay method presented here was patterned after procedures that were formulated by the U. S. Environmental Protection Agency (5), American Public Health Association (6), and the American Society for Testing and Materials (7).

2.0 OBJECTIVES

The primary objective of the toxicity test described herein is to evaluate the acute toxicity of a chemical substance to Daphnia magna under static conditions. This is achieved by determining LC_{50} levels of the toxicant during a 48 hour exposure period. An LC_{50} is the approximate concentration of the test material that produces 50 percent mortality of test daphnids after prescribed intervals. Mortality as used in this protocol is defined as the cessation of movement. The method is designed to yield LC_{50} values following 24 and 48 hours of exposure.

3.0 TESTING FACILITY

The study will be conducted by the Aquatic Toxicology Division of Analytical Bio-Chemistry Laboratories, Inc., 7200 East ABC Lane, P. O. Box 1097, Columbia, Missouri 65205.

4.0 RANGE-FINDING STUDY

4.1 General. For most chemical substances, the approximate toxic level to aquatic organisms is not known. Because this information is essential before a definitive toxicity test can be conducted, ABC routinely performs range-finding tests for static bioassays with daphnids. The information derived from this preliminary test will be used to set concentration levels for the definitive bioassay described in section 5.0.

4.2 Test Daphnids. The test lot of Daphnia magna will be obtained from an in-house culture. The taxonomic key presented by Pennak (12) will be used to identify to species the test daphnids. All test daphnids will be held in a controlled temperature area at 20 ±2°C. The lighting will be 50-70 footcandles on a 16 hour daylight photoperiod. During the holding period, they will be fed algae (Selenastrum capricornutum) supplemented with a trout chow suspension at least every 3 days. First-instar daphnids (<24 hours old) will be selected for testing and will not be fed during the test.

4.3 Test System. The range-finding test will be conducted in 250 ml glass beakers containing 200 ml of solution. These test vessels will be placed in a temperature controlled area with temperature maintained at 20 ±2°C. The dilution water used will be from a deep well source with chemical and physical characteristics shown in Table 2. The well water will be aged and activated biologically in a tank containing ≅1000 liters of water with living fish before delivering to the test system.

4.4 Test Material. A letter of authorization for the study should be sent with the test material or previous to its shipment and should contain the following chemical/physical properties of the compound if available: name of test material, code number, physical description, purity, stability, suggested storage conditions, water and organic solvent solubility, available toxicity information, and handling precautions. The test concentrations will be prepared on a weight/volume basis unless otherwise specified. A record of all sample weights and dilutions will be kept, checked by a second party, and furnished in the final report. Under certain experimental conditions, the sponsor may elect to confirm test concentrations by approved analytical techniques. Factors such as limited aqueous solubility, volatility and aquaria aeration may require analysis at 0 and 48 hours.

4.5 Test Procedure. The range-finding procedure is as follows:

4.5.1 Test daphnids will be selected from a sub-culture of first-instar (<24 hours old) individuals.

4.5.2 The range-finding test will be initiated by exposing groups of five to ten daphnids to at least one or more toxicant concentrations, usually spaced by a factor of 10. The test daphnids will be placed in the test chambers by stratified random assignment within 30 minutes after solution preparations. The initial toxicant concentrations most often used are 1, 10 and 100 mg/l. Numerous static tests by ABC have shown that a significant percentage of the compounds tested have aquatic toxicities which fall within this range. ABC will test up to a maximum of 1,000 mg/l in both the preliminary and definitive tests, unless otherwise requested by the study sponsor.

4.5.3 After 24 hours of exposure, the test chambers will be observed for mortality and adverse behavioral effects. A record will be maintained of mortality and abnormal behavior at each observation. Dependent upon this observation, additional test concentrations may be added at levels above or below the initial concentrations. This procedure will be followed until a toxic range is determined. For example, if the 24 hour exposure results in total mortality, new solutions will be prepared at a factor of 10 below the lowest initial concentration until no mortality or partial mortality is reached. In the converse situation, if no mortality is observed after 24 hours, new solutions will be added at concentrations spaced by a factor of 10 above the highest initial level until mortality is noted. In this manner, a bracket is formed for the toxic range of the compound.

4.5.4 The preliminary test will be conducted for a period of 24 to 48 hours - the exact duration dependent upon the results of the initial concentrations tested. In most cases, a preliminary test for 48 hours at 3 toxicant concentrations is sufficient to determine the toxic range.

4.5.5 Results of the range-finding study will be used to set the concentration range of the definitive study described in section 5.0. At least five toxicant concentrations selected from the logarithmic scale presented in Table 1, which fall within the preliminary test range, have proven to be adequate in assessing most compounds.

5.0 DEFINITIVE STUDY

5.1 General. Following the preliminary range-finding study discussed in section 4.0, the definitive test will be conducted by the procedures described below. Test-specific information regarding the sponsor, test material, proposed study dates, study personnel and study approvals will be included in section 8.0 at the time of protocol approval.

5.2 Test Daphnids. Aspects concerning the culture and acclimation of test daphnids will be the same as discussed in section 4.2.

5.3 Test System. The test system for the definitive study will be the same as outlined in section 4.3.

5.4 Test Material. Specific information regarding the test material is to be supplied by the sponsor and will be addressed in section 8.3 at the time of protocol approval. The remaining test material will be sent back to the study sponsor upon approval of the final report.

5.5 Test Procedure-Biological. The basic test procedure for the definitive bioassay will be as follows:

5.5.1 Test daphnids will be selected from a sub-culture of first instar (<24 hours old) individuals.

5.5.2 The definitive test will be initiated by exposing the test daphnids to at least 5 toxicant concentrations and a dilution water control. The test will be conducted using duplicate beakers per concentration, with 10 daphnids per beaker. The test concentrations used will be based upon the results of the range-finding test and will be selected from one of the logarithmic series presented in Table 1. The definitive test concentrations will be selected after discussing preliminary results with study sponsor. If a solvent is used in the preparation of test solutions, the control chamber will receive an aliquot of the solvent equivalent to the highest amount used in the test chambers. The test organisms will be placed in the test chambers by stratified random assignment within 30 minutes after solution preparations.

5.5.3 As alternate test designs, single or triplicate test chambers containing 10 daphnids each may be used, if so authorized by the sponsor.

5.5.4 The test chambers will be observed for mortality and adverse behavioral effects every 24 hours. A record will be maintained for mortality and abnormal behavior for each concentration tested.

5.6 Test Procedure-Chemical and Physical. The dissolved oxygen concentration will be measured in the control at the beginning of the test, while at 48 hours of the test dissolved oxygen measurements will be made in the control and the high, medium and low toxicant concentrations. The pH will be measured at least once in the control and the high, medium and low toxicant concentrations (5). If at any point in the study dissolved oxygen levels are observed to be below or approaching 40 percent saturation, ABC will contact the study director for authorization to artificially aerate the test chambers with compressed air for the duration of the study. The authorization procedure used will be that described in section 7.0.

5.7 Analysis of Results. The results of the definitive study will be statistically analyzed for 24 and 48 hour LC_{50} values and their corresponding 95 percent confidence limits. These values will be determined by an LC_{50} computer program developed by Stephan et. al. (11) or by manual methods described by Litchfield-Wilcoxon (9) and Stephan (10).

5.8 Report. One copy of the report will be submitted. The report will contain all original raw data. Additional copies will be provided, if requested by the sponsor, at a copy rate of $25 per copy. The report will include the following:

5.8.1 Study dates, name and address of test facility.

5.8.2 Objectives and test methods.

5.8.3 Reference to the statistical methods used for data analysis.

5.8.4 Description of test material (date of receipt, storage conditions, purity, physical characteristics, and method of preparing test concentrations).

5.8.5 Description of test design.

5.8.6 Summary of the data analysis, mortality observations and test water quality.

5.8.7 Location of raw data.

5.8.8 List and signatures of study personnel.

5.8.9 GLP compliance statement by study director and a statement by ABC's Quality Assurance Unit.

5.8.10 The report appendix will contain the original raw data for mortality observations and water quality, letter of test authorization, letters of authorized protocol changes, and a copy of the approved protocol.

5.9 Data Retention. All original raw data generated in the preliminary and definitive studies will be provided to the study sponsor in the appendix to the final report. A copy of the data will be retained in ABC's archives.

6.0 PROTOCOL CHANGES

In the event that modifications of this protocol are deemed necessary, a written statement of any changes and reason(s) proposed by the study sponsor or ABC will be submitted to the other party. All agreed changes will be expressed in writing, signed and dated by the sponsor's study director. The signed changes will be appended to the protocol and included with the final report. This protocol is subject to revision when felt necessary to comply with changes in federal regulations and state of the art methodology. The protocol for a specific study will not be changed while the study is in progress without discussion with the study sponsor.

7.0 SPONSOR AUTHORIZATIONS DURING THE STUDY

Should a problem develop while the study is in progress, ABC will notify the study director within 24 hours. The problem and suggested test modifications will be discussed by telephone. ABC will proceed with the changes felt necessary upon the verbal authorization of the study director. A letter for written authorization will then be submitted by ABC to the study director and handled in the same manner discussed in section 6.0.

8.0 TEST-SPECIFIC INFORMATION

8.1.1 General. The following items will be addressed for each static bioassay. This information is necessary to be in compliance with Good Laboratory Practice Regulations (4). Sections 8.2, 8.3, 8.7 and 8.9 are to be completed by the study sponsor. Sections 8.4, 8.5 and 8.6 will be completed by ABC.

8.1.2 GLP Compliance. To be in compliance with the Federal Good Laboratory Practice regulations, the report of the investigation conducted utilizing this protocol must contain a statement that the study was conducted in accordance with one of the following GLP's.

1. U.S. F.D.A. Good Laboratory Practice Regulations (21 CFR 58).

2. U.S. E.P.A. Good Laboratory Practice Standards; Toxic Substances Control (40 CFR 792).

3. U.S. E.P.A. Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160).

4. OECD Principles of Good Laboratory Practice; Annex 2 C(81) 30(Final).

5. Any state or local GLP which may apply.

The specific GLP regulation, for which this study specific protocol and resultant study must be in compliance with, is to be designated by the study sponsor in section 8.7 of this protocol.

8.2 Study Sponsor:

8.2.1 Company Monsanto Chemical Company - G2WD

8.2.2 Address 800 North Lindbergh Boulevard
St. Louis, Missouri 63167

8.2.3 Sponsor's Study Director

Dr. Richard C. Dirks — Name
_____ — Title

8.3 Test Material:

8.3.1 Name Azomethine (2,6-diethylphenyl)

8.3.2 Lot/Batch Number _____

8.3.3 Physical Description _____

8.3.4 Purity _____

8.3.5 Stability _____

8.3.6 Solubility: Water _____ Acetone _____ DMF _____
TEG _____ Ethanol _____ Methanol _____ Other _____

8.3.7 Handling Precautions _____

8.4 Test Concentrations: To be determined after preliminary testing and consultation with study sponsor.

8.4.1 Sponsor's Study Director notified of preliminary results: Date 2/25/85 ABC Biologist Lori Horgan.

8.4.2 Definitive test concentrations agreed upon: 5.6, 10, 18, 32 and 56 mg/L.

8.5 Study Dates:

8.5.1 Proposed starting date of definitive study Oct. 1984

8.5.2 Proposed completion date of definitive study Nov. 1984

8.6 ABC Study Personnel:

8.6.1 Study Director

Alan D. Forbis — Name
Aquatic Biologist III — Title

8.6.2 Aquatic Supervisor

Carl M. Thompson	Supervisor, Aquatic Toxicology
Name	Title

8.7 GLP Compliance (check the most appropriate):

EPA-FIFRA ✓; EPA-TSCA ___; FDA ___; OECD ___; Other ___.

8.8 Protocol Approvals. The following is to be signed by the appropriate study personnel:

8.8.1 Sponsor's Study Director

Richard C. Parker	Prod. Tox. Specialist	12/12/84
Name	Title	Date

8.8.2 ABC's Study Director

Adam Fabi	Aquatic Biologist III	10/9/84
Name	Title	Date

8.8.3 ABC's Group Leader

(Michael Williams/CT)	Group Leader Animal Toxicology	10/9/84
Name	Title	Date

8.9 Authorization to return the test material and sample:

8.9.1 Sponsor's authorized agent to receive the test material and sample.

Name	Title

8.9.2 Shipping Address

Company

Street Address

City State Zip Code

Phone Number

8.9.3 Hazardous shipment information

Proper Shipping Name

Class of Restricted Article (e.g. flammable, poison, radioactive, etc.)

TABLE 1: Guide to selection of experimental concentrations based on progressive bisection of intervals on logarithmic scale.

Col. 1	Col. 2	Col. 3	Col. 4	Col. 5
10.0	10.0	10.0	10.0	10.0
				8.7
			7.5	7.5
				6.5
		5.6	5.6	5.6
				4.9
			4.2	4.2
				3.7
3.2	3.2	3.2	3.2	3.2
				2.8
			2.4	2.4
				2.1
		1.8	1.8	1.8
				1.55
			1.35	1.35
				1.15
1.0	1.0	1.0	1.0	1.0

TABLE 2: Chemical characteristics of well water used by ABC's Aquatic Toxicology Division.

Parameters	Concentration
Temperature	15-20°C[b]
Dissolved Oxygen[a]	9.2-10.1 ppm[b]
pH	7.8-8.3[b]
Hardness ($CaCO_3$)	225-275 ppm[b]
Alkalinity ($CaCO_3$)	325-375 ppm[b]
Conductivity	700 µmhos/cm
NH_3-N	0.60 ppm
NO_3-NO_2-N	0.20 ppm
Ortho-Phosphate	0.10 ppm
Aluminum	<0.010 ppm
Arsenic	<0.0005 ppm
Cadmium	<0.002 ppm
Chromium	<0.006 ppm
Cobalt	<0.003 ppm
Copper	<0.002 ppm
Iron	<0.004 ppm
Lead	0.017 ppm
Mercury	0.0008 ppm
Nickel	<0.013 ppm
Silver	<0.0004 ppm
Zinc	0.001 ppm
Measured organophosphorus pesticides	c
Measured organochlorine pesticides plus PCB's	c

[a]After aeration.

[b]Represents seasonal variation, with the monthly range not exceeding 10%.

[c]See report appendix for individual analyses.

9.0 REFERENCES

(1) U.S. Congress. 1976. Toxic Substances Control Act. Public Law 94-469. Federal Register, October 11, 1976. 2003-2051.

(2) U.S. Environmental Protection Agency. 1978. Registration of pesticides in the United States, proposed guidelines. Federal Register, July 10, 1978: 29696-29741.

(3) U.S. Congress. 1977. Clean Water Act of 1977. Public Law 95-217. Federal Register, December 27, 1977: 1566-1611.

(4) (a) U.S. Food and Drug Administration. 1978. Nonclinical Laboratory Studies, Good Laboratory Practice Regulations (21 CFR, Part 58). Federal Register, Vol. 43, No. 247: 59986-60025.

(b) U.S. Environmental Protection Agency. 1983. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160). Federal Register, Vol 48, No. 230: 53946-53969.

(c) U.S. Environmental Protection Agency. 1983. Toxic Substances Control; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 792). Federal Register, Vol. 48; No. 230:53922-53944.

(d) Organization for Economic Cooperation and Development. 1981. OECD Guidelines for Testing of Chemicals, Principles of Good Laboratory Practice Annex 2, C(81) 30(Final):7-28.

(5) Committee on Methods for Toxicity Tests with Aquatic Organisms. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-009, April, 1975. 61 p.

(6) American Public Health Association. 1980. Standard Methods for the Examination of Water and Wastewater. 15th ed. Washington, D.C. 1134 p.

(7) American Society for Testing and Materials. 1980. Standard practice for conducting basic acute toxicity tests with fish, macroinvertebrates and amphibians. May, 1980, ASTM Committee E-35.23. 25 p.

(8) American Society for Testing and Materials. 1981. Proposed standard practice for conducting renewal life cyle toxicity tests with the Daphnid, Daphnia magna. Draft 8, ASTM Committee E-35.21. 29 p.

(9) Litchfield, J. T., Jr. and F. Wilcoxon. 1949. A Simplified Method of Evaluating Dose-Effect Experiments. Jour. Pharm. Exp. Ther. 96:99-113.

(10) Stephan, C. 1977. Methods for calculating an LC_{50}, p. 65-84. In F. L. Mayer and J. L. Hamelick (eds.). Aquatic Toxicology and Hazard Evaluation. ASTM Special Technical Publication 634. ASTM. Philadelphia.

(11) Stephan, C. E., K. A. Busch, R. Smith, J. Burke and R. W. Andrew. 1978. A computer program for calculating an LC_{50}. U. S. Environmental Protection Agency, Duluth, Minnesota, pre-publication manuscript, August, 1978.

(12) Pennak, R. W. 1978. Fresh-Water Invertebrates of the United States, 2nd Ed. 365 p.

Monsanto

DEPARTMENT OF ...ICINE & ENVIRONMENTAL HEALTH
...IPLE SUBMISSION
STUDY NO. AR-84-386 327, 328

PLEASE TYPE OR PRINT

I. SAMPLE IDENTIFICATION

PRODUCT NAME(S)	CHEMICAL NAME
Azomethine	Benzeneamine,2,6-diethyl N-methylene

P NO.	CHEM. ABSTRACTS REG. NO.	LOT OR I.D. NO., NOTE BOOK REF.
34781	35202-08-8	116-200

AMPLE SIZE	PURITY	SAMPLE DISPOSITION	
100 ml	99.2%	☒ DISCARD ☐ RETURN	☐ HOLD, NOTIFY BEFORE DISCARDING

II. CHEMICAL AND PHYSICAL PROPERTIES

TRUCTURAL FORMULA (COMPOSITION OF MIXTURE)

CONFIDENTIAL

MPIRICAL FORMULA	MOLECULAR WEIGHT	COLOR/PHYSICAL STATE
[illegible]	161.24	Light yellow liquid

ELTING POINT	BOILING POINT	VAPOR PRESSURE	SPECIFIC GRAVITY
		[illegible] @ 100°F	

OLUBILITY: WATER	ORGANIC SOLVENTS (SPECIFY)	OTHER
[illegible]	acetone, chloroform	

HYSICAL/CHEMICAL HAZARDS

- ☐ FLAMMABLE
- ☐ EXPLOSIVE
- ☐ OXIDIZER
- ☐ UNSTABLE TO LIGHT
- ☐ UNSTABLE TO HEAT
- ☐ UNSTABLE TO WATER
- ☐ POLYMERIZES READILY
- ☐ HYGROSCOPIC
- ☐ REACTS WITH _____
- ☐ NO SPECIAL PRECAUTIONS
- ☐ OTHER (SPECIFY)

THER PROPERTIES, SPECIAL REQUIREMENTS (SPECIFY)

stable

III. TOXICITY INFORMATION

ORAL LD_{50} _____
DERMAL LD_{50} _____
EYE IRRITATION _____
SKIN IRRITATION _____
SINGLE VAPOR INHALATION _____

_____ NO INFORMATION AVAILABLE
_____ SEE ATTACHMENT
_____ OTHER (SPECIFY)

IV. DOCUMENTATION

OMPOSITION & PURITY

- ☐ STATED ABOVE
- ☐ SEE ATTACHMENT
- ☒ STAFF TOXICOLOGY FILE

METHOD OF SYNTHESIS

- ☐ SEE ATTACHMENT
- ☐ STAFF TOXICOLOGY FILE
- ☐ OPERATING CO. FILE

UBMITTED BY: (Name, Location, Phone No., Date)	DMEH CONTACT: (Name, Location, Phone No., Date)
[illegible] Bldg. C33C, -124 2/22/85	Tim Long, C2ND, -2551 2/22/85

V. EHL USE

UDY NUMBER(S)	SUBSTANCE IDENTIFICATION CODE

WHITE COPY—LABORATORY COPY; YELLOW COPY—DMEH FILE COPY; PINK COPY—REQUESTOR'S COPY

3078 (REV. 1/80)

MASTER FILE
PROJECT NO. ABC 3871

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65205
Shipping Address: 7200 East ABC Lane, Columbia, MO 65202
(314) 474-8579 • Telex 821 814 • Answer Back (ABCLAB UD)

APR 2 1985

Static Acute Toxicity Report
#32233

Acute Toxicity of Azomethine (2,6-diethylphenyl) to Bluegill Sunfish (Lepomis macrochirus)

Monsanto Study Number AB-84-387

Submitted To:

Monsanto Chemical Company
Attn: Dr. Richard C. Dirks
800 N. Lindbergh Blvd.
St. Louis, MO 63167

March 27, 1985

Submitted By: Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P. O. Box 1097
Columbia, Missouri 65205

Prepared By:

William A. McAllister — 3-27-85 Date
William A. McAllister
Biologist III/Study Director

Paul Cohle — 3/29/85 Date
Paul Cohle
Biologist/Culturist II

Jane Bowman — 3-29-85 Date
Jane Bowman
Biologist I

Approved By:

Carl M. Thompson — 3-29-85 Date
Carl M. Thompson
Supervisor Aquatic Toxicology

Kevin F. Yount — 3/29/85 Date
Kevin F. Yount
Quality Assurance Officer

Michael Williams — 3-29-85 Date
Michael Williams, Ph.D.
Group Leader, Animal Toxicology

/dlj

Monsanto

FROM (NAME—LOCATION—PHONE) Dept. of Medicine & Environmental Health

DATE : July 29, 1985 CP 84 781

SUBJECT : 2,6-Diethylphenyl Azomethine Acute Aquatic Toxicity Study - Bluegill Sunfish

REFERENCE : (AB-84-387; ABC #32233)

TO : L.A. Suba
C2SC

cc. E.E. Debus - C2SC
S.F. Dirks
T.W. Fuhremann
R.L. Harness - C2SB
R.W. Street - C2SC
Toxdata

The results of the referenced acute static aquatic toxicity study with 2,6-diethylphenyl azomethine (lot 116-200, 99.2% pure) are summarized below. The study and quality assurance reviews were conducted by Analytical Bio-Chemistry Laboratories, Inc.

LC50 (mg/l)		
24 hr	48 hr	96 hr
40	40	38

The 96 hr no observable adverse effect level (NOEL) was 10 mg/l.

The water temperature, dissolved oxygen concentration, pH and ammonia concentration were within acceptable limits throughout the study.

On the basis of this test, 2,6-diethylphenyl azomethine is considered to be slightly toxic to bluegill sunfish.

Joel Kronenberg

Joel M. Kronenberg, PhD
Senior Product Toxicologist
Monsanto Company
Department of Medicine and
Environmental Health

dlj

SUMMARY

The acute toxicity of Azomethine (2,6-diethylphenyl) to Bluegill Sunfish (Lepomis macrochirus) was assessed using the methods outlined by the Committee on Methods for Toxicity Tests with Aquatic Organisms. Water quality parameters of temperature, dissolved oxygen and pH were measured throughout the test and were within acceptable limits.

As a method precision check, the bluegill sunfish were challenged with a reference compound, Antimycin A. The estimated 96-hour LC_{50} and 95% confidence limits (C.I.) were within the 95% confidence limits reported in the literature. Culture and acclimation records indicated that the fish were in good condition for testing.

The study was conducted at the following nominal concentrations of Azomethine: 5.6, 10, 18, 32, and 56 mg/l. Ten fish, with a mean weight of 0.28 (±0.06) g and a mean standard length of 23 (±1.8) mm, were exposed to each test concentration and control.

The results of the four day static fish toxicity studies using Azomethine and Antimycin A are summarized below. The 24 and 48-hour LC_{50} values were also determined.

Compound	96-hour LC_{50} (95% C.I.)
Azomethine	38 mg/l (18-56 mg/l)
Antimycin A	10×10^{-5} mg/l ($7.5\text{-}14 \times 10^{-5}$ mg/l)

Also, the results indicated a 96-hour, no-observed effect concentration of 10 mg/l, which was based on the lack of mortality and abnormal effects. Abnormal effects of mortality, surfacing, loss of equilibrium, light discoloration, fish on the bottom of test chambers, and quiescence were observed during the 96-hour exposure period.

INTRODUCTION

This static bioassay was performed by the Aquatic Toxicology Division of Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri, for Monsanto Chemical Company from March 14 to March 18, 1985, as authorized in a letter of November 20, 1984 (Appendix). The purpose of this test was to determine the 24, 48 and 96-hour LC_{50} levels for Azomethine to bluegill sunfish (Lepomis macrochirus). A preliminary range-finding study was conducted from February 22 to February 26, 1985 to determine the concentration range for the definitive bioassay. The study was conducted following the procedures outlined in ABC Protocol Number 7601 (Appendix), as approved by Dr. Richard C. Dirks, Monsanto Chemical Company, on October 10, 1984.

METHODS AND MATERIALS

The procedures for static bioassay, as described in Methods of Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians (1) and Standard Methods for Examination of Water and Wastewater (3) were used in this experiment. The bluegill sunfish (ABC Lot #4684) used in the test were obtained from Osage Catfisheries, Inc. in Osage Beach, Missouri. The fish were identified to species using the taxonomic keys developed by Eddy (4). All test fish were held in culture tanks on a 16-hour daylight photoperiod and observed for at least fourteen days prior to testing. Fish culture techniques used were basically those described by Brauhn et al. (5). A daily record of fish observations during the holding period, along with any prophylactic or therapeutic disease treatments, is included in the Appendix. During this period, the fish received a standard commercial fish food (Rangen's) daily until 48 hours prior to testing at which time feeding was discontinued. The bluegill sunfish used for this experiment had a mean weight of 0.28 (±0.06) g and a mean standard length of 23 (±1.8) mm. Weight and length measurements were made on the control group of fish at the termination of the test and are included in the Appendix.

The static fish bioassay was conducted in five gallon glass vessels containing 15 liters of soft reconstituted water composed of the following compounds in the amounts stated per liter of deionized water:

48 mg $NaHCO_3$
30 mg $CaSO_4 \cdot 2\ H_2O$
30 mg $MgSO_4$
2 mg KCl

This reconstituted water was prepared to yield a total hardness of 40-45 mg/l as $CaCO_3$, a total alkalinity of 30-35 mg/l as $CaCO_3$ and an initial pH of 7.2 to 7.6. The 0-hour measured control water parameters of this dilution water were dissolved oxygen 9.4 mg/l and pH 7.5. The well water source from which this dilution water was prepared had the characteristics shown in Table 1.

The test vessels were kept in a water bath at 22°C (±1.0). The test fish were acclimated to the dilution water and test temperature and

held without food for 48-96 hours prior to testing. An acclimation record is included in the Appendix.

A 96-hour range-finding test was conducted to determine the concentration range for the definitive study. The preliminary test concentrations were set at 10 and 100 mg/l. Based on the results of preliminary testing, five concentrations of the test compound, ranging in a logarithmic series from 5.6 to 56 mg/l, with ten fish per concentration were selected for the definitive bioassay. Also included was a dilution water control. The fish were added to the test chambers by random assignment within 30 minutes after addition of test material. All concentrations were observed once every 24 hours for mortality and abnormal effects such as surfacing, loss of equilibrium and dark discoloration.

The Azomethine (2,6-diethylphenyl) test compound was received on February 18, 1985, in good condition. The sample upon receipt was observed to be a yellow liquid and was stored at room temperature in the dark. Sample purity was specified as 99.2 % on the sample submission form. Test concentrations were prepared based on the total compound. The test concentrations were obtained by transferring appropriate weights of test compound directly to the test chambers. All test solutions were observed to contain an oily surface film, with globules of material noted on the bottom of the 32 and 56 mg/l test chambers. All standard weights and dilution values are listed in the Appendix.

Statistical analysis of the concentration vs. effect data (generally mortality) was obtained by employing a computerized LC_{50} program developed by Stephan et al. (7). This program calculated the LC_{50} statistic and its 95 percent confidence limits using the binomial, the moving average, and the probit tests. Three different methods of analyzing the data were used since no one method of analysis is appropriate for all possible sets of data that may be obtained. The method of calculation selected for presentation in this report was that which gave the narrowest confidence limits for the LC_{50} (6, 7).

RESULTS

The results of the 96-hour static toxicity test with Bluegill Sunfish (Lepomis macrochirus) exposed to Azomethine (2,6-diethylphenyl) are presented in Table 2. The 24, 48 and 96-hour LC_{50} values for Azomethine were 40, 40, and 38 mg/l, respectively. All results were based on the nominal concentrations of 5.6, 10, 18, 32, and 56 mg/l. The no-effect concentration based on the lack of mortality and abnormal effects after 96 hours of exposure was 10 mg/l. The abnormal effects of mortality, surfacing, loss of equilibrium, light discoloration, fish on the bottom of test chambers, and quiescense were observed in the 18, 32, and 56 mg/l test concentrations during the 96-hour exposure period.

The bluegill sunfish were challenged with a reference compound, Antimycin A, to verify method precision. The 96-hour LC_{50} for bluegill sunfish exposed to Antimycin A was 10×10^{-5} mg/l and was within the 95%

confidence intervals reported in the literature (2). An examination of the fish culture and acclimation records for this test indicated that the fish were in good condition for testing (Appendix).

Nominal test concentrations, mortality rates, and water quality data are presented in Table 3. The dissolved oxygen concentrations ranged from 5.2 to 9.6 mg/l during the test. These values represented 60 and 109% saturation at 23 and 22°C, respectively, and were considered adequate for testing (1). The pH values ranged from 7.0 to 7.6, with the pH levels in the test solutions remaining consistent with the control throughout the test .

The study was conducted following the intent of the Good Laboratory Practice Regulations (8) and the final report was reviewed by Analytical Bio-Chemistry Laboratories' Quality Assurance Unit. All original raw data was provided to Monsanto Chemical Company, with a copy retained at Analytical Bio-Chemistry Laboratories.

TABLE 1

Chemical Characteristics of Well Water used by
ABC's Aquatic Toxicology Division

Parameter	Concentration
Temperature	15-20°C[b]
Dissolved Oxygen[a]	9.2-10.2 ppm[b]
pH	7.8-8.3[b]
Hardness ($CaCO_3$)	225-275 ppm[b]
Alkalinity ($CaCO_3$)	325-375 ppm[b]
Conductivity	700 µmhos/cm
NH_3-N	0.60 ppm
NO_3-NO_2-N	0.20 ppm
Ortho-Phosphate	0.10 ppm
Aluminum	<0.010 ppm
Arsenic	<0.0005 ppm
Cadmium	<0.002 ppm
Chromium	<0.006 ppm
Cobalt	<0.003 ppm
Copper	<0.002 ppm
Iron	<0.004 ppm
Lead	0.017 ppm
Mercury	0.0008 ppm
Nickel	<0.013 ppm
Silver	<0.0004 ppm
Zinc	0.001 ppm
Measured organophosphorus pesticides	c
Measured organochlorine pesticides plus PCB's	c

[a]After aeration.

[b]Represents seasonal variation, with the monthly range not exceeding 10%.

[c]See report appendix for individual analyses.

TABLE 2

The Acute Toxicity of Azomethine (2,6-diethylphenyl) and Antimycin A to Bluegill Sunfish (Lepomis macrochirus)

Compound	LC_{50} in milligrams/liter (ppm)		
	24 hours	48 hours	96 hours
Azomethine[a]	40 (32-56)[b]	40 (32-56)	38 (18-56)
Antimycin A[c]	12×10^{-5}(1) d	10×10^{-5}(1) ($7.5\text{-}14 \times 10^{-5}$)	10×10^{-5}(1) ($7.5\text{-}14 \times 10^{-5}$)

[a]Bioassay as conducted at 22°C (±1.0), mean fish weight and length, 0.28 (±0.06) g and 23 (±1.8) mm.

[b]95% confidence limits.

[c]Antimycin A standard obtained from Sigma Chemical Company, Type III, crystalline, Lot 89C-0588.

[d]Insufficient data for calculation of 95% confidence limits.

The 96-hour no-effect concentration was 10 mg/l, based on the lack of mortality and abnormal effects.

All values were rounded to two significant figures following ABC S.O.P. #8.7.

LC_{50} calculated using:

(1) Binomial Method
(2) Moving Average Method
(3) Probit Method

TABLE 3

Mortality Rates and Water Quality Measurements During the Acute Toxicity Test of Azomethine (2,6-diethylphenyl) to Bluegill Sunfish (Lepomis macrochirus)

Nominal Concentration (mg/l)	Percent Mortality Hours			Water Quality								
				0 hours			48 hours			96 hours		
	24	48	96	Temp. °C	D.O.[a] mg/l	pH[b]	Temp. °C	D.O. mg/l	pH	Temp. °C	D.O. mg/l	pH
Control	0	0	0	22	9.4	7.5	22	7.1	7.0	23	6.2	7.2
5.6	0	0	0	22	9.4	7.5	22	7.2	7.3	23	6.3	7.2
10	0	0	0									
18	0	0	0									
32	10	10	20				22	7.0	7.2	23	5.2	7.2
56	100	100	100	22	9.6	7.6						

[a]Dissolved oxygen concentrations - Dissolved Oxygen Probe (YSI Model 54).

[b]pH - pH Probe (Corning Model 476182) used with a Corning Model 125 pH and mV meter.

NOTE: Dissolved oxygen saturation at the test temperatures of 22 and 23°C is 8.8 and 8.7 mg/l respectively.

LITERATURE CITED

(1) Committee on Methods for Toxicity Tests with Aquatic Organisms (C. E. Stephan, Chairman). 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-009, April, 1975. 61 p.

(2) Berger, B. L., R. E. Lennon and J. W. Hogan. 1969. Laboratory Studies on Antimycin A as a fish toxicant. U. S. Department of Interior, Investigations in Fish Control No. 26. 21 p.

(3) American Public Health Association. 1980. Standard Methods for the Examination of Water and Wastewater. 15th ed. Washington, DC. 1134 p.

(4) Eddy, Samuel. 1969. The Freshwater Fishes. 2nd ed. W. C. Brown Company, Dubuque, IA. 286 p.

(5) Brauhn, J. L. and R. A. Schoettger. 1975. Acquisition and Culture of Research Fish: Rainbow Trout, Fathead Minnows, Channel Catfish and Bluegills. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-011, May, 1975. 45 p.

(6) Stephan, C. 1977. Methods for calculating an LC_{50}, p. 65-84. In F. L. Mayer and J. L. Hamelink (eds.). Aquatic Toxicology and Hazard Evaluation. ASTM Special Technical Publication 634. ASTM. Philadelphia.

(7) Stephan, C. E., K. A. Busch, R. Smith, J. Burke and R. W. Andrew. 1978. A computer program for calculating an LC_{50}. U. S. Environmental Protection Agency, Duluth, Minnesota, pre-publication manuscript, August, 1978.

(8) (a) U.S. Food and Drug Administration. 1978. Nonclinical Laboratory Studies, Good Laboratory Practice Regulations (21 CFR, Part 58). Federal Register, Vol. 43, No. 247:59986-60025.

(b) U.S. Environmental Protection Agency. 1983. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160). Federal Register, Vol. 48, No. 230:53946-53969.

(c) U.S. Environmental Protection Agency. 1983. Toxic Substances Control; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 792). Federal Register, Vol. 48; No. 230:53922-53944.

(d) Organization for Economic Cooperation and Development. 1981. OECD Guidelines for Testing of Chemicals, Principles of Good Laboratory Practice Annex 2, C(81) 30(Final):7-28.

Quality Assurance Statement for final report #32233 entitled, "Acute Toxicity of Azomethine to Bluegill Sunfish (Lepomis macrochirus)," for Dr. Richard C. Dirks, Monsanto Chemical Company.

In accordance with ABC Laboratories intent that all studies conducted at our facilities are designed and function in conformance with good laboratory practice regulations and the protocols for individual laboratory studies, an inspection of the final report for Azomethine was conducted and found to be in an acceptable form by a member of our Quality Assurance Unit. An inspection of the daily mortality rate of the test organisms prior to the initiation of the study indicated they were in good health and should not bias the observed mortality in the study. A procedure audit, observing 96-hour daily observations, was conducted on March 18, 1985. No deviations were noted. A final inspection of all data and records on March 25, 1985 indicated that the report submitted to you is an accurate reflection of the study as it was conducted by ABC Laboratories.

Should you have any questions relating to the information provided in this statement or the function of our Quality Assurance Unit, please contact the Quality Assurance Unit at your convenience.

Kevin F. Yount 3/29/85
Kevin F. Yount Date
Quality Assurance Officer

Study Compliance Statement for ABC report #32233 entitled, "Acute Toxicity of Azomethine to Bluegill Sunfish (Lepomis macrochirus)," for Dr. Richard C. Dirks, Monsanto Chemical Company.

In accordance with ABC Laboratories' intent that all aquatic toxicity tests conducted by our facility follow good laboratory practices, ABC's study director for the above test herein confirms that the study was conducted in compliance with the U.S. E.P.A. Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160).

All original raw data was sent to Monsanto Chemical Company, with a copy retained at Analytical Bio-Chemistry Laboratories.

William A. McAllister 3-29-85
William A. McAllister Date
ABC Study Director

APPENDIX - RAW DATA

NOTE: Some of the records which appear in this raw data appendix have been provided as photocopies of original records on file at ABC. This has been done by necessity for certain data which are used commonly in several studies at ABC. Such records include reference toxicity test data, standard solution preparations, organism culture logs, and well water chemical screen results.

MORTALITY AND BEHAVIORAL OBSERVATIONS

☒ Definitive ☐ Preliminary

Test Material: Ayrmethrin
Study No.: ~~32236~~ 4 32233
Protocol No.: 7601
ABC Study
Director: W. A. McAllister

Lab Form No.: 32

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Test species: ☒ L. macrochirus ☐ S. gairdneri ☐ _____ (Lot #Y6F4)
No./Vessel: 10 Dil. Water: ☒ Recon. ☐ Well
Acclimation Mortality: < 1%
Date Initiated: 3-14-85 (12:10 PM) Date Terminated: 3-18-85

Test Conc. mg/l (ppm)	24 Hours		48 Hours		72 Hours		96 Hours	
	Dead	Obs.	Dead	Obs.	Dead	Obs.	Dead	Obs.
Control	0	N	0	N	0	N	0	N
5.6	0	N	0	N	0	N	0	N
10	0	N	0	N	0	N	0	N
18	0	2 LD/OB; 30B 5Q	0	2 LD/OB; 3 OB, 3Q	0	7 OB/Q; 3Q	0	7 OB/Q; 3Q
32	1	2 LOE/OB; 15 SUR 4 OB; 2Q	1	2 LOE/OB; 2 OB/Q	2	2 LOE/OB; 2 LOE; 4 OB/Q	2	1 SUR/Q; 3 OB/LOE; 4 OB/Q
56	10	—	10	-	10	—	10	-
Observer	JHB		JHB		JHB		JHB	
Date	3-15-85 10:30 AM		3-16-85 1:40 PM		3-17-85 2:00 PM		3-18-85 10:25 AM	

Remarks: N = Normal; LOE = Loss of Equilibrium; Q = Quiescent
SUR = Surfacing; LD = Light Discoloration; DK = Dark Discoloration; OB = On Bottom
All test levels 5.6 - 56 had surface film after addition & mixing of test compound. Also, 32 & 56 mg/l had globules of compound on bottom of test chamber. P.C. 3/14/85 2 D = Light Discoloration
at 96 hour all test levels, 5.6 to 32 ppm had surface film JHB 3-18-85
4 Entry Error P.C. 3/18/85

Prepared By: Jane Bowmer Date: 3-14-85
Checked By: Carl M. Thompson Date: 3-20-85

WATER QUALITY

Test Material: Azomethine
Study No.: 32233
Protocol No.: 7601
ABC Study Director: W. A. McAllister

Lab Form No.: 28a

Analytical Bio-Chemistry Laboratories
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Concentration mg/l	3-14-85 Day 0 JHB				3-16-85 Day 2 JHB				3/18/85 Day 4 PC				Day			
	Temp. °C	D.O.[a] mg/l	pH[b]		Temp. °C	D.O. mg/l	pH		Temp. °C	D.O. mg/l	pH		Temp. °C	D.O. mg/l	pH	
Control	22	9.4	7.5		22	7.1	7.0		23	6.2	7.2					
5.6	22	9.4	7.5		22	7.2	7.3		23	6.3	7.2					
10																
18																
32					22	7.0	7.2		23	5.2	7.2					
56	22	9.6	7.6													

[a]Dissolved oxygen concentrations-Dissolved Oxygen Probe (YSI Dissolved Oxygen System Model 54).
[b]pH-pH Probe (Corning Model 476182) used with Corning Model 125 pH and mV meter.

Remarks:

Prepared by: Jane Bowman Date: 3-14-85
Checked by: [signature] Date: 3 20-85

STUDY# 032233 Pg 0012 of 0053

5.6-56

MORTALITY AND BEHAVIORAL OBSERVATIONS

☐ Definitive ☑ Preliminary

Test Material: Azymethine
Study No.: 32233
Protocol No.: 7601
ABC Study
Director: R.A. McAllister

Lab Form No.: 32
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Test species: ☑ ~~L.~~ macrochirus ☐ S.gairdneri ☐ _____ (Lot # 4684)
No./Vessel: 5 Dil. Water: ☑ Recon. ☐ Well
Acclimation Mortality: 0
Date Initiated: 2-22-85 Date Terminated: 2-26-85

Test Conc. mg/l (ppm)	24 Hours		48 Hours		72 Hours		96 Hours	
	Dead	Obs.	Dead	Obs.	Dead	Obs.	Dead	Obs.
~~Control~~								
10	0	N	0	N	0	N	0	N
100	5	—	5	—	5	—	5	—
Observer	AF		AF		PC		JHB	
Date	2/23/85		2/27/85		2/25/85		2-26-85	

Remarks: N = Normal; LOE = Loss of Equilibrium; Q = Quiescent
SUR = Surfacing; DK = Dark Discoloration; OB = On Bottom
At 0 hrs only duplicate on surface of test chamber in 100 ppm test chamber JHB 2-22-85
Flaky surface film in 100 mg/l test chamber at 72 hours P.C. 2/25/85

Prepared By: Jane Downum Date: 2-22-85
Checked By: Cathy Thompson Date: 3-20-85

PREPARATION OF TEST CONCENTRATIONS (weight/volume)

Test Material: azamethiphos
Study No.: 32233
Protocol No.: 7601
Lot No.: — Purity: — %
ABC Study Director: m.a. mcallister

Lab Form No.: 18
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane,
P.O. Box 1097
Columbia, Missouri 65205

Sample Number	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Purity Correction	Dilution Volume (l)	Final Conc. (mg/l)
1	0.15	0.000	0.15	—	15	10
2	1.5	0.000	1.5	—	15	100
3						
4						
5						
6						

Balance Calibration: 0.500 g (class C wt.) + 0.000 g (tare) = 0.500 g (final Wt.)

Prepared By: Jane Bowman Date: 2-22-85
Checked By: Paul Cole Date: 2/22/85

Sample Number	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Purity Correction	Dilution Volume (l)	Final Conc. (mg/l)
1						
2						
3						
4						
5						
6						
7						
8						

Balance Calibration: _____ g (class C wt.) + _____ g (tare) = _____ g (final Wt.)

Prepared By: _____ Date: _____

Checked By: _____ Date: _____

PREPARATION OF TEST CONCENTRATIONS (weight/volume)

Test Material: Azamethiphos
Study No.: 32233
Protocol No.: 7601
Lot No.: — Purity: — %
ABC Study Director: W.A. McAllister

Lab Form No.: 18

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane,
P.O. Box 1097
Columbia, Missouri 65205

Sample Number	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Purity Correction	Dilution Volume (l)	Final Conc. (mg/l)
1	0.084	0.000	0.084	—	15	5.6
2	0.15	0.000	0.15	—	15	10
3	0.27	0.000	0.27	—	15	18
4	0.48	0.000	0.48	—	15	32
5	0.84	0.000	0.84	—	15	56
6						

Balance Calibration: 0.500 g (class C wt.) + 0.000 g (tare) = 0.501 g (final Wt.)

Prepared By: Jane Bowman Date: 3-14-85
Checked By: Paul Cobb Date: 3/14/85

Sample Number	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Purity Correction	Dilution Volume (l)	Final Conc. (mg/l)
1						
2						
3						
4						
5						
6						
7						
8						

Balance Calibration: _____ g (class C wt.) + _____ g (tare) = _____ g (final Wt.)

Prepared By: _____ Date: _____

Checked By: _____ Date: _____

DEFINITIVE CONCENTRATION NOTIFICATION

Firm: Monsanto
Address: 800 N. Lindbergh Blvd.
City/State/Zip: St. Louis, Mo.
Phone: (314) 694-8832

Lab Form No.: 186

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, MO 65202

Sponsor's Study Director: Joel Kronenberg
Person notified: same(✓) Other:

Date of Notification: 2/26/93

Notification of preliminary testing results with the following definitive test levels agreed upon:

Test Material	ABC #	Test Species	Test Conc. (mg/l)
Azomethine	32233	Bluegill Sunfish	5.6, 10, 18, 32 & 56

Notified By: Joel Cohli Date: 2/26/93

STUDY# 032233 pg 0016 of 0053

TEST ORGANISM MEASUREMENTS

Test Material: Azomethine
Study No.: 32233
Protocol No.: 7601
ABC Study Director: W. A. McAllister

Lab Form No.: 24

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, MO 65205

Test Species: Bluegill Sunfish Lot No.: 4684
Source: Osage Catfisheries, Osage Beach, Mo.
Date Measured: 3-18-85 Group Measured: Control

Number	Standard Length (mm)	Weight (g)
1	23	0.265
2	20	0.217
3	20	0.183
4	22	0.269
5	25	0.407
6	25	0.329
7	23	0.253
8	24	0.263
9	22	0.293
10	22	0.294
Mean (±Std. Dev.)	* 23 (± 1.8)	* 0.28 (± 0.06)

Remarks: * mean weight & length measurements calculated by Carl Thompson (CT 3-20-85)

Prepared By: William G. McAllister Date: 3-18-85
Checked By: Alan E. Fahrig Date: 3/20/85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Azomethine

Study No.: 32233

Test Species: Bluegill Sunfish

Exposure Period: 24~~48~~ Hrs

ABC Study Director: W. A. McAllister

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
56	10	10	100	.0976563
32	10	1	10	1.07422
18	10	0	0	.0976563
10	10	0	0	.0976563
5.6	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT 32 AND 56 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THIS LIMIT IS >95 PERCENT

AN APPROXIMATE LC50 OF 39.906 PPM IS OBTAINED BY NONLINEAR INTERPOLATION BETWEEN 32 AND 56

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE OR PROBIT METHOD CAN GIVE STATISTICALLY SOUND RESULTS.

****

Method Reported:

☒ Binomial ☐ Moving Average ☐ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: [signature] Date: 3-20-85

Checked By: [signature] Date: 3-20-85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Azomethine
Study No.: 32233
Test Species: Bluegill Sunfish
Exposure Period: 72 & 96 hrs
ABC Study Director: W. A. McAllister

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
56	10	10	100	.0976563
32	10	2	20	5.49875
18	10	0	0	.0976563
10	10	0	0	.0976563
5.6	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT 18 AND 56 CAN BE USED AS

STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS BECAUSE
THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THIS LIMIT IS >95 PERCENT
AN APPROXIMATE LC50 OF 38.1333 PPM IS OBTAINED BY

NONLINEAR INTERPOLATION BETWEEN 32 AND 56

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING
AVERAGE OR PROBIT METHOD CAN GIVE STATISTICALLY SOUND RESULTS.

****

Method Reported:

☒ Binomial ☐ Moving Average ☐ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: [signature] Date: 3-20-85
Checked By: [signature] Date: 3-20-85

MORTALITY AND BEHAVIORAL OBSERVATIONS

☑ Definitive ☐ Preliminary

Test Material: Antimycin A
Study No.: Method Validation Test
Protocol No.: 7601
ABC Study
Director: M. A. McAllister

Lab Form No.: 32
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Test species: ☑ L. macrochirus ☐ S. gairdneri ☐ _____ (Lot #468Y)
No./Vessel: 10 Dil. Water: ☒ Recon. ☐ Well
Acclimation Mortality: 0
Date Initiated: 2-22-85 Date Terminated: 2-26-85

Test Conc. mg/l (ppm)	24 Hours		48 Hours		72 Hours		96 Hours	
	Dead	Obs.	Dead	Obs.	Dead	Obs.	Dead	Obs.
Control	0	N	0	N	0	N	0	N
Solvent Control	0	N	0	N	0	N	0	N
0.000014	0	N	0	N	0	N	0	N
0.000024	0	N	0	N	0	N	0	N
0.000042	0	N	0	N	0	N	0	N
0.000075	0	N	0	N	0	N	0	7 SUR; 3N
0.00014	7	3 SUR	10	—	10	—	10	—
Observer	AF		AF		PC		JWB	
Date	2/23/85		2/24/85		2/25/85		2-26-85	

Remarks: N = Normal; LOE = Loss of Equilibrium; Q = Quiescent
SUR = Surfacing; DK = Dark Discoloration; OB = On Bottom

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By C. Wilhelm date 3-20-85

Prepared By: Jane Bowman Date: 2-22-85
Checked By: Carl J. Hansen Date: 3-20-85

COMPOUND PREPARATIONS

Test Material: Artemycin A
Study No.: Method Validation Test
Protocol No.: 7601
Lot No.: 89C-0588 Purity: — %
ABC Study Director: m.a. mc allister

Lab Form No.: 27
Analytical Bio-Chemistry Lab
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Preparation of Concentrated Working Standard

Date 3-7-84 Biologist Paul Cobb
Final Gross Weight 9.5454 g
Tare Weight 9.5154 g
Net Weight 0.0300 g
Adj. Net Weight — g*
*Corrected for purity of primary standard.
Dilution Volume 100 (acetone) ml
Concentration 0.30 mg/ml
Balance calibrated with class C weights:
0.0250 g (class C) + 20.0005 g (tare) = 20.0255 g (final wt.)

Preparation of ~~Preliminary Test~~ Working Stock Concentrations

Date 3-7-84 Biologist Paul Cobb

	Conc. of Work. Std. (mg/ml)	Aliq. Vol. (ml)	Dilution Vol. ~~(l)~~	Final Conc. ~~(mg/l)~~
1.	0.30	0.5	100 ml	0.0015 mg/l
2.				
3.				

Preparation of Concentrated ~~Working Standard~~

"This is an exact copy of The original document"
By [illegible] date 3-26-85

Date ____ Biologist ____
Final Gross Weight ____ g
Tare Weight ____ g
Net Weight ____ g
Adj. Net Weight ____ g*
*Corrected for purity of primary standard.
Dilution Volume ____ ml
Concentration ____ ~~mg/ml~~
Balance calibrated with class C weights:
____ g (class C) + ____ g (tare) = ____ g (final wt.)

Preparation of Definitive Test Concentrations

Date 2/22/85 Biologist Paul Cobb

	Conc. of Work. Std. (mg/ml)	Aliq. Vol. (ml)	Dilution Vol. (l)	Final Conc. (mg/l)
Solvent Control	—	1.4 (acetone)	15	—
1.	0.0015	0.14	15	0.000014
2.	0.0015	0.24	15	0.000024
3.	0.0015	0.42	15	0.000042
4.	0.0015	0.75	15	0.000075
5.	0.0015	1.4	15	0.00014
6.				
7.				

Prepared By: Joyce Bowman Date: 2-22-85
Checked By: Paul Cobb Date: 2/22/85

TEST ORGANISM MEASUREMENTS

Test Material: Antimycin A
Study No.: Methods Validation Test
Protocol No.: 7601
ABC Study Director: W.A. McAllister

Lab Form No.: 24
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, MO 65205

Test Species: Bluegill Sunfish Lot No.: 4684
Source: Osage Catfisheries, Osage Beach, Mo
Date Measured: 2/26/85 Group Measured: Solvent Control

Number	Standard Length (mm)	Weight (g)
1	23	0.297
2	22	0.264
3	22	0.275
4	22	0.268
5	25	0.346
6	23	0.310
7	19	0.165
8	22	0.259
9	22	0.287
10	20	0.212
Mean (±Std. Dev.)	22 ± 1.6	0.27 ± 0.050

Remarks:

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By C. Wilhelm date 3-20-85

Prepared By: [signature] Date: 2/26/85
Checked By: [signature] Date: 3-20-85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Antimycin A
Study No.: Methods Validation Test
Test Species: Bluegill Sunfish
Exposure Period: 24 hours
ABC Study Director: W.A. McAllister

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.00014	10	7	70	17.1875
.000075	10	0	0	.0976563
.000042	10	0	0	.0976563
.000024	10	0	0	.0976563
.000014	10	0	0	.0976563

AT A CONFIDENCE LEVEL OF 95 PERCENT THE BINOMIAL TEST
SHOWS THAT THE LC50 IS ABOVE .000075 PPM
AN APPROXIMATE LC50 OF 1.21409E-04 PPM IS OBTAINED BY

NONLINEAR INTERPOLATION BETWEEN .000075 AND .00014

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING
AVERAGE OR PROBIT METHOD CAN GIVE STATISTICALLY SOUND RESULTS.

****

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By C. Wilhelm **date** 3-20-85

Method Reported:

☑ Binomial ☐ Moving Average ☐ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: Paul Coule (CT) Date: 2-26-85
Checked By: Earl Ferguson Date: 3-20-85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Apramycin A
Study No.: Methods Validation Test
Test Species: Bluegill Sunfish
Exposure Period: 48, 72 & 96 hours
ABC Study Director: W. A. McCallister

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.00014	10	10	100	.0976563
.000075	10	0	0	.0976563
.000042	10	0	0	.0976563
.000024	10	0	0	.0976563
.000014	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT .000075 AND .00014 CAN BE USED AS

STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS BECAUSE
THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THIS LIMIT IS >95 PERCENT
AN APPROXIMATE LC50 OF 1.0247E-04 PPM IS OBTAINED BY

NONLINEAR INTERPOLATION BETWEEN .000075 AND .00014

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING
AVERAGE OR PROBIT METHOD CAN GIVE STATISTICALLY SOUND RESULTS.

****

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By C. Williams **date** 3-20-85

Method Reported:

☑ Binomial ☐ Moving Average ☐ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: Paul Cobb Date: 2/26/85

Checked By: Cathy Thomson Date: 3-20-85

FISH ACCLIMATION RECORD

Species: Bluegill Sunfish
Species Lot No.: 4684
Culture Tank No.: 7
Acclimation Tank No.: H

Lab Form No.: 119

Analytical Bio-Chemistry Labs
Aquatic Toxicologist Division
7200 ABC Lane, P. O. Box 1097
Columbia, MO 65205

No. Removed From Culture ~90 Date Removed 2/20/85 Date Returned 2/25/85

Dilution Water Type: ☑ Recon ☐ Well ☐ Salt

Acclimation Time (hrs.)	Date	Obs.	Acclimation Temp. (°C)	Acclimation Mortality	No. Used	Study No.
0	2/20	PC	18	—	----	----
24	2/21	PC	22	0	----	----
48	2/22	PC	22	0	70	anti A
					10	32233
					10	32236
72	2/23	AF	22	0		
96	2/24	AF	22	0		

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By C. Wilhelm date 3-19-85

Remarks: Note - all fish held without food during acclimation.

Prepared By: Paul Cohle Date 2/20/85
Checked By: William A. McAllister Date 2-25-85

FISH ACCLIMATION RECORD

Species: Bluegill Sunfish
Species Lot No.: 4684
Culture Tank No.: 7
Acclimation Tank No.: P

Lab Form No.: 119

Analytical Bio-Chemistry Labs
Aquatic Toxicologist Division
7200 ABC Lane, P. O. Box 1097
Columbia, MO 65205

No. Removed From Culture ~220 Date Removed 3-12-85 Date Returned 3-16-85

Dilution Water Type: ☒ Recon ☐ Well ☐ Salt

Acclimation Time (hrs.)	Date	Obs.	Acclimation Temp. (°C)	Acclimation Mortality	No. Used	Study No.
0	3-12-85	JHB	16	—	----	----
24	3-13	JHB	21	0	----	----
48	3-14	JHB	21	1	60	32236
					60	32870
					60	32233
72	3-15	JHB	22	0	15	32907
					5	32942
					10	32876
96	3-16	JHB	22	0		

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By C. Wilhelm date 3-19-85

Remarks: Note - all fish held without food during acclimation.

Prepared By: Jane Bowman Date 3-12-85

Checked By: Cathy Thompson Date 3-19-85

STUDY# 032233 pg 002 of 0053

FISH CULTURE RECORD

Species: Bluegill Sunfish
Lot No.: 4684 Tank No.: 7
Source: Osage Catfisheries
Osage Beach, Mo.
Date Received: 12/4/84 No. Received ~2000

Lab Form No.: 50
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P. O. Box 1097

Date	Obs. I.D.	Mortality	Feeding Schedule	Treatment Drug	Conc.	Time	Type	Comments
12/4	PC	2	12,2,4					
12/5	Cm	5	8,9.5, 4					
12/6	PC	4	9,11,12,3,4					
12/7	Cm	0	8,10,11,12,4					
12-8	Cm	0	8,10,3,5					
12-9	Cm	0	8.10,1,3					
12/10	Cm	0	9,11,1+4					
12/11	Cm	0	8,11,4					
12/12	Cm	0	8,11,1,3,4					
12/13	PC	0	8,10,12,2.5,4					
12/14	Cm	0	8,10.5,1,3,4					
12/15	Cm	0	10.5,11.5,12.5,7					
12/16	Cm	1	10.5,12,1					
12/17	Cm	0	9.5,11,12.5,1,9					
12/18	Cm	0	8.5,11,12.5,3,4					
12/19	Cm	2	8,10,12,2,4					
12/20	Cm	0	8,10,12,4					
12/21	PC	2	8,3,5					
12/22	LG	0	8 + 12.5					
12/23	LG	1	12 2 3					
12/24	AF	0	12, 12+2					
12/25	AF	0	8 + 12					
12/26	Cm	5	9.5,10.5,1,3,4					
12/27	Cm	2	8.10.5,3,1					

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By C. Wilhelm date 9-19-85

Prepared By: Paul Coble Date: 12/4/84
Checked By: [illegible] Date: 12-28-84

FISH CULTURE RECORD

Species: Bluegill/Sunfish
Lot No.: 4684 Tank No.: 7
Source: Osage Catfisheries Osage Beach Mo.
Date Received: 12-4-84 No. Received ~2000

Lab Form No.: 50
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P. O. Box 1097

Date	Obs. I.D.	Mortality	Feeding Schedule	Treatment Drug	Conc.	Time	Type	Comments
12-28	[illegible]	2	8,11,1,3					
12/29	DB	0	" " "					
12/30	DB	0	" " "					
12/31	PC	7	12,4					
1/1/85	PC	11	1,4					
1/2	PC	3	8,10,3,4					
1-3	JR	4	8,10,2,4					
1/4	PC	6	8,10,12					
1/5	LB	0	6,5,8,9,5,ps					
1/6	LB	0	10,11,12,1					
1/7	PC	32	8,10,12,4					
1/8	PC	8	9,11,1					
1/9	PC	11	10,11,4					12 pinheads removed.
1-10	JR	21	8,3,4					
1-11	PC	12+18	8,10,2,4					
1/12	PC	15+3	8,10					
1/13	DB	7	" " "					
1-14	JR	38	8,10,11,12,4					
1/15	PC	15	8,10,12,4	Formalin	125ppm	1 hour	Standing Bath	
1/16	PC	45	8,11,12,3,4	Nitrofurazone	10ppm	1 hour	Standing Bath	
1/17	PC	24	9,10,11,4	Formalin	100ppm	1 hour	Standing Bath	
1/18	PC	29	8,12,2,4	[illegible]	[illegible]	" "	" "	
1/19	AF	2+15	8,11,3	Formalin	200ppm	" "	" "	
1/19	PC	—	—	Nitrofurazone	10ppm	flow through	indefinite	

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By C. Wilhelm date 3-19-85

Prepared By: William A. McAllister Date: 12-28-84
Checked By: Jane Bowman Date: 2-22-85
+Entry Error B.C. 11/19/85

FISH CULTURE RECORD

Species: Bluegill Sunfish
Lot No.: 4684 Tank No.: 7
Source: Osage Catfisheries; Osage Beach, Mo.
Date Received: 12/4/84 No. Received ~2000

Lab Form No.: 50
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P. O. Box 1097

Date	Obs. I.D.	Mortality	Feeding Schedule	Treatment Drug	Conc.	Time	Type	Comments
1/20	AC	12	9,11,4					
1/21	PC	16	8,9,10.5,11,12,4					
1/22	JR	17	9,11,1,3,4					
1-23	Dan	4	8,10,12,4					
1/24	PC	17	8,12,2,4					
1/25	PC	4	8,10,12,2,4					
1/26	Dan	8	9,11,2,4					
1/27	Dan	6	9,11,4					
1/28	PC	15	10,11,1,4					
1-29	JB	4	8 12 4					
1/30	PC	2+1	8,11,1,4					~10 removed that were dark & mated
1-31	JHB	5	8,11,12,4					
2/1	PC	9	8,10,1,4					
2/2	PC	0+2	11.5 10.5,12					
2/3	PC	1	11 12 12					
2/4	PC	0	8,11,5					
2/5	PC	0	10,12,4					~8 removed that were dark & mated ~15 removed for acclimation
2/6	PC	0+2	8,10,12,4					
2/7	PC	0	8,9,11,12,4					
2/9	PC	5	8,11,1,4					
2/9	PC	3	11,12,13					
2/10	PC	3	11,1,4					
2/11	PC	1	9,11,4					
2-12	JHB	0	8,10,12,4					

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By C. Wellborn date 3-19-85

Prepared By: Paul Cole Date: 1/21/85
Checked By: Jane Bowman Date: 2-22-85

ANALYTICAL BIOCHEMISTRY LABORATORIES INC
P.O. Box 1097 • Columbia, MO 65205
Shipping Address: 7200 East ABC Lane, Columbia, MO 65202
314/474-6579 • Telex 821 814 • Answer Back (ABCLAB UD)

ABC PROTOCOL NO. 7601
(Revised July 11, 1984)

STATIC BIOASSAY PROCEDURE FOR DETERMINING THE ACUTE TOXICITY OF CHEMICAL SUBSTANCES TO FRESHWATER FISH

ABC Study Number 32233

Test Material 2,6-diethylphenyl azomethine ~~Azomethine~~

Test Species Bluegill Sunfish (Lepomis macrochirus)

AB-84-387

1.0 INTRODUCTION

Aquatic toxicity tests have been used extensively in the assessment of the environmental effects of chemical substances. Indeed, aquatic bioassays are required by federal laws such as the Toxic Substances Control Act (1), FIFRA (2), and the Clean Water Act of 1977 (3). With the testing guidelines for these laws in mind, as well as FDA's Good Laboratory Practice Regulations (4) which complement them, Analytical Bio-Chemistry Laboratories, Inc. has prepared the following protocol. The static bioassay method presented here was patterned after procedures that were formulated by the U. S. Environmental Protection Agency (5), American Public Health Association (6), and the American Society for Testing and Materials (7).

2.0 OBJECTIVES

The primary objective of the toxicity test described herein is to evaluate the acute toxicity of a chemical substance to freshwater fish under static conditions. This is achieved by determining LC_{50} levels of the toxicant during a 96 hour exposure period. An LC_{50} is the approximate concentration of the test material that produces 50 percent mortality of test fish after prescribed intervals. The method is designed to yield LC_{50} values following 24, 48 and 96 hours of exposure.

3.0 TESTING FACILITY

The study will be conducted by the Aquatic Toxicology Division of Analytical Bio-Chemistry Laboratories, Inc., 7200 East ABC Lane, P. O. Box 1097, Columbia, Missouri 65205.

4.0 RANGE-FINDING STUDY

4.1 General. For most chemical substances, the approximate toxic level to aquatic organisms is not known. Because this information is essential before a definitive toxicity test can be conducted, ABC routinely performs range-finding tests for static bioassays with fish. The information derived from this preliminary test will be used to set concentration levels for the definitive bioassay described in section 5.0.

4.2 Test Fish. The fish species to be used should be selected by the study sponsor from the list of recommended species in Table 1. The most common species used for toxicity testing includes bluegill sunfish (Lepomis macrochirus), rainbow trout (Salmo gairdneri), and fathead minnows (Pimephales promelas). Fish ranging in size from actively-feeding fry to 5.0 g will be used as test organisms. The fish standard length of the largest fish will be no more than twice that of the shortest fish. The fish will be obtained from an established commercial hatchery or in-house cultures. The particular source to be used is dependent upon the seasonal availability of test fish and will be listed at the time of protocol approval in the test-specific information of section 8.5, along with the species selected by the study sponsor.

The test fish lot will be from the same year class and will be identified to species using the taxonomic keys developed by Eddy (8) and cultured following the techniques described by Brauhn et. al. (9). All test fish will be held on a 16-hour daylight photoperiod and observed for at least 14 days prior to testing. A daily record of fish observations during the holding period, along with prophylactic and therapeutic disease treatments, will be kept and included with the final report. During the holding period, they will receive a standard commercial fish food (Rangen's®) at a maintenance rate of 3 to 5 percent of their body weight per day. The test lot will be held without food and acclimated to the test temperature for at least 48 hours prior to testing. If mortality of the test lot exceeds 10 percent in the 48 hours previous to testing, the fish will not be used. Previous to or concurrent with the test, the fish lot will be challenged against a reference compound, Antimycin A*, to determine their general health and suitability as test organisms. The results of the Antimycin A test will be compared against published toxicity values (10).

4.3 Test System. The range finding test will be conducted in five gallon widemouth glass jars containing 15 liters of test solution and five fish per concentration. These test vessels will be immersed in a circulating water bath with temperatures maintained within ±1°C of the desired test temperature (Table 1). For temperature control in the water bath, thermostatically controlled heating elements will be used for warmwater tests (22 ±1°C) and refrigeration units (Min-O-Cool®) for coldwater bioassays (12 ±1°C). The dilution water used will be a soft reconstituted water of the following makeup in deionized water: 48 mg/l $NaHCO_3$, 30 mg/l $CaSO_4 \cdot 2H_2O$, 30 mg/l $MgSO_4$, and 2.0 mg/l KCl. The water quality parameters of this dilution water are: pH: 7.2-7.6; total hardness: 40-48 mg/l $CaCO_3$; and total alkalinity: 30-35 mg/l $CaCO_3$. Also available, at the sponsor's request, is an alternate dilution water from a deep well source with chemical and physical characteristics shown in Table 3.

4.4 Test Material. A letter of authorization for the study should be sent with the test material or previous to its shipment and should contain the following chemical/physical properites of the compound if available: name of test material, code number, physical description, purity, stability, suggested storage conditions, water and organic solvent solubility, available toxicity information, and handling precautions. The test concentrations will be prepared on a weight/volume basis unless otherwise specified. A record of all sample weights and dilutions will be kept, checked by a second party, and furnished in the final report. Under certain experimental conditions, the sponsor may elect to confirm test concentrations by approved analytical techniques. Factors such as limited aqueous solubility, volatility and aquaria aeration may require analysis at 0 and 96 hours.

*Antimycin A standard obtained from Sigma Chemical Company, Type III, crystalline, Lot 125C-0152.

4.5 Test Procedure. The range-finding procedure is as follows:

4.5.1 Test fish will be acclimated to the test temperature and dilution water for at least 48 hours prior to testing, during which time they will be held without food.

4.5.2 The range-finding test will be initiated by exposing groups of five fish to two or three toxicant concentrations spaced by a factor of 10. If acute toxicity information is available from previous studies or it is indicated that the material is basically non-toxic by the study sponsor, only one preliminary test concentration may be used before the definitive test. ABC will test up to a maximum of 1,000 mg/l in the definitive test, unless otherwise requested by the study sponsor. The test fish will be placed in the test chambers by stratified random assignment within 30 minutes after solution preparations. The initial toxicant concentrations most often used are 1, 10 and 100 mg/l. Numerous static tests by ABC have shown that a significant percentage of the compounds tested have aquatic toxicities which fall within this range.

4.5.3 After 24 hours of exposure, the test chambers will be observed for mortality and/or adverse behavioral effects. Dead individuals will be removed at each observation and a record maintained of mortality and abnormal behavior. Dependent upon this observation, additional test concentrations may be added at levels above or below the initial concentrations. This procedure will be followed until a toxic range is determined. For example, if the 24 hour exposure results in total mortality, new solutions will be prepared at a factor of 10 below the lowest initial concentration until no mortality or partial mortality is reached. In the converse situation, if no mortality is observed after 24 hours, new solutions will be added at concentrations spaced by a factor of 10 above the highest initial level until mortality is noted. In this manner, a bracket is formed for the toxic range of the compound.

4.5.4 The preliminary test will be conducted for a period of 24 to 96 hours - the exact duration dependent upon the results of the initial concentrations tested. In most cases, a preliminary test for 48 hours at 2-3 toxicant concentrations is sufficient to determine the toxic range.

4.5.5 Results of the range-finding study will be used to set the concentration range of the definitive study described in section 5.0. At least five toxicant concentrations selected from the logarithmic scale presented in Table 2, which fall within the preliminary test range, have proven to be adequate in assessing most compounds.

5.0 DEFINITIVE STUDY

5.1 General. Following the preliminary range-finding study discussed in section 4.0, the definitive test will be conducted by

the procedures described below. Test-specific information regarding the sponsor, test material, test fish, proposed study dates, study personnel and study approvals will be included in section 8.0 at the time of protocol approval.

5.2 Test Fish. Aspects concerning the acquisition, culture and acclimation of test fish will be the same as discussed in section 4.2.

5.3 Test System. For all definitive testing, the test vessel size will conform to the maximum loading limitation of 0.8 grams of fish per liter of solution (5). One of the following types of glass test chambers will be used: (a) 5 gallon glass jars containing 15 liters of solution, (b) 40 liter aquaria containing 30 liters of solution, or (c) 100 liter aquaria containing 75 liters of solution. ABC will select the type of chamber to be used. In most instances, the test chambers used will be 5 gallon glass jars containing 15 liters of solution, which is a recommended test vessel for static bioassays (5). The water bath system described in section 4.3 will be used to control test temperatures. The test dilution water will be the same as discussed in section 4.3.

5.4 Test Material. Specific information regarding the test material is to be supplied by the sponsor and will be addressed in section 8.3 at the time of protocol approval. The remaining test sample will be sent back to the study sponsor upon approval of the final report.

5.5 Test Procedure-Biological. The basic test procedure for the definitive bioassay will be as follows:

5.5.1 The test fish will be acclimated to the test temperature and dilution water for at least 48 hours prior to testing, during which time they will be held without food.

5.5.2 The definitive test will be initiated by exposing groups of 10 organisms to at least 5 toxicant concentrations and a dilution water control. The test concentrations used will be based upon the results of the range-finding test and will be selected from one of the logarithmic series presented in Table 2. The definitive test concentrations will be selected after discussing preliminary results with study sponsor. If a solvent is used in the preparation of test solutions, an additional solvent control chamber will be used which will receive an aliquot of the solvent equivalent to the highest amount used in the test chambers. The test organisms will be placed in the test chambers by stratified random assignment within 30 minutes after solution preparations.

5.5.3 As an alternate test design, duplicate test chambers per concentration containing 5 fish each will be used to reduce biomass loading rates when using test fish near the upper size limit of that recommended.

5.5.4 The test chambers will be observed for mortality and/or adverse behavioral effects every 24 hours. Dead individuals

will be removed at each observation and a record maintained of mortality and abnormal behavior for each concentration tested.

5.5.5 Length and weight measurements will be made on either a representative group of the test fish prior to testing or on the control group at test termination.

5.6 Test Procedure-Chemical and Physical. Water quality parameters of temperature, dissolved oxygen and pH will be monitored throughout the test. Measurements of temperature, dissolved oxygen and pH will be made at 0, 48 and 96 hours of testing in the control, low concentration and highest concentration with surviving fish. If at any point in the study dissolved oxygen levels are observed to be below or approaching 40 percent saturation, ABC will contact the sponsor's study director for authorization to artificially aerate the test chambers with compressed air for the duration of the study. In cases where the dissolved oxygen reduction is felt to be compound-related, i.e., the control chamber is at an acceptable dissolved oxygen level, ABC recommends that the test solutions not be aerated. Aeration is also not recommended in instances where control levels are marginal, i.e., dissolved oxygen values fall slightly below 40% saturation. In the event aeration is required, it is recommended that the test concentration be measured by an accepted analytical method. The authorization procedure used will be that described in section 7.0.

5.7 Analysis of Results. The results of the definitive study will be statistically analyzed for 24, 48 and 96 hour LC_{50} values and their corresponding 95 percent confidence limits. These values will be determined by an LC_{50} computer program developed by Stephan et. al. (13) or by manual methods described by Litchfield and Wilcoxon (11) and Stephan (12).

5.8 Report. One copy of the report will be submitted. The report will contain all original raw data. Additional copies will be provided, if requested by the sponsor, at a copy rate of $25 per copy. The report will include the following:

5.8.1 Study dates, name and address of test facility.

5.8.2 Objectives and test methods.

5.8.3 Reference to the statistical methods used for data analysis.

5.8.4 Description of test material (date of receipt, storage conditions, purity, physical characteristics, and method of preparing test concentrations).

5.8.5 Description of test design.

5.8.6 Summary of the data analysis, mortality observations and test water quality.

5.8.7 Location of raw data.

5.8.8 List and signatures of study personnel.

5.8.9 GLP compliance statement by study director and a statement by ABC's Quality Assurance Unit.

5.8.10 The report appendix will contain the original raw data for mortality observations and water quality, results of the Antimycin A reference test, records of fish size and daily holding log, letter of test authorization, letters of authorized protocol changes, and a copy of the approved protocol.

5.9 Data Retention. All original raw data generated in the preliminary and definitive studies will be provided to the study sponsor in the appendix to the final report. A copy of the data will be retained in ABC's archives.

6.0 PROTOCOL CHANGES

In the event that modifications of this protocol are deemed necessary, a written statement of any changes and reason(s) proposed by the study sponsor or ABC will be submitted to the other party. All agreed changes will be expressed in writing, signed and dated by the sponsor's study director. The signed changes will be appended to the protocol and included with the final report. This protocol is subject to revision when felt necessary to comply with changes in Federal regulations and state of art methodology. The protocol for a specific study will not be changed while the study is in progress without discussion with the study sponsor.

7.0 SPONSOR AUTHORIZATIONS DURING THE STUDY

Should a problem develop while the study is in progress, ABC will notify the study director within 24 hours. The problem and suggested test modifications will be discussed by telephone. ABC will proceed with the changes felt necessary upon the verbal authorization of the study director. A letter for written authorization will then be submitted by ABC to the study director and handled in the same manner discussed in section 6.0.

8.0 TEST-SPECIFIC INFORMATION

8.1.1 General. The following items will be addressed for each static bioassay. This information is necessary to be in compliance with Good Laboratory Practice Regulations (4). Sections 8.2, 8.3, 8.8 and 8.10 are to be completed by the study sponsor. Sections 8.4, 8.5, 8.6 and 8.7 will be completed by ABC.

8.1.2 GLP Compliance. To be in compliance with the Federal Good Laboratory Practice regulations, the report of the investigation conducted utilizing this protocol must contain a statement that the study was conducted in accordance with one of the following GLP's.

1. U.S. F.D.A. Good Laboratory Practice Regulations (21 CFR 58).

2. U.S. E.P.A. Good Laboratory Practice Standards; Toxic Substances Control (40 CFR 792).

3. U.S. E.P.A. Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160).

4. OECD Principles of Good Laboratory Practice; Annex 2 C(81) 30(Final).

5. Any state or local GLP which may apply.

The specific GLP regulation, for which this study specific protocol and resultant study must be in compliance with, is to be designated by the study sponsor in section 8.8 of this protocol.

8.2 Study Sponsor:

8.2.1 Company Monsanto Chemical Company G2WD

8.2.2 Address 800 North Lindbergh Boulevard
St. Louis, Missouri 63167

8.2.3 Sponsor's Study Director

Dr. Richard C. Dirks _____
Name Title

8.3 Test Material:

8.3.1 Name Azomethine (2,6-diethylphenyl)

8.3.2 Lot/Batch Number _____

8.3.3 Physical Description _____

8.3.4 Purity _____

8.3.5 Stability _____

8.3.6 Solubility: Water _____ Acetone _____ DMF _____
TEG _____ Ethanol _____ Methanol _____ Other _____

8.3.7 Handling Precautions _____

_____

8.4 Test Concentrations: To be determined after preliminary testing and consultation with study sponsor.

8.4.1 Sponsor's Study Director notified of preliminary results: Date _____ ABC Biologist _____.

8.4.2 Definitive test concentrations agreed upon:

_____.

8.5 Test Fish:

8.5.1 Species Bluegill Sunfish (Lepomis macrochirus)

8.5.2 Supplier Osage Catfisheries, Inc.
Osage Beach, Missouri

8.6 Study Dates:

8.6.1 Proposed starting date of definitive study Oct. 1984

8.6.2 Proposed completion date of definitive study Nov. 1984

8.7 ABC Study Personnel:

8.7.1 Study Director

William A. McAllister	Aquatic Biologist III
Name	Title

8.7.2 Aquatic Supervisor

Carl M. Thompson	Supervisor, Aquatic Toxicology
Name	Title

8.8 GLP Compliance (check the most appropriate):

EPA-FIFRA ✓; EPA-TSCA ___; FDA ___; OECD ___; Other _____.

8.9 Protocol Approvals. The following is to be signed by the appropriate study personnel:

8.9.1 Sponsor's Study Director

Richard C. Dicks	Prod. Tox. Specialist	10/10/84
Name	Title	Date

8.9.2 ABC's Study Director

[signature]	Aquatic Biologist III	10/9/84
Name	Title	Date

8.9.3 ABC's Group Leader

	Group Leader Animal Toxicology	10/9/84
Name	Title	Date

8.10 Authorization to return the test material and sample:

8.10.1 Sponsor's authorized agent to receive the test material and sample.

Name	Title

8.10.2 Shipping Address

Company

Street Address

City State Zip Code

Phone Number

8.10.3 Hazardous shipment information

Proper Shipping Name

Class of Restricted Article (e.g. flammable, poison, radioactive, etc.)

TABLE 1: RECOMMENDED SPECIES AND TEST TEMPERATURES[a]

Recommended Species	Recommended Test Temperature (°C)
Rainbow Trout, Salmo gairdneri	12
Brook trout, Salvelinus fontinalis	12
Bluegill, Lepomis macrochirus	22
Fathead minnow, Pimephales promelas	22
Channel catfish, Ictalurus punctatus	22
Carp, Cyprinus carpio[b]	22

[a]Adapted from (5).

[b]Recommended for compounds used in Japan.

TABLE 2: Guide to selection of experimental concentrations based on progressive bisection of intervals on logarithmic scale.

Col. 1	Col. 2	Col. 3	Col. 4	Col. 5
10.0	10.0	10.0	10.0	10.0
				8.7
			7.5	7.5
				6.5
		5.6	5.6	5.6
				4.9
			4.2	4.2
				3.7
3.2	3.2	3.2	3.2	3.2
				2.8
			2.4	2.4
				2.1
		1.8	1.8	1.8
				1.55
			1.35	1.35
				1.15
1.0	1.0	1.0	1.0	1.0

TABLE 3: Chemical characteristics of well water used by ABC's Aquatic Toxicology Division.

Parameters	Concentration
Temperature	15-20°C[b]
Dissolved Oxygen[a]	9.2-10.1 ppm[b]
pH	7.8-8.3[b]
Hardness ($CaCO_3$)	225-275 ppm[b]
Alkalinity ($CaCO_3$)	325-375 ppm[b]
Conductivity	700 µmhos/cm
NH_3-N	0.60 ppm
NO_3-NO_2-N	0.20 ppm
Ortho-Phosphate	0.10 ppm
Aluminum	<0.010 ppm
Arsenic	<0.0005 ppm
Cadmium	<0.002 ppm
Chromium	<0.006 ppm
Cobalt	<0.003 ppm
Copper	<0.002 ppm
Iron	<0.004 ppm
Lead	0.017 ppm
Mercury	0.0008 ppm
Nickel	<0.013 ppm
Silver	<0.0004 ppm
Zinc	0.001 ppm
Measured organophosphorus pesticides	c
Measured organochlorine pesticides plus PCB's	c

[a]After aeration.

[b]Represents seasonal variation, with the monthly range not exceeding 10%.

[c]See report appendix for individual analyses.

9.0 REFERENCES

(1) U.S. Congress. 1976. Toxic Substances Control Act. Public Law 94-469. Federal Register, October 11, 1976. 2003-2051.

(2) U.S. Environmental Protection Agency. 1978. Registration of pesticides in the United States, proposed guidelines. Federal Register, July 10, 1978: 29696-29741.

(3) U.S. Congress. 1977. Clean Water Act of 1977. Public Law 95-217. Federal Register, December 27, 1977: 1566-1611.

(4) (a) U.S. Food and Drug Administration. 1978. Nonclinical Laboratory Studies, Good Laboratory Practice Regulations (21 CFR, Part 58). Federal Register, Vol. 43, No. 247: 59986-60025.

(b) U.S. Environmental Protection Agency. 1983. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160). Federal Register, Vol 48, No. 230: 53946-53969.

(c) U.S. Environmental Protection Agency. 1983. Toxic Substances Control; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 792). Federal Register, Vol. 48; No. 230:53922-53944.

(d) Organization for Economic Cooperation and Development. 1981. OECD Guidelines for Testing of Chemicals, Principles of Good Laboratory Practice Annex 2, C(81) 30(Final):7-28.

(5) Committee on Methods for Toxicity Tests with Aquatic Organisms. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-009, April, 1975. 61 p.

(6) American Public Health Association. 1975. Standard Methods for the Examination of Water and Wastewater. 14th ed. Washington, D.C. 1193 p.

(7) American Society for Testing and Materials. 1980. Standard practice for conducting basic acute toxicity tests with fish, macroinvertebrates and amphibians. May, 1980, ASTM Committee E-35.23. 25 p.

(8) Eddy, Samuel. 1969. The Freshwater Fishes. 2nd ed. W. C. Brown Company, Dubuque, IA. 286 p.

(9) Brauhn, J. L. and R. A. Schoettger. 1975. Acquisition and Culture of Research Fish: Rainbow Trout, Fathead Minnows, Channel Catfish and Bluegills. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-011, May, 1975. 45 p.

(10) Berger, B. L., R. E. Lennon and J. W. Hogan. 1969. Laboratory Studies on Antimycin A as a fish toxicant. U.S. Department of Interior, Investigations in Fish Control No. 26. 21 p.

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(13) Stephan, C. E., K. A. Busch, R. Smith, J. Burke and R. W. Andrew. 1978. A computer program for calculating an LC_{50}. U. S. Environmental Protection Agency, Duluth, Minnesota, pre-publication manuscript, August, 1978.

Monsanto

DEPARTMENT OF MEDICINE & ENVIRONMENTAL HEALTH
SAMPLE SUBMISSION
STUDY NO. AB-84-386, 387, 388

PLEASE TYPE OR PRINT

I. SAMPLE IDENTIFICATION

PRODUCT NAME(S)	CHEMICAL NAME
Azomethine	Benzeneamine, 2,6-diethyl N-methylene

P NO.	CHEM. ABSTRACTS REG. NO.	LOT OR I.D. NO., NOTE BOOK REF.
84781	35203-08-8	116-200

AMPLE SIZE	PURITY	SAMPLE DISPOSITION	
100 ml	99.2%	☒ DISCARD ☐ RETURN	☐ HOLD, NOTIFY BEFORE DISCARDING

II. CHEMICAL AND PHYSICAL PROPERTIES

TRUCTURAL FORMULA (COMPOSITION OF MIXTURE)

CONFIDENTIAL

MPIRICAL FORMULA	MOLECULAR WEIGHT	COLOR/PHYSICAL STATE
$C_{11}H_{15}N$	161.24	light yellow liquid

ELTING POINT	BOILING POINT	VAPOR PRESSURE	SPECIFIC GRAVITY
		4.4×10^{-3} psia at 100°F	

OLUBILITY: WATER	ORGANIC SOLVENTS (SPECIFY)	OTHER
insoluble	acetone, chloroform	

HYSICAL/CHEMICAL HAZARDS

- ☐ FLAMMABLE
- ☐ EXPLOSIVE
- ☐ OXIDIZER
- ☐ UNSTABLE TO LIGHT
- ☐ UNSTABLE TO HEAT
- ☐ UNSTABLE TO WATER
- ☐ POLYMERIZES READILY
- ☐ HYGROSCOPIC
- ☐ REACTS WITH _____
- ☒ NO SPECIAL PRECAUTIONS
- ☐ OTHER (SPECIFY)

THER PROPERTIES, SPECIAL REQUIREMENTS (SPECIFY)

stable

III. TOXICITY INFORMATION

ORAL LD_{50} 1470 mg/kg
DERMAL LD_{50} 1400 mg/kg
EYE IRRITATION severe
SKIN IRRITATION severe @ 4hrs corrosive @ 24hrs
SINGLE VAPOR INHALATION 40-83-12

- ____ NO INFORMATION AVAILABLE
- ____ SEE ATTACHMENT
- ____ OTHER (SPECIFY)

IV. DOCUMENTATION

OMPOSITION & PURITY

- ☒ STATED ABOVE
- ☐ SEE ATTACHMENT
- ☒ STAFF TOXICOLOGY FILE

METHOD OF SYNTHESIS

- ☐ SEE ATTACHMENT
- ☐ STAFF TOXICOLOGY FILE
- ☒ OPERATING CO. FILE

UBMITTED BY: (Name, Location, Phone No., Date)	DMEH CONTACT: (Name, Location, Phone No., Date)
Lydia A. Suba, C2SC, 4-2124 2/22/85	~~Tim Long, G2WD, 4-8851~~ Dr. Rosenberg 2/22/85

V. EHL USE

STUDY NUMBER(S)	SUBSTANCE IDENTIFICATION CODE

WHITE COPY—LABORATORY COPY; YELLOW COPY—DMEH FILE COPY; PINK COPY—REQUESTOR'S COPY

MASTER FILE
PROJECT NO. A 388

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65205
Shipping Address: 7200 East ABC Lane, Columbia, MO 65202
(314) 474-8579 • Telex 821 814 • Answer Back (ABCLAB UD)

7/20/85

Static Acute Toxicity Report
#32234

Monsanto #AB-84-388

Acute Toxicity of Azomethine (2,6 diethyl phenyl)
to Rainbow Trout (Salmo gairdneri)

Submitted To:

Monsanto Company
Attn: Joel M. Kronenberg, Ph.D.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167

March 15, 1985

AA028932

Submitted By: Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P. O. Box 1097
Columbia, Missouri 65205

Prepared By:

Paul Cohle (CT) 3-21-85
Paul Cohle Date
Biologist/Culturist II

William A. McAllister 3-22-85
William A. McAllister Date
Aquatic Biologist III/Study Director

Approved By:

Carl M. Thompson 3-21-85
Carl M. Thompson Date
Supervisor Aquatic Toxicology

Phillip M. Buckler 3/22/85
Phillip M. Buckler Date
Quality Assurance Officer

Michael Williams 3/22/85
Michael Williams, Ph.D. Date
Group Leader, Animal Toxicology

/lrk

Monsanto

FROM (NAME—LOCATION—PHONE) Dept. of Medicine & Environmental Health

DATE : July 29, 1985 CP 8478

SUBJECT : 2,6-Diethylphenyl Azomethine Acute Aquatic Toxicity Study - Rainbow Trout

REFERENCE : (AB-84-388; ABC #32234)

TO : L.A. Suba
C2SC

cc. E.E. Debus - C2SC
S.F. Dirks
T.W. Fuhremann
R.L. Harness - C2SB
R.W. Street - C2SC
Toxdata

The results of the referenced acute static aquatic toxicity study with 2,6-diethylphenyl azomethine (lot 116-200, 99.2% pure) are summarized below. The study and quality assurance reviews were conducted by Analytical Bio-Chemistry Laboratories, Inc.

LC50 (mg/l)		
24 hr	48 hr	96 hr
>32	42	42

The 96 hr no observable adverse effect level (NOEL) was 5.6 mg/l.

The water temperature, dissolved oxygen concentration, pH and ammonia concentration were within acceptable limits throughout the study.

On the basis of this test, 2,6-diethylphenyl azomethine is considered to be slightly toxic to rainbow trout.

Joel Kronenberg

Joel M. Kronenberg, PhD
Senior Product Toxicologist
Monsanto Company
Department of Medicine and
Environmental Health

dlj

AA028933

IN-10-M (REV. 10/83)

SUMMARY

The acute toxicity of Azomethine (2,6 diethyl phenyl) to Rainbow Trout (Salmo gairdneri) was assessed using the methods outlined by the Committee on Methods for Toxicity Tests with Aquatic Organisms. Water quality parameters of temperature, dissolved oxygen and pH were measured throughout the test and were within acceptable limits.

As a method precision check, the rainbow trout were challenged with a reference compound, Antimycin A. The estimated 96-hour LC_{50} and 95% confidence limits (C.I.) were within the 95% confidence limits reported in the literature. Culture and acclimation records indicated that the fish were in good condition for testing.

The study was conducted at the following nominal concentrations of Azomethine: 5.6, 10, 18, 32 and 56 mg/l. Ten fish, with a mean weight of 0.90 (±0.21) g and a mean standard length of 40 (±2.8) mm, were exposed to each test concentration and control.

The results of the four day static fish toxicity studies using Azomethine and Antimycin A are summarized below. The 24 and 48-hour LC_{50} values were also determined.

Compound	96-hour LC_{50} (95% C.I.)
Azomethine	42 mg/l (32-56 mg/l)
Antimycin A	3.3×10^{-5} mg/l ($2.6\text{-}4.2 \times 10^{-5}$ mg/l)

Also, the results indicated a 96-hour, no-observed effect concentration of 5.6 mg/l, which was based on the lack of mortality and abnormal effects. Abnormal effects of mortality, surfacing, loss of equilibrium, dark discoloration, fish on the bottom and/or quiescence were observed during the 96-hour exposure period.

INTRODUCTION

This static bioassay was performed by the Aquatic Toxicology Division of Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri, for Monsanto Company from February 26, 1985 to March 2, 1985, as authorized in a letter of November 20, 1984 (Appendix). The purpose of this test was to determine the 24, 48 and 96-hour LC_{50} levels for Azomethine to Rainbow Trout (Salmo gairdneri). A preliminary range-finding study was conducted from February 22, 1985 to February 26, 1985 to determine the concentration range for the definitive bioassay. The study was conducted following the procedures outlined in ABC Protocol Number 7601 (Appendix), as approved by Richard C. Dirks, Ph.D., Monsanto Company, on October 10, 1984.

METHODS AND MATERIALS

The procedures for static bioassay, as described in Methods of Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians (1) and Standard Methods for Examination of Water and Wastewater (3) were used in this experiment. The rainbow trout (ABC Lot #4784) used in the test were obtained from Spring Creek Trout Hatchery in Lewistown, Montana. The fish were identified to species using the taxonomic keys developed by Eddy (4). All test fish were held in culture tanks on a 16-hour daylight photoperiod and observed for at least fourteen days prior to testing. Fish culture techniques used were basically those described by Brauhn et al. (5). A daily record of fish observations during the holding period, along with any prophylactic or therapeutic disease treatments, is included in the Appendix. During this period, the fish received a standard commercial fish food (Rangen's) daily until 48 hours prior to testing at which time feeding was discontinued. The rainbow trout used for this experiment had a mean weight of 0.90 (±0.21) g and a mean standard length of 40 (±2.8) mm. Weight and length measurements were made on the control group of fish at the termination of the test and are included in the Appendix.

The static fish bioassay was conducted in five gallon glass vessels containing 15 liters of soft reconstituted water composed of the following compounds in the amounts stated per liter of deionized water:

48 mg $NaHCO_3$
30 mg $CaSO_4 \cdot 2\ H_2O$
30 mg $MgSO_4$
2 mg KCl

This reconstituted water was prepared to yield a total hardness of 40-45 mg/l as $CaCO_3$, a total alkalinity of 30-35 mg/l as $CaCO_3$ and an initial pH of 7.2 to 7.6. The 0-hour measured control water parameters of this dilution water were dissolved oxygen 10.0 mg/l and pH 7.4. The well water source from which this dilution water was prepared had the characteristics shown in Table 1.

The test vessels were kept in a water bath at 12°C (±1.0). The test fish were acclimated to the dilution water and test temperature and

held without food for 48-96 hours prior to testing. An acclimation record is included in the Appendix.

A 96-hour range-finding test was conducted to determine the concentration range for the definitive study. The preliminary test concentrations were set at 10 and 100 mg/l. Based on the results of preliminary testing, five concentrations of the test compound, ranging in a logarithmic series from 5.6 to 56 mg/l, with ten fish per concentration were selected for the definitive bioassay. Also included was a dilution water control. The fish were added to the test chambers by random assignment within 30 minutes after addition of test material. All concentrations were observed once every 24 hours for mortality and abnormal effects such as surfacing, loss of equilibrium and dark discoloration.

The Azomethine (2,6 diethyl phenyl) test compound was received on February 18, 1985, in good condition. The sample upon receipt was observed to be a yellow liquid and was stored at room temperature in the dark. Sample purity was not specified. Test concentrations were prepared based on the total compound. The test concentrations were obtained by transferring appropriate weights of test compound directly to the test chambers. After addition and mixing of test compound in test chambers on day 0, a light oily surface film was noted in all Azomethine test chambers. Also, a few globular droplets were noted at the bottom of the 56 mg/l chamber. After 72 hours of testing, a light surface film was still present in all test concentrations containing live fish (5.6-32 mg/l). All standard weights and dilution values are listed in the Appendix.

Statistical analysis of the concentration vs. effect data (generally mortality) was obtained by employing a computerized LC_{50} program developed by Stephan et al. (7). This program calculated the LC_{50} statistic and its 95 percent confidence limits using the binomial, the moving average, and the probit tests. Three different methods of analyzing the data were used since no one method of analysis is appropriate for all possible sets of data that may be obtained. The method of calculation selected for presentation in this report was that which gave the narrowest confidence limits for the LC_{50} (6, 7).

RESULTS

The results of the 96-hour static toxicity test with Rainbow Trout (Salmo gairdneri) exposed to Azomethine (2,6 diethyl phenyl) are presented in Table 2. The 24, 48 and 96-hour LC_{50} values for Azomethine were >56, 42 and 42 mg/l, respectively. All results were based on the nominal concentrations of 5.6, 10, 18, 32 and 56 mg/l. The no-effect concentration based on the lack of mortality and abnormal effects after 96 hours of exposure was 5.6 mg/l. The abnormal effects of mortality, surfacing, loss of equilibrium, dark discoloration, fish on the bottom and/or quiescence were observed in the 10, 18, 32 and 56 mg/l test concentrations during the 96-hour exposure period.

The rainbow trout were challenged with a reference compound, Antimycin A, to verify method precision. The 96-hour LC_{50} for rainbow trout exposed to Antimycin A was 3.3×10^{-5} mg/l and was within the 95% confidence intervals reported in the literature (2). An examination of the fish culture and acclimation records for this test indicated that the fish were in good condition for testing (Appendix).

Nominal test concentrations, mortality rates, and water quality data are presented in Table 3. The dissolved oxygen concentrations ranged from 7.8 to 10 mg/l during the test. These values represented 72 and 90% saturation at 12 and 11°C, respectively, and were considered adequate for testing (1). The pH values ranged from 6.8 to 7.5. The pH values for the lowest and highest test concentrations measured remained consistent with the control.

The study was conducted following the intent of the Good Laboratory Practice Regulations (8) and the final report was reviewed by Analytical Bio-Chemistry Laboratories' Quality Assurance Unit. All original raw data was provided to Monsanto Company, with a copy retained at Analytical Bio-Chemistry Laboratories.

TABLE 1

Chemical Characteristics of Well Water used by
ABC's Aquatic Toxicology Division

Parameter	Concentration
Temperature	15-20°C[b]
Dissolved Oxygen[a]	9.2-10.2 ppm[b]
pH	7.8-8.3[b]
Hardness ($CaCO_3$)	225-275 ppm[b]
Alkalinity ($CaCO_3$)	325-375 ppm[b]
Conductivity	700 µmhos/cm
NH_3-N	0.60 ppm
NO_3-NO_2-N	0.20 ppm
Ortho-Phosphate	0.10 ppm
Aluminum	<0.010 ppm
Arsenic	<0.0005 ppm
Cadmium	<0.002 ppm
Chromium	<0.006 ppm
Cobalt	<0.003 ppm
Copper	<0.002 ppm
Iron	<0.004 ppm
Lead	0.017 ppm
Mercury	0.0008 ppm
Nickel	<0.013 ppm
Silver	<0.0004 ppm
Zinc	0.001 ppm
Measured organophosphorus pesticides	c
Measured organochlorine pesticides plus PCB's	c

[a]After aeration.

[b]Represents seasonal variation, with the monthly range not exceeding 10%.

[c]See report appendix for individual analyses.

TABLE 2

The Acute Toxicity of Azomethine (2,6 diethyl phenyl) and Antimycin A to Rainbow Trout (Salmo gairdneri)

Compound	LC_{50} in milligrams/liter (ppm)		
	24 hours	48 hours	96 hours
Azomethine[a]	d	42[(1)] (32-56)[b]	42[(1)] (32-56)
Antimycin A[c]	d	5.6×10^{-5}[(3)] ($4.6\text{-}6.9) \times 10^{-5}$)	3.3×10^{-5}[(3)] ($2.6\text{-}4.2 \times 10^{-5}$)

[a]Bioassay as conducted at 12°C (±1.0), mean fish weight and length, 0.90 (±0.21) g and 40 (±2.0) mm.

[b]95% confidence limits.

[c]Antimycin A standard obtained from Sigma Chemical Company, Type III, crystalline, Lot 89C-0588.

[d]Insufficient mortality for the statistical calculation of a reliable LC_{50}.

The 96-hour no-effect concentration was 5.6 mg/l, based on the lack of mortality and abnormal effects.

All values were rounded to two significant figures following ABC S.O.P. #8.7.

LC_{50} calculated using:

(1) Binomial Method
(2) Moving Average Method
(3) Probit Method

TABLE 3

Mortality Rates and Water Quality Measurements During the Acute Toxicity Test of Azomethine (2,6 diethyl phenyl) to Rainbow Trout (Salmo gairdneri)

Nominal Concentration (mg/l)	Percent Mortality Hours			Water Quality								
				0 hours			48 hours			96 hours		
	24	48	96	Temp. °C	D.O.[a] mg/l	pH[b]	Temp. °C	D.O. mg/l	pH	Temp. °C	D.O. mg/l	pH
Control	0	0	0	11	10.0	7.4	12	8.9	7.0	12	7.9	6.9
5.6	0	0	0	11	10.0	7.5	12	8.6	7.0	12	7.8	6.8
10	0	0	0									
18	0	0	0									
32	0	0	0				12	8.5	7.0	12	7.8	6.8
56	50	100	100	11	10.0	7.5						

[a]Dissolved oxygen concentrations - Dissolved Oxygen Probe (YSI Model 54).

[b]pH - pH Probe (Corning Model 476182) used with a Corning Model 125 pH and mV meter.

NOTE: Dissolved oxygen saturation at the test temperature of 12°C is 10.8 mg/l and at 11°C is 11.1 mg/l.

LITERATURE CITED

(1) Committee on Methods for Toxicity Tests with Aquatic Organisms (C. E. Stephan, Chairman). 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-009, April, 1975. 61 p.

(2) Berger, B. L., R. E. Lennon and J. W. Hogan. 1969. Laboratory Studies on Antimycin A as a fish toxicant. U. S. Department of Interior, Investigations in Fish Control No. 26. 21 p.

(3) American Public Health Association. 1980. Standard Methods for the Examination of Water and Wastewater. 15th ed. Washington, DC. 1134 p.

(4) Eddy, Samuel. 1969. The Freshwater Fishes. 2nd ed. W. C. Brown Company, Dubuque, IA. 286 p.

(5) Brauhn, J. L. and R. A. Schoettger. 1975. Acquisition and Culture of Research Fish: Rainbow Trout, Fathead Minnows, Channel Catfish and Bluegills. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-011, May, 1975. 45 p.

(6) Stephan, C. 1977. Methods for calculating an LC_{50}, p. 65-84. In F. L. Mayer and J. L. Hamelink (eds.). Aquatic Toxicology and Hazard Evaluation. ASTM Special Technical Publication 634. ASTM. Philadelphia.

(7) Stephan, C. E., K. A. Busch, R. Smith, J. Burke and R. W. Andrew. 1978. A computer program for calculating an LC_{50}. U. S. Environmental Protection Agency, Duluth, Minnesota, pre-publication manuscript, August, 1978.

(8) (a) U.S. Food and Drug Administration. 1978. Nonclinical Laboratory Studies, Good Laboratory Practice Regulations (21 CFR, Part 58). Federal Register, Vol. 43, No. 247:59986-60025.

(b) U.S. Environmental Protection Agency. 1983. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160). Federal Register, Vol. 48, No. 230:53946-53969.

(c) U.S. Environmental Protection Agency. 1983. Toxic Substances Control; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 792). Federal Register, Vol. 48; No. 230:53922-53944.

(d) Organization for Economic Cooperation and Development. 1981. OECD Guidelines for Testing of Chemicals, Principles of Good Laboratory Practice Annex 2, C(81) 30(Final):7-28.

Quality Assurance Statement for final report #32234 entitled, "Acute Toxicity of Azomethine 2,6 diethyl phenyl to Rainbow Trout (Salmo gairdneri)," for Joel M. Kronenberg, Ph.D., Monsanto Company, St. Louis, Missouri.

In accordance with ABC Laboratories intent that all studies conducted at our facilities are designed and function in conformance with good laboratory practice regulations and the protocols for individual laboratory studies, an inspection of the final report for Azomethine 2,6 diethyl phenyl was conducted and found to be in an acceptable form by a member of our Quality Assurance Unit. An inspection of the daily mortality rate of the test organisms prior to the initiation of the study indicated they were in good health and should not bias the observed mortality in the study. Measurement of 48-hour water quality parameters was monitored on February 28, 1985. No deviations were noted. A final inspection of all data and records on March 12, 1985 indicated that the report submitted to you is an accurate reflection of the study as it was conducted by ABC Laboratories.

Should you have any questions relating to the information provided in this statement or the function of our Quality Assurance Unit, please contact the Quality Assurance Unit at your convenience.

Phillip M. Buckler 3/22/85
Phillip M. Buckler Date
Quality Assurance Officer

Study Compliance Statement for ABC report #32234 entitled, "Acute Toxicity of Azomethine 2,6 diethyl phenyl to Rainbow Trout (Salmo gairdneri)," for Joel M. Kronenberg, Ph.D., Monsanto Company, St. Louis, Missouri.

In accordance with ABC Laboratories' intent that all aquatic toxicity tests conducted by our facility follow good laboratory practices, ABC's study director for the above test herein confirms that the study was conducted in compliance with the U.S. E.P.A. Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160).

All original raw data was sent to Monsanto Company, with a copy retained at Analytical Bio-Chemistry Laboratories.

William A. McAllister 3-22-85
William A. McAllister Date
ABC Study Director

APPENDIX - RAW DATA

NOTE: Some of the records which appear in this raw data appendix have been provided as photocopies of original records on file at ABC. This has been done by necessity for certain data which are used commonly in several studies at ABC. Such records include reference toxicity test data, standard solution preparations, organism culture logs, and well water chemical screen results.

MORTALITY AND BEHAVIORAL OBSERVATIONS

☒ Definitive ☐ Preliminary

Test Material: Azamethiphos

Study No.: 32234

Protocol No.: 7601

ABC Study

Director: Wm McAllister

Lab Form No.: 32

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Test species: ☐ L. macrochirus ☒ ~~S.~~ gairdneri ☐ _____ (Lot # 4784)

No./Vessel: 10 Dil. Water: ☒ Recon. ☐ Well

Acclimation Mortality: < 1%

Date Initiated: 2-26-85 (initiated at 4:00 PM) Date Terminated: 3/2/85

Test Conc. mg/l (ppm)	24 Hours		48 Hours		72 Hours		96 Hours	
	Dead	Obs.	Dead	Obs.	Dead	Obs.	Dead	Obs.
Control	0	N	0	N	0	N	0	N
5.6	0	N	0	N	0	N	0	N
10	0	N	0	1 SUR; 9 N	0	5 SUR; 5 N	0	10 SUR
18	0	4 SUR; 4 Q; 2 N	0	4 SUR; 6 Q	0	4 SUR; 6 N	0	10 SUR
32	0	6 SUR; 1 SUR/LOE; 1 Q 1 LOE/DK; 1 LOE	0	3 LOE/OB; 2 LOE; 4 LOE/SUR; 1 Q	0	9 DR/OB/LOE; 1 DK/Q	0	10 OB/LOE
56	5	4 LOE/OB/DK; 1 LOE/DK	10	—	10	—	10	—
Observer Date	JHB 2:50 PM 2-27-85		JHB 2:20 PM 2-28-85		JHB 3:30 PM 3-1-85		DB 3/2/85 (12:45 PM)	

Remarks: N = Normal; LOE = Loss of Equilibrium; Q = Quiescent
SUR = Surfacing; DK = Dark Discoloration; OB = On Bottom

Fish added to test chambers at 4:00 PM 2-26-85 Light oily surface film noted in 5.6 PPM to 56 PPM test chambers. Also 56 PPM has a few droplets at bottom of test chamber JHB 2-26-85 Light surface film still present at 72 hours in 5.6 to 32 PPM test chambers JHB 3-1-85

Prepared By: Jane Bowman Date: 2-21-85

Checked By: William A. McAllister Date: 3-11-85

MORTALITY AND BEHAVIORAL OBSERVATIONS

☐ Definitive ☑ Preliminary

Test Material: Azinphos methyl
Study No.: 32234
Protocol No.: 7601
ABC Study
Director: w.a. mcallister

Lab Form No.: 32

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Test species: ☐ L.macrochirus ☑ S.gairdneri ☐ _____ (Lot #4784)
No./Vessel: 5 Dil. Water: ☑ Recon. ☐ Well
Acclimation Mortality: 2%
Date Initiated: 2-22-85 Date Terminated: 2/26/85

Test Conc. mg/l (ppm)	24 Hours		48 Hours		72 Hours		96 Hours	
	Dead	Obs.	Dead	Obs.	Dead	Obs.	Dead	Obs.
~~Control~~								
10	0	N	0	N	0	3Q 2N	0	4 SUR/Q 1 Q
100	5	-	5	-	5	—	5	—
Observer	AF		AF		PC		JZB	
Date	2/23/85		2/24/85		2/25/85		2-26-85	

Remarks: N = Normal; LOE = Loss of Equilibrium; Q = Quiescent
SUR = Surfacing; DK = Dark Discoloration; OB = On Bottom
oily surface film noted in 100 mg/l after mixing P.C. 2/22/85
large oil-like globules on bottom & flaky surface film in 100 mg/l test chamber at 72 hours P.C. 2/25/85.

Prepared By: Jane Bowman Date: 2-22-85
Checked By: William A. McAllister Date: 3-1-85

PREPARATION OF TEST CONCENTRATIONS (weight/volume)

Test Material: Azymethiin
Study No.: 32234
Protocol No.: 7601
Lot No.: — Purity: — %
ABC Study Director: w a mcallister

Lab Form No.: 18
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane,
P.O. Box 1097
Columbia, Missouri 65205

Sample Number	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Purity Correction	Dilution Volume (l)	Final Conc. (mg/l)
1						
2						
3						
4						
5						
6						

Balance Calibration: _____ g (class C wt.) + _____ g (tare) = _____ g (final Wt.)

Prepared By: _____ Date: _____

Checked By: _____ Date: _____

Sample Number	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Purity Correction	Dilution Volume (l)	Final Conc. (mg/l)
1	0.014	0.000	0.014	—	1.5	5.6
2	0.15	0.000	0.15	—	1.5	10
3	0.27	0.000	0.27	—	1.5	18
4	0.48	0.000	0.48	—	1.5	32
5	0.84	0.000	0.84	—	1.5	56
6						
7						
8						

Balance Calibration: 0.500 g (class C wt.) + 0.000 g (tare) = 0.501 g (final Wt.)

Prepared By: Jane B. Burner Date: 2-26-05

Checked By: Paul Cobb Date: 2/26/05

PREPARATION OF TEST CONCENTRATIONS (weight/volume)

Test Material: Azomethine
Study No.: 32234
Protocol No.: 7601
Lot No.: — Purity: — %
ABC Study Director: N. A. McAllister

Lab Form No.: 18
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane,
P.O. Box 1097
Columbia, Missouri 65205

Sample Number	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Purity Correction	Dilution Volume (l)	Final Conc. (mg/l)
1	0.15	0.000	0.15	—	15	10
2	1.5	0.000	~~0.1~~ 1.50	—	15	100
3						
4						
5						
6						

Balance Calibration: 0.500 g + 0.000 g = 0.500 g
(class C wt.) (tare) (final Wt.)

Entry error JHB 2-22-85

Prepared By: Jane Bowman Date: 2-22-85
Checked By: Paul Cohle Date: 2/22/85

Sample Number	Gross Weight (g)	Tare Weight (g)	Net Weight (g)	Purity Correction	Dilution Volume (l)	Final Conc. (mg/l)
1						
2						
3						
4						
5						
6						
7						
8						

Balance Calibration: _____ g + _____ g = _____ g
(class C wt.) (tare) (final Wt.)

Prepared By: _____ Date: _____

Checked By: _____ Date: _____

DEFINITIVE CONCENTRATION NOTIFICATION

Firm: Monsanto
Address: 800 N Lindbergh Blvd
City/State/Zip: St. Louis, MO 63167
Phone: (314) 694-1000

Lab Form No.: 186

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, MO 65202

Sponsor's Study Director: Joel Kronenberg
Person notified: same(✓) Other:

Date of Notification: 2-26-85

Notification of preliminary testing results with the following definitive test levels agreed upon:

Test Material	ABC #	Test Species	Test Conc. (mg/l)
Azomethine	32234	Rainbow Trout	5.6, 10, 18, 32, 56

Notified By: [signature] Date: 2/26/85

TEST ORGANISM MEASUREMENTS

Test Material: Azomethine
Study No.: 32234
Protocol No.: 7601
ABC Study Director: W. A. McAllister

Lab Form No.: 24

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, MO 65205

Test Species: Rainbow Trout Lot No.: 4784
Source: Spring Creek Trout Hatchery, Livingston, Montana
Date Measured: 3/2/85 by DB Group Measured: CONTROL

Number	Standard Length (mm)	Weight (g)
1	40	.77
2	39	.90
3	44	1.2
4	35	.50
5	38	.82
6	40	.89
7	40	.93
8	39	.80
9	45	1.2
10	40	.97
Mean (±Std. Dev.)	40 ± 2.7	.94 ± 0.21

Remarks:

Prepared By: [signature] Date: 2/26/85
Checked By: [signature] Date: 3-11-85

STUDY# 032234 pg 001 of 0054

WATER QUALITY

Test Material: Glyphosate

Study No.: 32234

Protocol No.: 1601

ABC Study Director: M. McCall

Lab Form No.: 28a

Analytical Bio-Chemistry Laboratories
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Concentration mg/l	2/26/85 Day 0 RJ/JHB				2-28-85 Day 2 JHB				3/2/85 Day 4 DB				Day			
	Temp. °C	D.O.[a] mg/l	pH[b]		Temp. °C	D.O. mg/l	pH		Temp. °C	D.O. mg/l	pH		Temp. °C	D.O. mg/l	pH	
[illegible]	11	10.0	7.4		12	8.9	7.0		12	7.9	6.9					
[illegible]	11	10.0	7.5		12	8.6	7.0		12	7.8	6.8					
[illegible]																
[illegible]																
[illegible]					12	8.5	7.0		12	7.8	6.8					
[illegible]	11	10.0	7.5													

[a] Dissolved oxygen concentrations-Dissolved Oxygen Probe (YSI Dissolved Oxygen System Model 54).

[b] pH-pH Probe (Corning Model 476182) used with Corning Model 125 pH and mV meter.

Remarks:

Prepared by: [illegible] Date: 2-26-85

Checked by: [illegible] Date: 3-11-85

LC$_{50}$ COMPUTER ANALYSIS DATA SHEET

Test Material: Azinmethin

Study No.: 32234

Test Species: Rainbow Trout

Exposure Period: 24 hours

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

ABC Study Director: W. A. McAllister

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
56	10	5	50	32.3047
32	10	0	0	.0976563
18	10	0	0	.0976563
10	10	0	0	.0976563
5.6	10	0	0	.0976563

AT A CONFIDENCE LEVEL OF 95 PERCENT THE BINOMIAL TEST
SHOWS THAT THE LC50 IS ABOVE 32 PPM
THE USEFULLNESS OF ANY LC50 CALCULATED FROM THIS DATA IS
QUESTIONABLE BECAUSE A CONCENTRATION EFFECT RELATIONSHIP HAS NOT BEEN
DEMONSTRATED OVER A RESONABLE RANGE (E.G. <37 TO >63) OF PERCENT DEAD.
56 PPM CAN BE USED AS AN APPROXIMATE LC50 FOR THIS SET OF DATA.

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING
AVERAGE OR PROBIT METHOD CAN GIVE STATISTICALLY SOUND RESULTS.

****

Method Reported:

☐ Binomial ☐ Moving Average ☐ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC$_{50}$.

Prepared By: Jan Bowman Date: 3-5-85

Checked By: William A. McAllister Date: 3-11-85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Azomethine
Study No.: 32234
Test Species: Rainbow Trout
Exposure Period: 48, 72 and 96 hour
ABC Study Director: W. A. McAllister

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
56	10	10	100	.0976563
32	10	9	0	.0976563
18	10	[illegible]	0	.0976563
[illegible]	10	[illegible]	0	.0976563
5.6	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT 32 AND 56 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THIS LIMIT IS 95 PERCENT

AN APPROXIMATE LC50 OF 42.332 PPM IS OBTAINED BY NONLINEAR INTERPOLATION BETWEEN 32 AND 56

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE OR PROBIT METHOD CAN GIVE STATISTICALLY SOUND RESULTS.

****

Method Reported:

☒ Binomial ☐ Moving Average ☐ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: Jan Bowman Date: 3-5-85

Checked By: William A. McAllister Date: 3-11-85

MORTALITY AND BEHAVIORAL OBSERVATIONS

[✓] Definitive [ ] Preliminary

Test Material: Antimycin A
Study No.: Method Validation Test
Protocol No.: 7601
ABC Study
Director: W.A. McAllister

Lab Form No.: 32
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Test species: [ ] L.macrochirus [✓] S.gairdneri [ ] (Lot #4784)
No./Vessel: 10 Dil. Water: [✓] Recon. [ ] Well
Acclimation Mortality: 0
Date Initiated: 2/20/85 Date Terminated: 2/24/85

Test Conc. mg/l (ppm)	24 Hours		48 Hours		72 Hours		96 Hours	
	Dead	Obs.	Dead	Obs.	Dead	Obs.	Dead	Obs.
Control	0	N	0	N	0	N	0	N
Solvent Control	0	N	0	N	0	N	0	N
0.000014	0	N	0	N	1	9N	1	9N
0.000024	0	N	0	N	0	N	0	N
0.000042	0	N	1	3SUR 2N; 4Q	7	3Q	8	2Q/DK
0.000075	7	1SUR 2N	9	1Q	10	—	10	—
0.00014	5	2SUR 3Q	10	—	10	—	10	—
Observer Date	PC 2/21/85		PC 2/22/85		AF 2/23/85		AF 2/24/85	

Remarks: N = Normal; LOE = Loss of Equilibrium; Q = Quiescent
SUR = Surfacing; DK = Dark Discoloration; OB = On Bottom

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By [illegible] date [illegible]

Prepared By: Paul Cohle Date: 2/26/85
Checked By: [illegible] Date: 2-25-85

STUDY# 032234 pg 0020 of 0054

COMPOUND PREPARATIONS

Test Material: Antimycin A
Study No.: Method Validation Test
Protocol No.: 7601
Lot No.: 79C-0588 Purity: — %
ABC Study Director: W. A. McAllister

Lab Form No.: 27
Analytical Bio-Chemistry Lab
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

Preparation of Concentrated Working Standard

Date 3/7/84 Biologist Paul Cobb
Final Gross Weight 9.5454 g
Tare Weight 9.5154 g
Net Weight 0.0300 g
Adj. Net Weight —— g*
*Corrected for purity of primary standard.
Dilution Volume 100 (acetone) ml
Concentration 0.30 mg/ml
Balance calibrated with class C weights:
0.0250 g (class C) + 20.0005 g (tare) = 20.0255 g (final wt.)

Preparation of ~~Preliminary Test~~ Secondary Stock Concentrations

Date 3/7/84 Biologist Paul Cobb

	Conc. of Work. Std. (mg/ml)	Aliq. Vol. (ml)	Dilution Vol. ~~(l)~~	Final Conc. ~~(mg/l)~~
1.	0.30	0.5	100 ml	0.0015 mg/ml
2.				
3.				

Preparation of Concentrated Working Standard

Date —— Biologist ——
Final Gross Weight —— g
Tare Weight —— g
Net Weight —— g
Adj. Net Weight —— g*
*Corrected for purity of primary standard.
Dilution Volume —— ml
Concentration —— mg/ml
Balance calibrated with class C weights:
—— g (class C) + —— g (tare) = —— g (final wt.)

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Preparation of Definitive Test Concentrations

Date 2/20/85 Biologist Paul Cobb

	Conc. of Work. Std. (mg/ml)	Aliq. Vol. (ml)	Dilution Vol. (l)	Final Conc. (mg/l)
Solvent Control	——	1.4 (acetone)	15	——
1.	0.0015	0.14	15	0.000014
2.	0.0015	0.24	15	0.000024
3.	0.0015	0.42	15	0.000042
4.	0.0015	0.75	15	0.000075
5.	0.0015	1.4	15	0.00014
6.				
7.				

Prepared By: Paul Cobb Date: 2/20/85
Checked By: William A. McAllister Date: 2-20-85

TEST ORGANISM MEASUREMENTS

Test Material: Antimycin A
Study No.: Method Validation Test
Protocol No.: 7601
ABC Study Director: A. Forbes

Lab Form No.: 24

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, MO 65205

Test Species: S. gairdneri Lot No.: 4784
Source: Spring Creek Trout Hatchery, Lewistown, Montana
Date Measured: 2/24/85 Group Measured: Control

Number	Standard Length (mm)	Weight (g)
1	38	0.76
2	38	0.75
3	33	0.73
4	37	0.68
5	39	0.76
6	42	1.11
7	36	0.57
8	42	1.10
9	42	1.04
10	35	0.62
Mean (±Std. Dev.)	38 (±3.1) PC 2/25/85	0.78 (±0.23) PC 2/25/85

Remarks:

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By [illegible] date [illegible]

Prepared By: Alan D. Forbes Date: 2/24/85
Checked By: Paul Cahill Date: 2/25/85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Antimycin A
Study No.: Methods Validation Test
Test Species: Rainbow Trout
Exposure Period: 24 hours
ABC Study Director: W.A. McAllister

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.00014	10	5	50	62.3047
.000075	10	0	0	.0976563
.000042	10	0	0	.0976563
.000024	10	0	0	.0976563
.000014	10	0	0	.0976563

AT A CONFIDENCE LEVEL OF 95 PERCENT THE BINOMIAL TEST
SHOWS THAT THE LC50 IS ABOVE .000075 PPM
THE USEFULLNESS OF ANY LC50 CALCULATED FROM THIS DATA IS
QUESTIONABLE BECAUSE A CONCENTRATION EFFECT RELATIONSHIP HAS NOT BEEN
DEMONSTRATED OVER A RESONABLE RANGE (E.G.<37 TO >63) OF PERCENT DEAD.
.00014 PPM CAN BE USED AS AN APPROXIMATE LC50 FOR THIS SET OF DATA.

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING
AVERAGE OR PROBIT METHOD CAN GIVE STATISTICALLY SOUND RESULTS.

****

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By [signature] date 5-6-85

Method Reported:

☐ Binomial ☐ Moving Average ☐ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: Paul Cohle Date: 2/25/85
Checked By: William A. McAllister Date: 2-25-85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Antimycin A
Study No.: Methods Validation Test
Test Species: Rainbow Trout
Exposure Period: 48 hours
ABC Study Director: W.A. McAllister

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.00014	10	10	100	.0976563
.000075	10	9	90	1.07422
.000042	10	1	10	1.07422
.000024	10	0	0	.0976563
.000014	10	0	0	.0976563

THE BINOMIAL TEST SHOWS THAT .000042 AND .000075 CAN BE USED AS

STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS BECAUSE
THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THIS LIMIT IS >95 PERCENT
AN APPROXIMATE LC50 OF 5.61248E-05 PPM IS OBTAINED BY

NONLINEAR INTERPOLATION BETWEEN .000042 AND .000075

----RESULTS CALCULATED USING THE MOVING AVERAGE METHOD----

SPAN	G	LC50 PPM	95 PERCENT CONFIDENCE LIMITS LOWER	UPPER
3	.115914	5.68714E-05	4.49315E-05	7.224E-05
2	.167754	5.61249E-05	4.00414E-05	6.98794E-05
2	.167754	5.61249E-05	4.57344E-05	7.72577E-05
1	.28942	5.61248E-05	4.70649E-05	6.6929E-05

----------RESULTS CALCULATED USING THE PROBIT METHOD----------

ITERATIONS	G	H	CHI-SQUARE	PROBABILITY
6	.333711	1	4.58336E-03	.999918

SLOPE = 10.1911
95 PERCENT CONFIDENCE LIMITS = 4.30398 AND 16.0783

LC50 = 5.61291E-05

95 PERCENT CONFIDENCE LIMITS = 4.58413E-05 AND 6.90972E-05

****

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Method Reported: By [illegible] date 1-6-85

☐ Binomial ☐ Moving Average ☑ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: Paul Cobb Date: 2/25/85

Checked By: Willi A. McAllister Date: 2-25-85

LC_{50} COMPUTER ANALYSIS DATA SHEET

Test Material: Antimycin A
Study No.: Method Validation Test
Test Species: Rainbow Trout
Exposure Period: 96 hours
ABC Study Director: W.A. McAllister

Lab Form No.: 42

Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P.O. Box 1097
Columbia, Missouri 65205

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****

CONC. PPM	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.00014	10	10	100	.0976563
.000075	10	10	100	.0976563
.000042	10	8	80	5.46875
.000024	10	0	0	.0976563
.000014	10	1	10	1.07422

THE BINOMIAL TEST SHOWS THAT .000024 AND .000075 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THIS LIMIT IS >95 PERCENT
AN APPROXIMATE LC50 OF 3.52171E-05 PPM IS OBTAINED BY NONLINEAR INTERPOLATION BETWEEN .000024 AND .000042

----RESULTS CALCULATED USING THE MOVING AVERAGE METHOD----

SPAN	G	LC50 PPM	95 PERCENT CONFIDENCE LIMITS LOWER	UPPER
4	.178919	3.47742E-05	2.33021E-05	4.80627E-05
3	.17095	3.63345E-05	2.79055E-05	5.0018E-05

----------RESULTS CALCULATED USING THE PROBIT METHOD----------

ITERATIONS	G	H	CHI-SQUARE	PROBABILITY
5	.253823	1	7.70636	.0524861

SLOPE = 5.81315
95 PERCENT CONFIDENCE LIMITS = 2.88444 AND 8.74187

LC50 = 3.28038E-05
95 PERCENT CONFIDENCE LIMITS = 2.5578E-05 AND 4.23314E-05

****

Method Reported:

☐ Binomial ☐ Moving Average ☑ Probit

Note: Method selected is that which gives the narrowest confidence limits for LC_{50}.

Prepared By: Paul Cobb Date: 2/25/85
Checked By: Willis A. McAllister Date: 2-25-85

FISH CULTURE RECORD

Species: Rainbow Trout
Lot No.: 4784 Tank No.: 2
Source: Spring Creek Trout Hatchery, Townstown, Montana

Lab Form No.: 50
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P. O. Box 1097

Date Received: 12/11/84 No. Received ~4000

Date	Obs. I.D.	Mortality	Feeding Schedule	Treatment Drug	Conc.	Time	Type	Comments
12/11	PC	75						arrived as eggs
12/12	DC	29+51						
12/13	PC	101+20						
12/14	PC	57+37						Changed A.C. filter
12/15	[illegible]	25+9						
12/16	[illegible]	32+49						
12/17	[illegible]	45+35+66						
12/18	[illegible]	19+20						
12/19	[illegible]	68+34+43						
12/20	[illegible]	57						~20 [illegible]
12/21	LG	31+18						
12/22	LG	15						
12/23	LG	39						
12/24	[illegible]	[illegible]						
12/25	AF	– 4						100% hatch
12/26	[illegible]	14+25	10.5, 1, 2, 4					moved to tank two
12/27	[illegible]	0	8, 10.5, 2, 4					
12/28	[illegible]	24						
12/29	DB	1	" "					
12/30	DB	1	" "					
12/31	PC	~50	[illegible], 15, 4					
1/1/85	PC	11	1, 4					
1/2	PC	10	8, 11, 1, 2, 4					
1-3	[illegible]	10	8, 10, 12, 2, 4					~300 removed to release crowding

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Prepared By: Paul Cohle Date: 12/11/84
Checked By: [illegible] Date: [illegible]

4 [illegible] removed 12/25/84 AF

FISH CULTURE RECORD

Species: Rainbow Trout
Lot No.: 4784 Tank No.: 2
Source: Spring Creek Trout Hatchery; Livingston, Montana
Date Received: 12-11-84 No. Received ~4000

Lab Form No.: 50
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P. O. Box 1097

Date	Obs. I.D.	Mortality	Feeding Schedule	Treatment Drug	Conc.	Time	Type	Comments
1-4	JH	2	8,10,12,4					
1/5	LG	0	6.5 8 9.5,12					
1/6	LG	0	10 " 12 1					
1/7	PC	5	8,12,4					
1/8	PC	0	9,11,1					
1/9	PC	0	11,9,4					
1-10	JH	0	8,12,4					
1/11	PC	2	8,12,4					
1/12	PC	0	8					
1/13	DB	0	" "					
1-14	JH	0	8,12,4					
1/15	PC	0	8,4					
1/16	PC	0	8,4					
1/17	PC	0	8, 4					
"	"	"	"					
1/19	JH	-	8,11,1					
1/20	JH	0	9,					
1/21	PC	0	8,12,4					
1-22	JH	3	9,4					
1-23	[illegible]	0	8, 4					
1-24	JH	0	8/4					
1/25	PC	0	8					
1/26	[illegible]	0	9					
1/27	[illegible]	1	9					

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Prepared By: Jane Hillesh Date: 1-4-85
Checked By: Paul Cobb Date: 2/25/85

FISH CULTURE RECORD

Species: Rainbow Trout
Lot No.: 4784 Tank No.: 2
Source: Spring Creek Trout Hatchery; Lewistown, Montana

Lab Form No.: 50
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P. O. Box 1097

Date Received: 12/11/84 No. Received ~4000

Date	Obs. I.D.	Mortality	Feeding Schedule	Treatment Drug	Conc.	Time	Type	Comments
1/28	PC	0	10					Removed some due to crowding.
1-29	JB	0	8 + 4					
1/30	PC	0	8, 4					
1-31	JHB	0	8					
2-1	JHB	0	8					
2/2	LG	0	12					
2/3	LG	0	2					
2/4	PC	1	8					
2/5	PC	1	10, 4					
2-6	JHB	0	4					
2/7	PC	0	8					
2-8	JHB	0	8					
[illegible]	[illegible]	0	11, 3					
2/10	PC	0	11					
2/11	PC	0	12, 4					
2-12	JHB	0	8					
2-13	JHB	0	8					
2/14	PC	0	8					
2-15	JHB	0	8					
2/16	LG	0	10					
2/17	LG	0	11.5					
2/18	PC	0	8					[illegible] for [illegible]
2/19	PC	-	8					
2-20	JHB	0	8					

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By [illegible] date [illegible]

Prepared By: Paul Cohl Date: 1/28/85
Checked By: Jane Bowman Date: 2-25-85

[illegible] LG 2/16/85

STUDY# 032234

FISH CULTURE RECORD

Species: Rainbow Trout
Lot No.: 4784 Tank No.: 2
Source: Spring Creek Trout Hatchery, Lewistown, Montana

Lab Form No.: 50
Analytical Bio-Chemistry Labs
Aquatic Toxicology Division
7200 ABC Lane, P. O. Box 1097

Date Received: 12-11-84 No. Received ~4000

Date	Obs. I.D.	Mortality	Feeding Schedule	Treatment				Comments
				Drug	Conc.	Time	Type	
2-21	JHB	0	8					
2/22	PC	0	8					
2/23	AF	0	9					
2/24	AF	0	7					
2-25	JHB	0	8					
2-26	JHB	0	9					
2-27	JHB	0	8					
2-28	JHB	0	8					
3-1	JHB	1	8					
3/2	DB	0	8					
3/3	DB	0	8					
3/4	PC	0	8					

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By [illegible] date [illegible]

Prepared By: Jane Bowman Date: 2-21-85
Checked By: Paul Cobb Date: 3/7/85

FISH ACCLIMATION RECORD

Species: Rainbow Trout
Species Lot No.: 4724
Culture Tank No.: 3
Acclimation Tank No.: R

Lab Form No.: 119

Analytical Bio-Chemistry Labs
Aquatic Toxicologist Division
7200 ABC Lane, P. O. Box 1097
Columbia, MO 65205

No. Removed From Culture 200 Date Removed 2/18/95 Date Returned *

Dilution Water Type: ☑ Recon ☐ Well ☐ Salt

Acclimation Time (hrs.)	Date	Obs.	Acclimation Temp. (°C)	Acclimation Mortality	No. Used	Study No.
0	2/18	PC	15	—	----	----
24	2/19	PC	11	0	----	----
48	2/20	PC	12	0	70	Antimycin A
72	2/21	PC	12	0+1	15	32859
					15	32871
					15	32869
96	2/22	PC	12	0	10	32234
					10	32237

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Remarks: Note - all fish held without food during acclimation. * Remaining fish were terminated on 2/24/95 by A.F (PC.)

Prepared By: Paul Cobb Date 2/18/95

Checked By: [illegible] Date 2-25-95

FISH ACCLIMATION RECORD

Species: S. gairdneri
Species Lot No.: 4784
Culture Tank No.: 2
Acclimation Tank No.: R

Lab Form No.: 119

Analytical Bio-Chemistry Labs
Aquatic Toxicologist Division
7200 ABC Lane, P. O. Box 1097
Columbia, MO 65205

No. Removed From Culture 300 Date Removed 2/24 Date Returned 2-28

Dilution Water Type: ☒ Recon ☐ Well ☐ Salt

Acclimation Time (hrs.)	Date	Obs.	Acclimation Temp. (°C)	Acclimation Mortality	No. Used	Study No.
0	2/24	AF	17	—	----	----
24	2/25	PC	13	1	----	----
48	2-26	JHB	12	0	60	32234
					60	32237
72	2/27	PC	12	0	60	32859
96	2-28	JHB	12	0		

"This is an exact copy of The original document"
By [illegible] date 3-1-85

Remarks: Note - all fish held without food during acclimation.

Prepared By: [illegible] Date 2/24/85
Checked By: Jane Bowman Date 3-5-85

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65205 • (314) 474-8579

February 10, 1984

ANALYTICAL RESULTS FOR:

Aquatic Division
Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P.O. Box 1097
Columbia, MO 65205

Water Analysis Results

ABC Lab No.	30896-1
Sample I.D.	ABC Deep Well Water
NH_3-N	0.6 mg/l
NO_3-NO_2-N	0.20 mg/l
Total Phosphorus	<0.01 mg/l
Al	<10 µg/l
Co	<3 µg/l
Fe	<4 µg/l
As	<0.5 µg/l
Cd	<2 µg/l
Cr	<6 µg/l
Cu	2 µg/l
Pb	17 µg/l
Hg	0.8 µg/l
Ni	<13 µg/l
Ag	<0.4 µg/l
Zn	1 µg/l

<Indicates less than, if present at all.

Floyd E. Kaiser
Nutritional Group Supervisor

FEK/kkg

Please note that the original data for the analysis reported in this table are in ABC's archives.

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65205 • (314) 474-8579

December 6, 1983

ANALYTICAL RESULTS FOR:

Aquatic Division
Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P. O. Box 1097
Columbia, MO 65205

Analysis of Well Water for Organophosphates

ABC Lab No.	Customer I. D.	Compound	ppb
30637-1	Lab Well Water	Diazinon	<0.055
		Methyl Parathion	<0.14
		Malathion	<0.15
		Ethyl Parathion	<0.15

Stanley Shaffer
Residue Chemist

SS/kg

Please note that the original data for the analysis reported in this table are in ABC's archives.

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC.
P.O. Box 1097 • Columbia, MO 65205 • (314) 474-8579

December 6, 1983

ANALYTICAL RESULTS FOR:

Aquatic Division
Analytical Bio-Chemistry Laboratories, Inc.
7200 East ABC Lane
P. O. Box 1097
Columbia, MO 65205

Analysis of Well Water for Nonionic
Chlorinated Hydrocarbon Residue

ABC Lab No.	30637-1
Customer I. D.	Aquatic Well Water
Compound	ppb
αBHC	<0.02
βBHC	<0.02
γBHC	<0.02
δBHC	<0.02
Heptachlor	<0.02
Heptachlor Expoxide	<0.04
αChlordane	<0.04
βChlordane	<0.04
Tech Chlordane	<0.08
Aldrin	<0.02
Dieldrin	<0.05
p,p'-DDE	<0.05
o,p'-DDT	<0.08
p,p'-DDD	<0.08
p,p'-DDT	<0.08
Endrin	<0.08
Methoxychlor	<0.30
Toxaphene	<0.80
Aroclor 1242	<0.80
Aroclor 1016	<0.80
Aroclor 1254	<0.80
Aroclor 1260	<0.80
HCB	<0.01
Mirex	<0.10

<indicates less than, if present at all.

Stanley Shaffer
Residue Chemist

SS/kg

Please note that the original data for the analysis reported in this table are in ABC's archives.

ANALYTICAL BIO-CHEMISTRY LABORATORIES, INC
P.O. Box 1097 • Columbia, MO 65205
Shipping Address 7200 East ABC Lane Columbia MO 65202
314/474-8579 • Telex 821 814 • Answer Back (ABCLAB UD)

ABC PROTOCOL NO. 7601

(Revised July 11, 1984)

STATIC BIOASSAY PROCEDURE FOR DETERMINING THE ACUTE TOXICITY OF CHEMICAL SUBSTANCES TO FRESHWATER FISH

ABC Study Number 32234

Test Material ~~Azomethine~~ 2,6-diethylphenyl azomethine

Test Species Rainbow Trout (Salmo gairdneri)

AB-84-388

1.0 INTRODUCTION

Aquatic toxicity tests have been used extensively in the assessment of the environmental effects of chemical substances. Indeed, aquatic bioassays are required by federal laws such as the Toxic Substances Control Act (1), FIFRA (2), and the Clean Water Act of 1977 (3). With the testing guidelines for these laws in mind, as well as FDA's Good Laboratory Practice Regulations (4) which complement them, Analytical Bio-Chemistry Laboratories, Inc. has prepared the following protocol. The static bioassay method presented here was patterned after procedures that were formulated by the U. S. Environmental Protection Agency (5), American Public Health Association (6), and the American Society for Testing and Materials (7).

2.0 OBJECTIVES

The primary objective of the toxicity test described herein is to evaluate the acute toxicity of a chemical substance to freshwater fish under static conditions. This is achieved by determining LC_{50} levels of the toxicant during a 96 hour exposure period. An LC_{50} is the approximate concentration of the test material that produces 50 percent mortality of test fish after prescribed intervals. The method is designed to yield LC_{50} values following 24, 48 and 96 hours of exposure.

3.0 TESTING FACILITY

The study will be conducted by the Aquatic Toxicology Division of Analytical Bio-Chemistry Laboratories, Inc., 7200 East ABC Lane, P. O. Box 1097, Columbia, Missouri 65205.

4.0 RANGE-FINDING STUDY

4.1 General. For most chemical substances, the approximate toxic level to aquatic organisms is not known. Because this information is essential before a definitive toxicity test can be conducted, ABC routinely performs range-finding tests for static bioassays with fish. The information derived from this preliminary test will be used to set concentration levels for the definitive bioassay described in section 5.0.

4.2 Test Fish. The fish species to be used should be selected by the study sponsor from the list of recommended species in Table 1. The most common species used for toxicity testing includes bluegill sunfish (Lepomis macrochirus), rainbow trout (Salmo gairdneri), and fathead minnows (Pimephales promelas). Fish ranging in size from actively-feeding fry to 5.0 g will be used as test organisms. The fish standard length of the largest fish will be no more than twice that of the shortest fish. The fish will be obtained from an established commercial hatchery or in-house cultures. The particular source to be used is dependent upon the seasonal availability of test fish and will be listed at the time of protocol approval in the test-specific information of section 8.5, along with the species selected by the study sponsor.

The test fish lot will be from the same year class and will be identified to species using the taxonomic keys developed by Eddy (8) and cultured following the techniques described by Brauhn et. al. (9). All test fish will be held on a 16-hour daylight photoperiod and observed for at least 14 days prior to testing. A daily record of fish observations during the holding period, along with prophylactic and therapeutic disease treatments, will be kept and included with the final report. During the holding period, they will receive a standard commercial fish food (Rangen's®) at a maintenance rate of 3 to 5 percent of their body weight per day. The test lot will be held without food and acclimated to the test temperature for at least 48 hours prior to testing. If mortality of the test lot exceeds 10 percent in the 48 hours previous to testing, the fish will not be used. Previous to or concurrent with the test, the fish lot will be challenged against a reference compound, Antimycin A*, to determine their general health and suitability as test organisms. The results of the Antimycin A test will be compared against published toxicity values (10).

4.3 Test System. The range finding test will be conducted in five gallon widemouth glass jars containing 15 liters of test solution and five fish per concentration. These test vessels will be immersed in a circulating water bath with temperatures maintained within ±1°C of the desired test temperature (Table 1). For temperature control in the water bath, thermostatically controlled heating elements will be used for warmwater tests (22 ±1°C) and refrigeration units (Min-O-Cool®) for coldwater bioassays (12 ±1°C). The dilution water used will be a soft reconstituted water of the following makeup in deionized water: 48 mg/l $NaHCO_3$, 30 mg/l $CaSO_4 \cdot 2H_2O$, 30 mg/l $MgSO_4$, and 2.0 mg/l KCl. The water quality parameters of this dilution water are: pH: 7.2-7.6; total hardness: 40-48 mg/l $CaCO_3$; and total alkalinity: 30-35 mg/l $CaCO_3$. Also available, at the sponsor's request, is an alternate dilution water from a deep well source with chemical and physical characteristics shown in Table 3.

4.4 Test Material. A letter of authorization for the study should be sent with the test material or previous to its shipment and should contain the following chemical/physical properites of the compound if available: name of test material, code number, physical description, purity, stability, suggested storage conditions, water and organic solvent solubility, available toxicity information, and handling precautions. The test concentrations will be prepared on a weight/volume basis unless otherwise specified. A record of all sample weights and dilutions will be kept, checked by a second party, and furnished in the final report. Under certain experimental conditions, the sponsor may elect to confirm test concentrations by approved analytical techniques. Factors such as limited aqueous solubility, volatility and aquaria aeration may require analysis at 0 and 96 hours.

*Antimycin A standard obtained from Sigma Chemical Company, Type III, crystalline, Lot 125C-0152.

4.5 Test Procedure. The range-finding procedure is as follows:

4.5.1 Test fish will be acclimated to the test temperature and dilution water for at least 48 hours prior to testing, during which time they will be held without food.

4.5.2 The range-finding test will be initiated by exposing groups of five fish to two or three toxicant concentrations spaced by a factor of 10. If acute toxicity information is available from previous studies or it is indicated that the material is basically non-toxic by the study sponsor, only one preliminary test concentration may be used before the definitive test. ABC will test up to a maximum of 1,000 mg/l in the definitive test, unless otherwise requested by the study sponsor. The test fish will be placed in the test chambers by stratified random assignment within 30 minutes after solution preparations. The initial toxicant concentrations most often used are 1, 10 and 100 mg/l. Numerous static tests by ABC have shown that a significant percentage of the compounds tested have aquatic toxicities which fall within this range.

4.5.3 After 24 hours of exposure, the test chambers will be observed for mortality and/or adverse behavioral effects. Dead individuals will be removed at each observation and a record maintained of mortality and abnormal behavior. Dependent upon this observation, additional test concentrations may be added at levels above or below the initial concentrations. This procedure will be followed until a toxic range is determined. For example, if the 24 hour exposure results in total mortality, new solutions will be prepared at a factor of 10 below the lowest initial concentration until no mortality or partial mortality is reached. In the converse situation, if no mortality is observed after 24 hours, new solutions will be added at concentrations spaced by a factor of 10 above the highest initial level until mortality is noted. In this manner, a bracket is formed for the toxic range of the compound.

4.5.4 The preliminary test will be conducted for a period of 24 to 96 hours - the exact duration dependent upon the results of the initial concentrations tested. In most cases, a preliminary test for 48 hours at 2-3 toxicant concentrations is sufficient to determine the toxic range.

4.5.5 Results of the range-finding study will be used to set the concentration range of the definitive study described in section 5.0. At least five toxicant concentrations selected from the logarithmic scale presented in Table 2, which fall within the preliminary test range, have proven to be adequate in assessing most compounds.

5.0 DEFINITIVE STUDY

5.1 General. Following the preliminary range-finding study discussed in section 4.0, the definitive test will be conducted by

the procedures described below. Test-specific information regarding the sponsor, test material, test fish, proposed study dates, study personnel and study approvals will be included in section 8.0 at the time of protocol approval.

5.2 Test Fish. Aspects concerning the acquisition, culture and acclimation of test fish will be the same as discussed in section 4.2.

5.3 Test System. For all definitive testing, the test vessel size will conform to the maximum loading limitation of 0.8 grams of fish per liter of solution (5). One of the following types of glass test chambers will be used: (a) 5 gallon glass jars containing 15 liters of solution, (b) 40 liter aquaria containing 30 liters of solution, or (c) 100 liter aquaria containing 75 liters of solution. ABC will select the type of chamber to be used. In most instances, the test chambers used will be 5 gallon glass jars containing 15 liters of solution, which is a recommended test vessel for static bioassays (5). The water bath system described in section 4.3 will be used to control test temperatures. The test dilution water will be the same as discussed in section 4.3.

5.4 Test Material. Specific information regarding the test material is to be supplied by the sponsor and will be addressed in section 8.3 at the time of protocol approval. The remaining test sample will be sent back to the study sponsor upon approval of the final report.

5.5 Test Procedure-Biological. The basic test procedure for the definitive bioassay will be as follows:

5.5.1 The test fish will be acclimated to the test temperature and dilution water for at least 48 hours prior to testing, during which time they will be held without food.

5.5.2 The definitive test will be initiated by exposing groups of 10 organisms to at least 5 toxicant concentrations and a dilution water control. The test concentrations used will be based upon the results of the range-finding test and will be selected from one of the logarithmic series presented in Table 2. The definitive test concentrations will be selected after discussing preliminary results with study sponsor. If a solvent is used in the preparation of test solutions, an additional solvent control chamber will be used which will receive an aliquot of the solvent equivalent to the highest amount used in the test chambers. The test organisms will be placed in the test chambers by stratified random assignment within 30 minutes after solution preparations.

5.5.3 As an alternate test design, duplicate test chambers per concentration containing 5 fish each will be used to reduce biomass loading rates when using test fish near the upper size limit of that recommended.

5.5.4 The test chambers will be observed for mortality and/or adverse behavioral effects every 24 hours. Dead individuals

will be removed at each observation and a record maintained of mortality and abnormal behavior for each concentration tested.

5.5.5 Length and weight measurements will be made on either a representative group of the test fish prior to testing or on the control group at test termination.

5.6 Test Procedure-Chemical and Physical. Water quality parameters of temperature, dissolved oxygen and pH will be monitored throughout the test. Measurements of temperature, dissolved oxygen and pH will be made at 0, 48 and 96 hours of testing in the control, low concentration and highest concentration with surviving fish. If at any point in the study dissolved oxygen levels are observed to be below or approaching 40 percent saturation, ABC will contact the sponsor's study director for authorization to artificially aerate the test chambers with compressed air for the duration of the study. In cases where the dissolved oxygen reduction is felt to be compound-related, i.e., the control chamber is at an acceptable dissolved oxygen level, ABC recommends that the test solutions not be aerated. Aeration is also not recommended in instances where control levels are marginal, i.e., dissolved oxygen values fall slightly below 40% saturation. In the event aeration is required, it is recommended that the test concentration be measured by an accepted analytical method. The authorization procedure used will be that described in section 7.0.

5.7 Analysis of Results. The results of the definitive study will be statistically analyzed for 24, 48 and 96 hour LC_{50} values and their corresponding 95 percent confidence limits. These values will be determined by an LC_{50} computer program developed by Stephan et. al. (13) or by manual methods described by Litchfield and Wilcoxon (11) and Stephan (12).

5.8 Report. One copy of the report will be submitted. The report will contain all original raw data. Additional copies will be provided, if requested by the sponsor, at a copy rate of $25 per copy. The report will include the following:

5.8.1 Study dates, name and address of test facility.

5.8.2 Objectives and test methods.

5.8.3 Reference to the statistical methods used for data analysis.

5.8.4 Description of test material (date of receipt, storage conditions, purity, physical characteristics, and method of preparing test concentrations).

5.8.5 Description of test design.

5.8.6 Summary of the data analysis, mortality observations and test water quality.

5.8.7 Location of raw data.

5.8.8 List and signatures of study personnel.

5.8.9 GLP compliance statement by study director and a statement by ABC's Quality Assurance Unit.

5.8.10 The report appendix will contain the original raw data for mortality observations and water quality, results of the Antimycin A reference test, records of fish size and daily holding log, letter of test authorization, letters of authorized protocol changes, and a copy of the approved protocol.

5.9 Data Retention. All original raw data generated in the preliminary and definitive studies will be provided to the study sponsor in the appendix to the final report. A copy of the data will be retained in ABC's archives.

6.0 PROTOCOL CHANGES

In the event that modifications of this protocol are deemed necessary, a written statement of any changes and reason(s) proposed by the study sponsor or ABC will be submitted to the other party. All agreed changes will be expressed in writing, signed and dated by the sponsor's study director. The signed changes will be appended to the protocol and included with the final report. This protocol is subject to revision when felt necessary to comply with changes in Federal regulations and state of art methodology. The protocol for a specific study will not be changed while the study is in progress without discussion with the study sponsor.

7.0 SPONSOR AUTHORIZATIONS DURING THE STUDY

Should a problem develop while the study is in progress, ABC will notify the study director within 24 hours. The problem and suggested test modifications will be discussed by telephone. ABC will proceed with the changes felt necessary upon the verbal authorization of the study director. A letter for written authorization will then be submitted by ABC to the study director and handled in the same manner discussed in section 6.0.

8.0 TEST-SPECIFIC INFORMATION

8.1.1 General. The following items will be addressed for each static bioassay. This information is necessary to be in compliance with Good Laboratory Practice Regulations (4). Sections 8.2, 8.3, 8.8 and 8.10 are to be completed by the study sponsor. Sections 8.4, 8.5, 8.6 and 8.7 will be completed by ABC.

8.1.2 GLP Compliance. To be in compliance with the Federal Good Laboratory Practice regulations, the report of the investigation conducted utilizing this protocol must contain a statement that the study was conducted in accordance with one of the following GLP's.

1. U.S. F.D.A. Good Laboratory Practice Regulations (21 CFR 58).

2. U.S. E.P.A. Good Laboratory Practice Standards; Toxic Substances Control (40 CFR 792).

3. U.S. E.P.A. Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160).

4. OECD Principles of Good Laboratory Practice; Annex 2 C(81) 30(Final).

5. Any state or local GLP which may apply.

The specific GLP regulation, for which this study specific protocol and resultant study must be in compliance with, is to be designated by the study sponsor in section 8.8 of this protocol.

8.2 Study Sponsor:

8.2.1 Company Monsanto Chemical Company G2WD

8.2.2 Address 800 North Lindbergh Boulevard
St. Louis, Missouri 63167

8.2.3 Sponsor's Study Director

Dr. Richard C. Dirks _____
Name Title

8.3 Test Material:

8.3.1 Name Azomethine (2,6-diethyl phenyl)

8.3.2 Lot/Batch Number _____

8.3.3 Physical Description _____

8.3.4 Purity _____

8.3.5 Stability _____

8.3.6 Solubility: Water _____ Acetone _____ DMF _____
TEG _____ Ethanol _____ Methanol _____ Other _____

8.3.7 Handling Precautions _____

8.4 Test Concentrations: To be determined after preliminary testing and consultation with study sponsor.

8.4.1 Sponsor's Study Director notified of preliminary results: Date _____ ABC Biologist _____.

8.4.2 Definitive test concentrations agreed upon:

_____.

8.5 Test Fish:

8.5.1 Species Rainbow Trout (Salmo gairdneri)

8.5.2 Supplier Trout Lodge
McMillan, WA

8.6 Study Dates:

8.6.1 Proposed starting date of definitive study Oct. 1984

8.6.2 Proposed completion date of definitive study Nov. 1984

8.7 ABC Study Personnel:

8.7.1 Study Director

William A. McAllister	Aquatic Biologist III
Name	Title

8.7.2 Aquatic Supervisor

Carl M. Thompson	Supervisor, Aquatic Toxicology
Name	Title

8.8 GLP Compliance (check the most appropriate):

EPA-FIFRA ✓; EPA-TSCA ___; FDA ___; OECD ___; Other _____.

8.9 Protocol Approvals. The following is to be signed by the appropriate study personnel:

8.9.1 Sponsor's Study Director

Richard C. Durkee	Prod Test Specialist	10/10/84
Name	Title	Date

8.9.2 ABC's Study Director

William A. McAllister	Aquatic Biologist III	10/9/84
Name	Title	Date

8.9.3 ABC's Group Leader

	Group Leader Animal Toxicology	10/9/84
Name	Title	Date

8.10 Authorization to return the test material and sample:

8.10.1 Sponsor's authorized agent to receive the test material and sample.

Name	Title

8.10.2 Shipping Address

Company

Street Address

City State Zip Code

Phone Number

8.10.3 Hazardous shipment information

Proper Shipping Name

Class of Restricted Article (e.g. flammable, poison, radioactive, etc.)

TABLE 1: RECOMMENDED SPECIES AND TEST TEMPERATURES[a]

Recommended Species	Recommended Test Temperature (°C)
Rainbow Trout, Salmo gairdneri	12
Brook trout, Salvelinus fontinalis	12
Bluegill, Lepomis macrochirus	22
Fathead minnow, Pimephales promelas	22
Channel catfish, Ictalurus punctatus	22
Carp, Cyprinus carpio[b]	22

[a]Adapted from (5).

[b]Recommended for compounds used in Japan.

TABLE 2: Guide to selection of experimental concentrations based on progressive bisection of intervals on logarithmic scale.

Col. 1	Col. 2	Col. 3	Col. 4	Col. 5
10.0	10.0	10.0	10.0	10.0
				8.7
			7.5	7.5
				6.5
		5.6	5.6	5.6
				4.9
			4.2	4.2
				3.7
3.2	3.2	3.2	3.2	3.2
				2.8
			2.4	2.4
				2.1
		1.8	1.8	1.8
				1.55
			1.35	1.35
				1.15
1.0	1.0	1.0	1.0	1.0

TABLE 3: Chemical characteristics of well water used by ABC's Aquatic Toxicology Division.

Parameters	Concentration
Temperature	15-20°C[b]
Dissolved Oxygen[a]	9.2-10.1 ppm[b]
pH	7.8-8.3[b]
Hardness ($CaCO_3$)	225-275 ppm[b]
Alkalinity ($CaCO_3$)	325-375 ppm[b]
Conductivity	700 µmhos/cm
NH_3-N	0.60 ppm
NO_3-NO_2-N	0.20 ppm
Ortho-Phosphate	0.10 ppm
Aluminum	<0.010 ppm
Arsenic	<0.0005 ppm
Cadmium	<0.002 ppm
Chromium	<0.006 ppm
Cobalt	<0.003 ppm
Copper	<0.002 ppm
Iron	<0.004 ppm
Lead	0.017 ppm
Mercury	0.0008 ppm
Nickel	<0.013 ppm
Silver	<0.0004 ppm
Zinc	0.001 ppm
Measured organophosphorus pesticides	c
Measured organochlorine pesticides plus PCB's	c

[a]After aeration.

[b]Represents seasonal variation, with the monthly range not exceeding 10%.

[c]See report appendix for individual analyses.

9.0 REFERENCES

(1) U.S. Congress. 1976. Toxic Substances Control Act. Public Law 94-469. Federal Register, October 11, 1976. 2003-2051.

(2) U.S. Environmental Protection Agency. 1978. Registration of pesticides in the United States, proposed guidelines. Federal Register, July 10, 1978: 29696-29741.

(3) U.S. Congress. 1977. Clean Water Act of 1977. Public Law 95-217. Federal Register, December 27, 1977: 1566-1611.

(4) (a) U.S. Food and Drug Administration. 1978. Nonclinical Laboratory Studies, Good Laboratory Practice Regulations (21 CFR, Part 58). Federal Register, Vol. 43, No. 247: 59986-60025.

(b) U.S. Environmental Protection Agency. 1983. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160). Federal Register, Vol 48, No. 230: 53946-53969.

(c) U.S. Environmental Protection Agency. 1983. Toxic Substances Control; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 792). Federal Register, Vol. 48; No. 230:53922-53944.

(d) Organization for Economic Cooperation and Development. 1981. OECD Guidelines for Testing of Chemicals, Principles of Good Laboratory Practice Annex 2, C(81) 30(Final):7-28.

(5) Committee on Methods for Toxicity Tests with Aquatic Organisms. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-009, April, 1975. 61 p.

(6) American Public Health Association. 1975. Standard Methods for the Examination of Water and Wastewater. 14th ed. Washington, D.C. 1193 p.

(7) American Society for Testing and Materials. 1980. Standard practice for conducting basic acute toxicity tests with fish, macroinvertebrates and amphibians. May, 1980, ASTM Committee E-35.23. 25 p.

(8) Eddy, Samuel. 1969. The Freshwater Fishes. 2nd ed. W. C. Brown Company, Dubuque, IA. 286 p.

(9) Brauhn, J. L. and R. A. Schoettger. 1975. Acquisition and Culture of Research Fish: Rainbow Trout, Fathead Minnows, Channel Catfish and Bluegills. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-011, May, 1975. 45 p.

(10) Berger, B. L., R. E. Lennon and J. W. Hogan. 1969. Laboratory Studies on Antimycin A as a fish toxicant. U.S. Department of Interior, Investigations in Fish Control No. 26. 21 p.

(11) Litchfield, J. T., Jr. and F. Wilcoxon. 1949. A Simplified Method of Evaluating Dose-Effect Experiments. Jour. Pharm. Exp. Ther. 96:99-113.

(12) American Society for Testing and Materials. 1977. Aquatic Toxicology and Hazard Evaluation. ASTM-STP 634. 315 p.

(13) Stephan, C. E., K. A. Busch, R. Smith, J. Burke and R. W. Andrew. 1978. A computer program for calculating an LC_{50}. U. S. Environmental Protection Agency, Duluth, Minnesota, pre-publication manuscript, August, 1978.

Monsanto

DEPARTMENT OF MEDICINE & ENVIRONMENTAL HEALTH
SAMPLE SUBMISSION
STUDY NO. ~~AB-84-386~~, 387, 388

PLEASE TYPE OR PRINT

I. SAMPLE IDENTIFICATION

PRODUCT NAME(S)	CHEMICAL NAME	
Azomethine	Benzeneamine, 2,6-diethyl N-methylene	
P NO.	**CHEM. ABSTRACTS REG. NO.**	**LOT OR I.D. NO., NOTE BOOK REF.**
84781	35203-08-8	116-200
AMPLE SIZE	**PURITY**	**SAMPLE DISPOSITION**
100 ml	99.2%	☒ DISCARD ☐ RETURN ☐ HOLD, NOTIFY BEFORE DISCARDING

II. CHEMICAL AND PHYSICAL PROPERTIES

TRUCTURAL FORMULA (COMPOSITION OF MIXTURE)

CONFIDENTIAL

MPIRICAL FORMULA	MOLECULAR WEIGHT	COLOR/PHYSICAL STATE
$C_{11}H_{15}N$	161.24	light yellow liquid

ELTING POINT	BOILING POINT	VAPOR PRESSURE	SPECIFIC GRAVITY
		4×10^{-3} psia at 100°F	

OLUBILITY: WATER	ORGANIC SOLVENTS (SPECIFY)	OTHER
insoluble	acetone, chloroform	

HY AL/CHEMICAL HAZARDS

- ☐ LAMMABLE
- ☐ EXPLOSIVE
- ☐ OXIDIZER
- ☐ UNSTABLE TO LIGHT
- ☐ UNSTABLE TO HEAT
- ☐ UNSTABLE TO WATER
- ☐ POLYMERIZES READILY
- ☐ HYGROSCOPIC
- ☐ REACTS WITH _____
- ☒ NO SPECIAL PRECAUTIONS
- ☐ OTHER (SPECIFY)

THER PROPERTIES, SPECIAL REQUIREMENTS (SPECIFY)

stable

III. TOXICITY INFORMATION

ORAL LD_{50} 1470 mg/kg
DERMAL LD_{50} 1400 mg/kg
EYE IRRITATION severe
SKIN IRRITATION severe @ 4hrs corrosive @ 24hrs
SINGLE VAPOR INHALATION _____

- ____ NO INFORMATION AVAILABLE
- ____ SEE ATTACHMENT
- ____ OTHER (SPECIFY)

40-83-12

IV. DOCUMENTATION

OMPOSITION & PURITY

- ☒ STATED ABOVE
- ☐ SEE ATTACHMENT
- ☒ STAFF TOXICOLOGY FILE

METHOD OF SYNTHESIS

- ☐ SEE ATTACHMENT
- ☐ STAFF TOXICOLOGY FILE
- ☒ OPERATING CO. FILE

UBMITTED BY: (Name, Location, Phone No., Date)	DMEH CONTACT: (Name, Location, Phone No., Date)
Lynda A. Suba, C2SC, 4-2124 2/22/85	~~Tim Long, G2WD, 4-8851~~ Ard Kronberg 2/22/85

V. EHL USE

TUDY NUMBER(S)	**SUBSTANCE IDENTIFICATION CODE**
STUDY# 032234	pg 0035 of 0054

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3078 (REV. 1/80)

MASTER FILE
PROJECT NO. BD-85-119

Bio/dynamics Inc.

Division of Biology and Safety Evaluation

BD-85-119

BIO/DYNAMICS INC.

PROJECT NUMBER: 5868-85

CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH DIETHYLPHENYL AZOMETHINE

Submitted to: Monsanto Company
800 N. Lindbergh Blvd., G2WD
St. Louis, Missouri 63167

Attn: Dr. Joel Kronenberg

Date: May 1985

AA022956

I. INTRODUCTION

A. PROJECT NO.: 5868-85

B. TEST MATERIAL: Diethylphenyl Azomethine

C. SPONSOR CODE: M-6

D. STUDY: Closed-Patch Repeated Insult Dermal Sensitization Study in Guinea Pigs (Modified Buehler Method)

E. BIO/DYNAMICS PROTOCOL NO.: M6/GP-1
ISSUE 2 MAY 1984

F. PURPOSE: This study is designed to evaluate the allergic contact sensitization potential of the test material in guinea pigs.

G. STUDY DESIGN REFERENCE:

The method employed is a modification of that described in: E.V. Buehler in "Delayed Contact Hypersenstitivity in the Guinea Pig", Arch. Dermatol 91: 171-175, (1965) and H.L. Ritz and E.V. Buehler in "Planning, Conduct and Interpretation of Guinea Pig Sensitization Patch Tests", in Current Concepts in Cutaneous Toxicity (Victor A. Drill and Paul Lazar, eds.), pp. 25-40; Academic Press, 1980.

H. TESTING FACILITY: Bio/dynamics Inc.
P.O. Box 43
Mettlers Road
East Millstone, N.J. 08873

I. SPONSOR: Monsanto Company
800 N. Lindbergh Blvd, G2WD
St. Louis, Missouri 63167

ATTENTION: Dr. Joel Kronenberg

J. DATE OF AUTHORIZATION:*

K. PROPOSED STUDY DATES:* Animal Receipt:
Range-Finding:
First Induction:
Challenge:
Termination:

L. STUDY PERSONNEL Study Director: Carol S. Auletta
Supervisor: Donna L. Blasczak
Technician-In-Charge: Janet Erickson

M. STUDY CONDUCT: This study will be conducted following good laboratory practices.

*To be completed upon authorization of study.

II. EXPERIMENTAL DESIGN:

Test/Control Material	Number of Animals	Concentration Induction	Concentration Challenge
Vehicle (Negative Control)	10 (5M, 5F)	100%	100%
Vehicle (Irritation Control)[a]	6 (3M, 3F)	none	100%
DNCB (Positive Control)	10 (5M, 5F)	0.5%	0.3%
DNCB Irritation Control[a]	6 (3M, 3F)	none	0.3%
Test Material(s)[b]	10 (5M, 5F) per material	c	d
Test Material Irritation Control[a]	6 (3M, 3F)	none	d

[a]Irritation control groups are treated at challenge only. The same six animals can serve as irritation controls for up to four test/control materials.
[b]More than one test material may be tested concurrently with the same negative and positive control groups.
[c]Minimal irritant concentration; 100% if non-irritating (See IVE).
[d]Maximum non-irritant concentration (See IVE).

III. MATERIALS:

A. TEST ANIMALS — Albino guinea pigs

1. Stock: — Hartley

a. Reason for Selection: — Standard laboratory animal for dermal sensitization studies. The Hartley Albino breed is used because of its availability and because of the existing historical data base for comparative evaluation.

b. Supplier: — Hazleton Dutchland Laboratory Animals
Denver, Pennsylvania
Or other acceptable supplier

III. MATERIALS (cont.):

2. Number:
   Range-finding: 6 (3 male, 3 female) (or as indicated by experimental findings)
   Induction & Challenge: 10 (5 male 5 female) per test material and control group*
   Challenge Only: 6 per four materials* (3 male, 3 female)
   *See Experimental Design

3. Age: 3-4 weeks at receipt
   5-6 weeks old at study initiation

4. Weight: Approximately 200-250 grams at receipt
   Approximately 300-500 grams at initiation of study

5. Equilibration Period: Range-finding: at least one week.
   Sensitization Study: at least two weeks

   Observations: All animals will be checked for viability twice daily. Prior to assignment to study all animals will receive a physical examination to ascertain suitability for study.

6. Husbandry: Currently acceptable practices of good animal husbandry will be followed, e.g., Guide for the Care and Use of Laboratory Animals; DHEW Publication No. (NIH) 78-23 Revised 1978.

   a. Housing: Individually housed

   b. Cages: Suspended, stainless steel with wire mesh bottoms.

   c. Environmental Conditions:

      1. Temperature: 65-75°F is considered an acceptable temperature range for guinea pigs; room temperature will be monitored twice daily and maintained within this range to the maximum extent possible.

      2. Humidity: 30-70% is considered an acceptable humidity range for guinea pigs; room humidity will be monitored and recorded daily and maintained within this range to the maximum extent possible.

      3. Light Cycle: 12 hours light, 12 hours dark (controlled by an automatic timer).

III. MATERIALS (cont.):

d. Food: Charles River Vitamin C - Fortified Guinea Pig diet or acceptable substitute ad libitum.

e. Water: Automatic watering system, ad libitum, Municipal water supply (Elizabethtown Water Co.)

f. Contaminants: There are no known contaminants reasonably expected to be found in food or water which would interfere with the results of this study.

7. Identification: Each animal will be identified with a monel ear tag, bearing a unique number, prior to testing.

8. Selection: Animals will be randomly placed in cages upon receipt and will be placed on study as available at the time of study initiation. Any animals considered unsuitable because of poor health, outlying body weights, or unacceptable skin, will be excluded.

B. TEST MATERIAL: Diethylphenyl Azomethine

Handling Information: As described in Appendix A. Unless otherwise noted, the identity, strength, purity, composition, stability and method of synthesis, fabrication and/or derivation of the test materials(s) will be documented by the sponsor.

C. VEHICLE: Vehicle varies, depending on the nature of the test substance (commonly-used vehicles are deionized water, saline, paraffin oil, acetone, and ethanol). Whenever possible, the induction exposures will be performed using 80% ethanol as the vehicle and challenge will be performed using acetone as the vehicle. This combination of vehicles has been shown by Ritz and Buehler (op. cit.) to provide optimal results.

D. POSITIVE CONTROL: Dinitrochlorobenzene (DNCB).

IV. METHODS:

A. Route of Administration:

Dermal, to the clipped skin of the back and sides.

B. Justification for Route of Administration:

The study is intended to provide information on the health hazards likely to arise from exposure to the test material by the dermal route; skin contact is a possible worker and consumer exposure route. The Buehler method is an acceptable method for evaluating the potential of test materials to produce dermal sensitization.

C. Duration of Study:

6-7 weeks

D. Schedule:

This test consists of two segments, 1) attempted induction of sensitization and 2) challenge of animals to evaluate presence and/or extent of sensitization. The following summary describes the sequence of steps. Detailed information is presented below.

Weeks 1 to 3 - Induction of sensitization by closed-patch technique, 3 times per week for 3 weeks (generally on Mondays, Wednesdays and Fridays)

Week 5 - Challenge by closed-patch technique

Week 6 - Re-challenge if necessary.

E. Doses:

Prior to initiation of the study, a range-finding study will be performed as described in Appendix B. Based on this study, doses will be selected as follows:

Induction: Minimal irritant concentration (the lowest concentration which produces some irritation, i.e., scores of 1 or higher in one or more animals). Non-irritating materials will be administered at 100% concentration.

Challenge: Maximum non-irritant concentration (the highest concentration which does not produce scores of 1 or higher in any animal and which produces scores of ± in less than half of the animals.) This concentration will be applied at challenge to animals treated during the induction phase and to animals which have not been previously treated (irritation control groups).

Rechallenge: If a rechallenge is required, the dose will be the same as the original challenge dose.

IV. METHODS (cont.):

F. Preparation of Animals:

The hair on the application site (back and sides) will be clipped short with an electric clipper on the day prior to the first application and prior to challenge and rechallenge. Additional clipping will be performed as needed.

G. Preparation of Test and Control Materials:

Liquids will be used as received or diluted with an appropriate vehicle. Particlulates will be ground to a powder using a mortar and pestle. Powders will be dissolved or suspended in an appropriate vehicle or administered dry and moistened with an appropriate vehicle. Mixtures will be prepared at least weekly, or more frequently if indicated. Actual procedures and vehicles used will be documented in the raw data.

H. Administration of Test and Control Materials:

1. Induction Phase:

Materials will be administered beneath a surgical gauze square, 1" x 1", eight single layers thick, placed directly on the test site and secured with tape or beneath a Hilltop chamber®. Liquids will be applied to saturation (approximately 0.2 to 0.4 ml); the same volume will be applied to all animals receiving the same material. Powders will be administered in an amount which completely covers the test site (0.2 to 0.4 cc, measured volumetrically) and will be moistened with an appropriate amount of vehicle (approximately 0.2 to 0.4 ml). The same amounts of test material and vehicle will be applied to all animals receiving the same material. The test site will be to one side of the midline, as close to the midline as possible. The patch will be covered by overlapping, impermeable plastic and firmly secured by an elastic adhesive bandage wound around the torso of the animal. The patch will be left in place for 6 hours after which it will be removed and the skin wiped free of any excess material. This will be repeated 3 times per week for 3 weeks, for a total of 9 applications. If severe irritation or tissue damage (necrosis) is seen at the application site, the location of subsequent patches will be adjusted so that patches are not placed over severely irritated or damaged skin. However, all induction applications will be applied to the same side of the animal.

IV. METHODS (cont.):

H. Administration of Test and Control Materials (cont.):

2. Challenge Phase:

a. Test Animals:

Approximately fourteen days after the last sensitizing exposure, the challenge treatment will be administered. The materials will be administered in the same manner as in the induction phase, at a site on the opposite side of the midline from the site used for induction. After six hours of exposure, the patches will be removed and the skin wiped free of any excess material. If reactions are equivocal, a second challenge will be performed approximately one week after the initial challenge, using a previously-untreated site.

b. Irritation Control Animals:

In order to differentiate dermal reactions produced by irritation from those produced by sensitization, 6 animals (previously untreated) will be subjected to the same challenge procedure as the animals which have received nine sensitizing exposures. Up to four patches (four different materials) may be placed on a single animal for this purpose.

V. EXPERIMENTAL EVALUATION:

A. VIABILITY CHECK: Twice Daily

B. OBSERVATIONS: Animals will be observed prior to treatment and weekly during the study for general health; unusual observations will be recorded. (Animals which are not considered to be in good health prior to treatment will not be placed on study).

C. EVALUATION OF DERMAL RESPONSE:

1. Intervals:

a. Induction:

Dermal evaluations will be made approximately 24 and 48 hours after each induction exposure to confirm that a slightly-irritating concentration of DNCB and an appropriate concentration of the test material have been selected and to evaluate response for possible preliminary indications of sensitization. If the concentration selected is non-irritating after the first exposure and is less than 100%, consideration will be given to increasing the concentration at subsequent inductions.

b. Challenge:

Dermal evaluations will be made approximately 24 and 48 hours after the challenge application(s).

V. EXPERIMENTAL EVALUATION (cont.):

2. Methods:

Reactions will be scored according to the system in Appendix C.

D. BODY WEIGHTS:

Body weights will be obtained from all animals at the following intervals:

Pretest (Day prior to first induction)
Termination (Day prior to first challenge)

VI. POST-MORTEM:

Necropsy:

A gross necropsy will be performed on any animal which dies spontaneously. Abnormal observations will be recorded but no tissues will be saved. Postmortem examinations will not be performed on animals which survive throughout the study.

VII. ALLERGENICITY RATING:

Redness at the challenge site which is clearly greater than that seen in the irritation control animals is considered an allergic response. In general, dermal scores of 1 or greater (in the absence of dermal response in irritation control animals) are considered clearly indicative of sensitization. Scores of $\pm$ (barely perceptible erythema) are considered equivocal, although a high percentage of scores of $\pm$ in treated animals with no dermal response in irritation control animals is considered suggestive of sensitization.

VIII. RAW DATA:

Data for all parameters outlined above will be recorded and retained permanently, with the original study protocol, on file in the Bio/dynamics Archives.

IX. REPORT:

Two copies of the report will be sent to the sponsor following the termination of the study. The report will contain the following:

Introduction
Materials and methods
Narrative discussion of study results
Table of individual dermal scores
Table of individual and mean body weights (pretest and termination)
Table of individual gross pathologic findings (if applicable)

X. QUALITY ASSURANCE:

Each study will be subjected to a final report audit by Quality Assuranc personnel. In addition, studies will be randomly selected for procedure audits. The subject of the procedure audit will be randomly selected from the following list:

Protocol Generation/Documentation
Prestudy Preparation
Test and/or Control Material Preparation
Test and/or Control Material Determination
Periodic Measurements/Assessments
Facilities - Personnel
Necropsy - Animal Termination

XI. PROTOCOL REVIEWED AND ACCEPTED:

BY: _____ Date: 5/23/85
For: Bio/dynamics, Inc.

BY: _____ Date: 5/28/85
For: Monsanto Company

ATTACHMENT A

TEST AND/OR CONTROL MATERIAL HANDLING INFORMATION

PROJECT NO(S): _____ _____ _____ _____ _____ _____

This form is designed to specify test material handling and disposition instructions and to provide procedures (if known) in case of accidental exposure to the substance. As with all data, this information will be considered confidential and will be available only to persons involved with the study or studies using this substance. Please provide as complete information as possible for each category below and/or attach the information in your own form and return to Study Director of your study at Bio/dynamics, Inc., Box 43, E. Millstone, N.J. 08873.

I. IDENTIFICATION

TEST MATERIAL (Name or Code Number) _____

BATCH OR LOT NO.: _____

PHYSICAL DESCRIPTION: _____

PURITY: _____

DENSITY (IF KNOWN):* _____

TEST MATERIAL IS SOLUBLE IN (CHECK ONE) WATER _____; ACETONE _____; ALCOHOL _____; OIL _____; OTHER _____

II. STORAGE INFORMATION

MATERIAL SHOULD BE STORED IN:

_____ Temperature-monitored room (60°-85°F); _____ Freezer

_____ Refrigerator _____ Other _____

III. STABILITY

LENGTH OF TIME MATERIAL IS STABLE UNDER CONDITIONS DESCRIBED ABOVE: _____

EXPIRATION DATE: DATE: _____ INDICATED ON LABEL: YES/NO (circle one)

STABILITY IN COMMON VEHICLES:	Unknown	Less than 4 hours	Up to 4 hours	Up to 24 hours	Other (Specify)
WATER	_____	_____	_____	_____	_____
METHYCELLULOSE	_____	_____	_____	_____	_____
CORN OIL	_____	_____	_____	_____	_____
ORGANIC SOLVENTS (ACETONE, ETHANOL)	_____	_____	_____	_____	_____
OTHER (SPECIFY: _____)	_____	_____	_____	_____	_____

If stability of neat material or of material in vehicle to be used in study is unknown:

_____ Instructions for analysis will be provided

_____ Samples are to be submitted to sponsor for analysis _____ Analysis will not be required

IV. HANDLING (EMPLOYEE SAFETY) INFORMATION

KNOWN HAZARDS: (if available, attach summary of pertinent results of any previous toxicity studies).

Approximate rodent oral LD_{50} = _____ mg/kg (if unavailable, enter NK, not known)

Is material a probable eye/skin irritant? yes/no

OTHER PERTINENT INFORMATION: _____

PRECAUTIONS: Use of protective clothing (laboratory coats), latex gloves, safety glasses and dust masks is routine. Precautions in excess of the above should be specified:

_____ Routine precautions adequate. Other _____

IN CASE OF EMERGENCY RELATED TO THIS SUBSTANCE, CONTACT:

_____ (Person) of _____ (Company) at _____ (Phone #)

V. DISPOSITION

All materials will be returned to the sponsor. Person and address to whom samples are to be returned:

Name: _____ Shipping Instruction: _____

Address: _____ _____

_____ _____

_____ _____

NOTE: PLEASE ENCLOSE APPROPRIATE SHIPPING LABELS FOR RETURN

VI. SIGNATURE

Information submitted by: _____

Company: _____ Date: _____

*Optional - Please provide if available

APPENDIX B

Dermal Sensitization Study in Guinea Pigs - Range Finding Study

In order to evaluate the irritation potential of the test substance, six animals per test substance will be subjected to preliminary studies as follows:

Animals will be closely clipped over the back and sides with an electric clipper. The Sponsor or Study Director will decide upon up to four different test material concentrations, based on knowledge of the test material. If there is no information on the suspected irritancy, the following concentrations will be used: 100%, 50%, 25% and 10%. Each guinea pig will be dosed with up to four different concentrations, at four different sites (one concentration/site), two on either side of the spinal column. If it is anticipated that the material will be administered in ethanol for induction and acetone for challenge, the range-finding study will be performed using an acetone vehicle, since determination of a non-irritating concentration for challenge is more critical than selection of a slightly irritating concentration for induction.

Substances will be administered beneath a surgical gauze square 1" x 1", eight single layers thick or beneath a Hilltop chamber®, placed directly on the test site and secured with tape. Liquids will be applied to saturation (approximately 0.2 to 0.4 ml); the same volume will be applied to all animals receiving the same material. Powders will be administered in an amount which completely covers the test site (0.2 to 0.4 cc, measured volumetrically) and will be moistened with an appropriate amount of vehicle (approximately 0.2 to 0.4 ml). The same amounts of test material and vehicle will be applied to all animals receiving the same material. The patches will be left in place for 6 hours, after which they will be removed and the skin wiped free of excess test materials.

Observations for signs of dermal irritation will be recorded at 24 and 48 hours after application. At each observation, all treated sites will scored using the scoring system in Appendix C.

If significant irritation (erythema scores of 1 or greater) is observed at the lowest concentration, additional studies similar to that described above will be performed with lower concentrations.

APPENDIX C

No reaction ---------- 0

Very slight (barely perceptible) erythema, usually nonconfluent -------- ±

Slight erythema, usually confluent ---------- 1

Moderate erythema ---------- 2

Severe erythema, with or without edema, necrosis, or eschar formation -- 3

If edema, necrosis or eschar formation occur, they will also be indicated, using the following code:

Edema ------ Ed
Necrosis --- N
Eschar ----- E

Monsanto

DEPARTMENT OF MEDICINE & ENVIRONMENTAL HEALTH
SAMPLE SUBMISSION

STUDY NO. 3085-[illegible]

PLEASE TYPE OR PRINT

I. SAMPLE IDENTIFICATION

PRODUCT NAME(S)	CHEMICAL NAME	
Diethyl phenyl azomethine	Benzeneamine 2,6-diethyl N-methylene	
P NO.	CHEM. ABSTRACTS REG. NO.	LOT OR I.D. NO., NOTE BOOK REF.
[illegible]	35203-08-8	9-2-35-200
SAMPLE SIZE	PURITY	SAMPLE DISPOSITION
200 grams	98.37%	☑ DISCARD ☐ RETURN ☐ HOLD, NOTIFY BEFORE DISCARDING

II. CHEMICAL AND PHYSICAL PROPERTIES

STRUCTURAL FORMULA (COMPOSITION OF MIXTURE)

[redacted]

Dermal Sensitization

EMPIRICAL FORMULA	MOLECULAR WEIGHT	COLOR/PHYSICAL STATE
$C_{11}H_{15}N$	161.24	light yellow liquid

MELTING POINT	BOILING POINT	VAPOR PRESSURE	SPECIFIC GRAVITY
		4×10^{-3} psia at 100°F	

SOLUBILITY: WATER	ORGANIC SOLVENTS (SPECIFY)	OTHER
insoluble	acetone, chloroform	

PHYSICAL/CHEMICAL HAZARDS

FLAMMABLE	☐ UNSTABLE TO LIGHT	☑ POLYMERIZES READILY	☑ NO SPECIAL PRECAUTIONS
☐ EXPLOSIVE	☐ UNSTABLE TO HEAT	☐ HYGROSCOPIC	☐ OTHER (SPECIFY)
☐ OXIDIZER	☐ UNSTABLE TO WATER	☐ REACTS WITH _____	

OTHER PROPERTIES, SPECIAL REQUIREMENTS (SPECIFY)

[redacted] Do not use if precipitates appear

III. TOXICITY INFORMATION

ORAL LD_{50} 1490 mg/kg

DERMAL LD_{50} [illegible]

EYE IRRITATION [illegible] severe

SKIN IRRITATION [illegible] severe-corrosive

SINGLE VAPOR INHALATION 0.83 mg/L (nominal), 6 hr
no mortality

☐ NO INFORMATION AVAILABLE
☐ SEE ATTACHMENT
☐ OTHER (SPECIFY)

RD-73-42 and 4-84-5

IV. DOCUMENTATION

COMPOSITION & PURITY	METHOD OF SYNTHESIS
☑ STATED ABOVE	☐ SEE ATTACHMENT
☐ SEE ATTACHMENT	☐ STAFF TOXICOLOGY FILE
☐ STAFF TOXICOLOGY FILE	☑ OPERATING CO. FILE

SUBMITTED BY: Name, Location, Phone No., Date)		DMEH CONTACT: (Name, Location, Phone No., Date)	
Cynthia A. Suba, C2SC, 4-2124	8/7/86	Joel Kronenberg, DCWD, 4-8832	8/7/86

V. EHL USE

STUDY NUMBER(S)	SUBSTANCE IDENTIFICATION CODE

WHITE COPY—LABORATORY COPY; YELLOW COPY—DMEH FILE COPY; PINK COPY—REQUESTOR'S COPY

Monsanto

DEPARTMENT OF ME[illegible]INE & ENVIRONMENTAL HEALTH
SA[illegible]LE SUBMISSION

STUDY NO. BD-85-[redacted] 119

PLEASE TYPE OR PRINT

I. SAMPLE IDENTIFICATION

[illegible]ODUCT NAME(S): [illegible]iethyl [illegible]henyl azomethine		CHEMICAL NAME: Benzeneamine 2,5-diethyl N-methylene
[illegible] NO.: [illegible]	CHEM. ABSTRACTS REG. NO.: 35203-08-8	LOT OR I.D. NO., NOTE BOOK REF.: 5-30-85-205
[illegible]MPLE SIZE: [illegible]00 grams	PURITY: 95.5%	SAMPLE DISPOSITION: ☒ DISCARD ☐ RETURN ☐ HOLD, NOTIFY BEFORE DISCARDING

II. CHEMICAL AND PHYSICAL PROPERTIES

[illegible]TRUCTURAL FORMULA (COMPOSITION OF MIXTURE)

*REference:
nbp 2697506

[illegible]MPIRICAL FORMULA: [illegible]	MOLECULAR WEIGHT: 161.24		COLOR/PHYSICAL STATE: light yellow liquid
[illegible]IELTING POINT:	BOILING POINT:	VAPOR PRESSURE: $4x10^{-3}$ psia at 100°F	SPECIFIC GRAVITY: -
[illegible]OLUBILITY: WATER: insoluble	ORGANIC SOLVENTS (SPECIFY): acetone, chloroform		OTHER:

[illegible]HYSICAL/CHEMICAL HAZARDS

- FLAMMABLE
- ☐ EXPLOSIVE
- ☐ OXIDIZER
- ☐ UNSTABLE TO LIGHT
- ☐ UNSTABLE TO HEAT
- ☐ UNSTABLE TO WATER
- ☐ POLYMERIZES READILY
- ☐ HYGROSCOPIC
- ☐ REACTS WITH _____
- ☒ NO SPECIAL PRECAUTIONS
- ☐ OTHER (SPECIFY)

[illegible]THER PROPERTIES, SPECIAL REQUIREMENTS (SPECIFY)

[illegible]table

III. TOXICITY INFORMATION

[illegible]ORAL LD_{50}: 1490 mg/kg
DERMAL LD_{50}: 1400 mg/kg
EYE IRRITATION: ~~[illegible]~~ severe
SKIN IRRITATION: ~~[illegible]~~ severe
SINGLE VAPOR INHALATION: 0.33 mg/L (nominal), 6 hr. no mortality

____ NO INFORMATION AVAILABLE
____ SEE ATTACHMENT
____ OTHER (SPECIFY)

40-83-12

IV. DOCUMENTATION

[illegible]OMPOSITION & PURITY
- ☒ STATED ABOVE
- ☐ SEE ATTACHMENT
- ☐ STAFF TOXICOLOGY FILE

METHOD OF SYNTHESIS
- ☐ SEE ATTACHMENT
- ☐ STAFF TOXICOLOGY FILE
- ☒ OPERATING CO. FILE

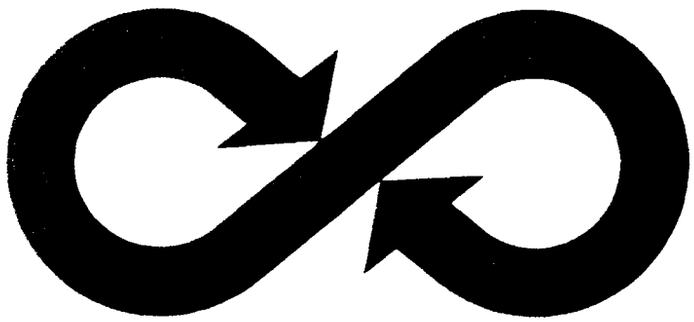
[illegible]UBMITTED BY: (Name, Location, Phone No., Date): [illegible]dia A. Suba, C2SC, 4-2124 5/30/85	DMEH CONTACT: (Name, Location, Phone No., Date): Joel Kronenberg, G2WD, 498832 5/30/85

V. EHL USE

[illegible]TUDY NUMBER(S):	SUBSTANCE IDENTIFICATION CODE:

WHITE COPY—LABORATORY COPY; YELLOW COPY—DMEH FILE COPY, PINK COPY REQUESTOR'S COPY

[illegible] 1.80)



Bio/dynamics Inc.

Division of Biology and Safety Evaluation

BIO/DYNAMICS PROJECT NO.: 5868-85

MONSANTO REFERENCE NO.: BD-85-119

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS (Buehler Method)

TEST MATERIAL: Diethylphenyl Azomethine

Submitted to: Monsanto Company
800 N. Lindbergh Blvd., G2WD
St. Louis, Missouri 63167

Attn: Dr. Joel Kronenberg

Date: December 4, 1985

I. INTRODUCTION

This study was conducted for the Monsanto Company in order to evaluate the allergic contact sensitization potential of Diethylphenyl Azomethine in guinea pigs. This study was performed at Bio/dynamics, Inc., Mettlers Road, East Millstone, New Jersey 08873, and used procedures based on the methods described by E.V. Buehler in "Delayed Contact Hypersensitivity in the Guinea Pig", Arch. Dermatol 91: 171-175 (1965) and H.L. Ritz and E.V. Buehler in "Planning, Conduct and Interpretation of Guinea Pig Sensitization Patch Tests", in Current Concepts in Cutaneous Toxicity (Victor A. Drill and Paul Lazar, eds.), pp. 25-40; Academic Press, 1980.

This report has been reviewed by the Quality Assurance Unit of Bio/dynamics, Inc. to assure its conformance with the protocol and the raw data.

II. EXPERIMENTAL DESIGN

Group	Test/Control Material	Number of Animals	Concentration		
			Induction	Challenge	Re-challenge
IA	Acetone (Vehicle Control)	10 (5M, 5F)	100%	100%	-
IIA	Acetone (Irritation Control)	10 (5M, 5F)	-	100%	-
IIA	DNCB (Positive Control)[a]	10 (5M, 5F)	0.5%[b]	0.3%[c]	-
IIB	DNCB (Irritation Control)[a,d]	10 (5M, 5F)	-	0.3%[c]	-
IIIA	Diethylphenyl Azomethine	10 (5M, 5F)	5%[c]	1%[c]	1%[c]
IIIB	Diethylphenyl Azomethine (Irritation Control)[a,d]	10 (5M, 5F)	-	1%[c]	-
IIIC	Diethylphenyl Azomethine (Irritation Control)[a,d]	10 (5M, 5F)	-	-	1%[c]

[a]Control groups were also used for Bio/dynamics Project Nos: 5996-85 and 6071-85, conducted concurrently with this study.
[b]Vehicle: 80% ethanol.
[c]Vehicle: acetone.
[d]Irritation control groups were tested at challenge only.
M=Male; F=Female

III. DATES OF STUDY

Animal Receipt:	July 22, 1985
Range-Finding:	August 7-11, 1985
Induction: (First through Ninth Inductions)	August 14 through September 2, 1985
Challenge:	September 16,1985
Re-challenge:	September 23, 1985
Study Termination:	September 25, 1985

IV. STUDY PERSONNEL

Study Director:	Carol S. Auletta, B.A., D.A.B.T.
Supervisor:	Janet Erickson, A.A.S., AALAS, R.L.A.T.
Technician-in-Charge:	Mary Webb, B.S. AALAS L.A.T.

V. MATERIALS

A. Test and Control Materials:

1. Test Material:	Diethylphenyl Azomethine
Lot Number:	8-2-85-200
Purity:	98.57%
Description:	Light yellow liquid
Date of Receipt:	August 6, 1985
Received From:	Monsanto Company
Storage:	Room temperature
Vehicle:	Acetone

V. MATERIALS (cont.)

2. Positive Control Material:	2,4-dinitrochlorobenzene (DNCB)
Description:	Yellow granules
Lot Number:	A1B
Supplier:	Eastman Kodak Company Rochester, New York
Storage:	Room temperature
Vehicles:	80% Ethanol (Induction) Acetone (Challenge)
B. Test Animals:	Guinea Pigs
Stock:	Hartley Albino
Reason for Selection:	Standard laboratory animal for dermal sensitization studies. The Hartley Albino breed is used because of its availability and because of the existing historical data base for comparative evaluation.
Supplier:	Hazleton-Dutchland, Inc. Denver, PA
Number of Animals:	1. Range-finding: 12 (6 males, 6 females) 2. Sensitization Study: 30 (three groups of five males and five females) 3. Irritation Controls: Challenge and Re-challenge: 20 (two groups of five males and five females).
Age:	3-4 weeks at receipt 5-6 weeks old at study initiation
Pretest Weight Range (Sensitization Study Animals):	Males: 337-451 grams Females: 335-410 grams
Husbandry:	Currently acceptable practices of good animal husbandry were followed, e.g., Guide for the Care and Use of Laboratory Animals; DHEW Publication No. (NIH) 78-23 Revised 1978.

V. MATERIALS (cont.)

B. Test Animals (cont.):

Housing:	Individually in suspended stainless steel cages.
Food:	Agway Prolab Guinea Pig Diet, ad libitum.
Water:	Automatic watering system, ad libitum (Elizabethtown Water Company).
Environmental Conditions:	1. Temperature: 65-75°F is considered an acceptable temperature range for guinea pigs; room temperature was monitored and recorded twice daily and maintained within this range to the maximum extent possible. 2. Humidity: 30-70% is considered an acceptable humidity range for guinea pigs; humidity was monitored and recorded once daily and maintained within this range to the maximum extent possible. 3. Light Cycle: 12 hours light, 12 hours dark (controlled by an automatic timer).
Animal Identification:	Each animal was identified with a monel ear tag bearing its unique animal number.
Selection:	Animals were randomly placed in cages upon receipt and were placed on study as available. Those of questionable health or with outlying body weights were not placed on study.

VI. METHODS

A. Route of Administration:

Dermal, to the clipped skin of the back and sides.

VI. METHODS (cont.)

B. Justification for Route of Administration:

The study is intended to provide information on the health hazards likely to arise from exposure to the test material by the dermal route; skin contact is a possible worker and consumer exposure route. The Buehler method is an acceptable method for evaluating the potential of test materials to produce dermal sensitization.

C. Range-Finding Study:

Prior to initiation of the study, a range-finding study was performed in order to select a slightly irritating concentration for topical induction and a non-irritating concentration for the challenge application. Six animals were treated topically with undiluted test material (100%) and with concentrations of 50%, 25% and 10% v/v of the test material in acetone (4 concentrations per animal). Because irritation was seen at the lowest concentration, six additional animals received concentrations of 5, 1, 0.5 and 0.1% of the test material in acetone. The test material mixtures were applied beneath a Hilltop Chamber® in a volume of 0.3 ml. The chamber was then occluded with impermeable plastic and secured by an elastic adhesive bandage (Elastoplast®) which was wound around the torso of the animal. The chambers were left in place for six hours, after which they were removed and the skin was wiped free of any excess material. Observations for irritation were made at 24 and 48 hours.

D. Doses:

Based on results of the range-finding study (presented in Appendix A), the following concentrations were selected for study:

Induction (minimal irritant concentration):	5%
Challenge (maximum non-irritant concentration):	1%

E. Preparation of Animals:

The hair on the application site (back and sides) was clipped short with an electric clipper on the day prior to the first application and prior to challenge. Additional clipping was performed as needed during the induction period.

F. Preparation of Test and Control Materials:

1. Positive Control: DNCB

a) Induction: 0.05 g of DNCB was added to 10 ml of 80% ethanol to produce a 0.005 g/ml (0.5% w/v) mixture.

b) Challenge: 0.03 g of DNCB was added to 10 ml of acetone to produce a 0.003 g/ml (0.3% w/v) mixture.

VI. METHODS (cont.)

F. Preparation of Test and Control Materials (cont.)

2. Test Material:

a) Induction:	0.5 ml of Diethylphenyl Azomethine was added to 9.5 ml of acetone to produce a 0.05 ml/ml (5% wv/v) mixture.
b) Challenge:	0.1 ml of Diethylphenyl Azomethine was added to 9.9 ml of acetone to produce a 0.01 ml/ml (1% v/v) mixture.
3. Frequency of Preparation:	Fresh mixtures were prepared prior to each administration.

G. Dosing Procedure:

1. Induction Phase

The test and control materials were administered in a volume of 0.3 ml beneath a Hilltop Chamber® placed directly on the test site. The test site was on the right side of the midline, as close to the midline as possible. The gauze patch was covered by overlapping, impermeable plastic. This was firmly secured by an elastic adhesive bandage (Elastoplast®) which was wound around the torso of the animal. The patch was left in place for 6 hours after which it was removed and the skin was wiped free of any excess material. This was repeated three times per week for three weeks, for a total of nine exposures. Due to signs of severe irritation and tissue damage seen in some animals treated with DNCB and Diethylphenyl Azomethine beginning after the third or fourth induction exposure, the location of the dosing site was adjusted so that patches were not placed over damaged skin.

2. Challenge

a. Test Animals

Fourteen days after the last induction exposure, the challenge treatment was administered. The test or control substance was administered in the same manner as in the induction phase, but at a second site, on the left side of the midline. After six hours of exposure, the patches were removed and the skin wiped free of any excess material.

b. Irritation Control Animals:

In order to differentiate dermal reactions produced by irritation from those produced by sensitization, previously untreated animals were subjected to the same challenge procedures as the animals which received the nine induction exposures.

VI. METHODS (cont.)

G. Dosing Procedure (cont.):

3. Re-Challenge:

Seven days after the challenge exposure, the re-challenge treatment was administered. Animals were clipped as before and the test material was administered in the same manner as in the challenge phase but at a previously untreated site. After six hours of exposure, the patches were removed and the skin wiped free of any excess test material. A separate group of ten previously untreated animals (5 males, 5 females) was used as an irritation control group for re-challenge.

VII. EXPERIMENTAL EVALUATION

A. Viability Check:	Twice daily
B. In-Life Observations:	Weekly
C. Body Weights:	Pretest (Day prior to first induction) Termination (Day prior to challenge)

D. Evaluation of Dermal Response:

1. Intervals:

Induction:	24 and 48 hours after each induction application.
Challenge:	24 and 48 hours after dosing
Re-challenge:	24 and 48 hours after dosing

2. Methods:

Dermal responses were scored according to the scale presented in Appendix B.

VIII. RAW DATA STORAGE

All raw data and the original study protocol and final report will be retained on file in the Bio/dynamics Archives.

IX. RESULTS AND DISCUSSION

A. Mortality

All animals survived throughout the study.

B. Body Weights (Table I)

All animals, control and treated, gained weight throughout the study. Gains in control and Diethylphenyl Azomethine-treated animals were considered comparable.

C. Dermal Responses (Table II, Induction Scores; Table III, Summary of Challenge Scores; Table IV, Individual Challenge Scores)

1. Induction

No significant irritation was seen in acetone-treated animals throughout the induction period.

Animals treated with DNCB exhibited slight dermal irritation after the first or second induction and severe dermal responses (moderate to severe erythema, edema, necrosis) beginning after three induction exposures. The initial response confirmed that a slightly-irritating concentration of DNCB was being applied. However, the severity of subsequent responses suggest the presence of either cumulative irritation or dermal sensitization. Responses at challenge to this material subsequently confirmed that sensitization had occurred.

Mild to moderate dermal irritation was seen after the first two induction exposures to the test material, Diethylphenyl Azomethine. Beginning with the third exposure, severe dermal responses (moderate to severe erythema, edema, necrosis) were apparent in most animals. Irritation continued throughout the induction period. These data suggest some cumulative irritation or sensitization potential.

IX. RESULTS AND DISCUSSION

C. Dermal Responses (cont.)

2. Challenge

Dermal scores of 1 or greater (in the absence of dermal response in irritation control animals) are considered clearly indicative of sensitization. Scores of ± (barely perceptible erythema) are considered equivocal, although a high percentage of scores of ± in treated animals with no dermal response in irritation control animals is considered suggestive of sensitization.

No dermal responses were seen in any of the acetone-treated animals (Groups IA and IB), thus confirming that no sensitization to this vehicle had occurred.

All ten animals treated with DNCB (Group IIA) exhibited dermal responses at challenge to a non-irritating concentration, as confirmed by a lack of significant response by control animals (Group IIB) to the same concentration. This positive response to a known sensitizer demonstrated the susceptibility of this group of animals to sensitization.

One of the ten animals challenged with Diethylphenyl Azomethine (Group IIIA) exhibited a clear dermal response (score of one) at challenge and four animals exhibited questionable responses (score of ± at 24 and/or 48 hours). No dermal response occurred in irritation control animals (Group IIIB). Because this response was considered equivocal, a second challenge was performed. No definitive responses were seen, but four animals exhibited scores of ± at 24 and/or 48 hours; no responses were seen in irritation control animals. Only two of the animals which gave questionable responses at re-challenge were the same as animals responding at the initial challenge.

IX. RESULTS AND DISCUSSION

C. Dermal Responses (cont.)

2. Challenge

Because the second challenge did not clarify the initial response and because no definitive responses were seen at re-challenge, these results do not demonstrate any clear sensitization potential for this material.

X. CONCLUSION

Under conditions of this study, Diethylphenyl Azomethine exhibited no clear potential to produce dermal sensitization in guinea pigs.

Carol S. Auletta 12/4/85

Carol S. Auletta, B.A., D.A.B.T. Date
Study Director
Manager, Acute Toxicology

Ira W. Daly 12/4/85

Ira W. Daly, PH.D., D.A.B.T. Date
Director of Toxicology

TABLE I

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

INDIVIDUAL BODY WEIGHTS (GRAMS)

PRETEST AND TERMINATION

	Animal No. and Sex	Pretest	Termination	Weight Gain
Group IA Acetone	6037 M	338	574	236
	6038 M	329	654	325
	6039 M	347	631	284
	6042 M	408	728	320
	6049 M	331	589	258
	Mean	351	635	285
	S.D.	33	61	39
	6143 F	406	583	177
	6160 F	396	636	240
	6161 F	377	581	204
	6162 F	383	556	173
	6163 F	426	598	172
	Mean	398	591	193
	S.D.	19	29	29
Group IIA DNCB	6050 M	362	519	157
	6067 M	384	646	262
	6068 M	443	778	335
	6069 M	440	656	216
	6070 M	451	677	226
	Mean	416	655	239
	S.D.	40	92	66
	6164 F	335	519	184
	6165 F	350	527	177
	6166 F	344	580	236
	6167 F	389	548	159
	6168 F	410	621	211
	Mean	366	559	193
	S.D.	32	42	30

M=Male
F=Female
SD=Standard Deviation

TABLE I (cont.)

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

INDIVIDUAL BODY WEIGHTS (GRAMS)

PRETEST AND TERMINATION

	Animal No. and Sex	Pretest	Termination	Weight Gain
Group IIIA Diethylphenyl Azomethine	6071 M	431	720	289
	6072 M	423	697	274
	6073 M	389	653	264
	6074 M	337	587	250
	6075 M	399	618	219
	Mean	396	655	259
	S.D.	37	55	27
	6169 F	380	563	182
	6170 F	378	590	212
	6171 F	389	586	197
	6172 F	341	544	203
	6173 F	368	559	191
	Mean	371	568	197
	S.D.	18	19	11

M=Male
F=Female
SD=Standard Deviation

TABLE II

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

INDIVIDUAL DERMAL SCORES AT INDUCTION[a]

GROUP IA MATERIAL: Acetone

Animal No. and Sex	Induction:	1		2		3		4		5		6		7		8		9	
	Interval (Hr):	24	48	24	48	24	48	24	48	24	48	24	48	24	48	24	48	24	48
6037 M		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6038 M		0	0	0	0	0	0	0	0	0	0	0	±	0	0	0	0	0	0
6039 M		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6042 M		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6049 M		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6143 F		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6160 F		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6161 F		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6162 F		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6163 F		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

[a]Scored according to scale presented in Appendix B.
M=Male; F=Female

TABLE II (cont.)

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

INDIVIDUAL DERMAL SCORES AT INDUCTION[a,b]

GROUP IIA MATERIAL: DNCB - 0.5%

Animal No. and Sex	Induction:	1		2		3		4		5		6		7		8		9	
	Interval (Hr):	24	48	24	48	24	48	24	48	24	48	24	48	24	48	24	48	24	48
6050 M		±,Ed	1,Ed	1,Ed	2,Ed	3,Ed, N	3,Ed, N	3,Ed N	3,Ed, N,E	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N,E	2,Ed, d	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N
6067 M		±,Ed	1	2,Ed	1,Ed	3,Ed, N	3,Ed, N	2,Ed, d	2,Ed, d	3,Ed, N	3,Ed, N	2,Ed	3,Ed, N	2,Ed	3,Ed, N	2,Ed	1,Ed	2,Ed	3,Ed
6068 M		0,c	0	±	±	3,Ed, N	3,Ed, N	2,Ed	2,Ed, d	3,Ed	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed	2,Ed	3,Ed, N,D	3,Ed, N,E
6069 M		±,Ed	1,Ed	1,Ed	2,Ed	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	2,Ed	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed	3,Ed	3,Ed, N,E	3,Ed, N,E
6070 M		0,Ed	±	1,Ed	1,Ed	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N,E	3,Ed, N	3,Ed, N,E
6164 F		±,Ed	1,Ed	2,Ed	1,Ed	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N,E	2,Ed	2,Ed	3,Ed, N	3,Ed, N	3,Ed, d	3,Ed, N	2,Ed	3,Ed, N	3,Ed, N	3,Ed, N
6165 F		±,Ed	1,Ed	1,Ed	±,Ed	3,Ed, N	3,Ed, N	2,Ed, d	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed	3,Ed, N	3,Ed, N	3,Ed, N,E	2,Ed	1,Ed	3,Ed, N,E	3,Ed, N,E
6166 F		0,Ed	1,Ed	1,Ed	2,Ed	3,Ed, N	3,Ed, N,E	3,Ed, N	3,Ed, N	3,Ed	3,Ed, N	3,Ed, d	3,Ed, N	3,Ed, N,c	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N
6167 F		1,Ed	1	2	1	3,Ed, N,D	3,Ed, N,D	2,Ed, d	2,Ed, d	3,Ed, N	3,Ed, N	2,Ed, d	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N,E	3,Ed, N,E
6168 F		±,Ed	1	2	1	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	3,Ed, N	2,Ed	2,Ed

[a]Scored according to scale presented in Appendix B.
[b]Due to signs of severe irritation and tissue damage seen in some animals, beginning after the fourth induction exposure, the location of the dosing site was adjusted so that patches were not placed over damaged skin for subsequent inductions.
[c]Patch not intact at end of 6-hour exposure.
[d]One small area of necrosis.

Ed=Edema E=Eschar
N=Necrosis M=Male
D=Desquamation F=Female

TABLE II (cont.)

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

INDIVIDUAL DERMAL SCORES AT INDUCTION[a,b]

GROUP IIIA MATERIAL: Diethylphenyl Azomethine

Animal No. and Sex	Induction: Interval (Hr):	1		2		3		4		5		6		7		8		9	
		24	48	24	48	24	48	24	48	24	48	24	48	24	48	24	48	24	48
6071 M		±,Ed	0	±	0	2,Ed	3,Ed, D	3,Ed, N	3,Ed, N,E	1,Ed	±	3,Ed, N	3,Ed, N,E	2,Ed	2,Ed	3,Ed D	2,Ed, D,c	3,Ed, N,E	3,Ed, N,E
6072 M		0	0	0	0	2,Ed	3,Ed, c	3,Ed, N	3,Ed, N,E	1,Ed	1	3,Ed, N	3,Ed, N	1,Ed	1,Ed	2,Ed	2,Ed, D	3,Ed, N,E	3,Ed, N,D,E
6073 M		±	±	1,Ed	1,Ed	3,Ed, N,D	3,Ed, N	2,Ed	2,Ed	2,Ed	2,Ed	3,Ed, N	3,Ed, N,E	1,Ed	1,Ed	2,Ed	2,Ed, D	3,Ed, N,E	3,Ed, N,E,D
6074 M		0	±	1,Ed	1,Ed	3,Ed, N,D	3,Ed, N	2,Ed	2,Ed	2,Ed	2,Ed, D	3,Ed, N	3,Ed, N,E	±	±	0	0	2,Ed	2,Ed
6075 M		0	±	1,Ed	±	2,Ed, D	2,Ed, D	3,Ed, N	3,Ed, N,E	1,Ed	1,Ed	3,Ed, N	3,Ed, N	1,Ed	2,Ed	3,Ed, c	2,Ed, c	1,Ed	1
6169 F		±	0	±,Ed	±,Ed	3,Ed, N,D	3,Ed, N,E	0	0	0	0	3,Ed	3,Ed, D	3,Ed, N	3,Ed, N	±	0	2,Ed	2,Ed, D,c
6170 F		±	±	±	±	3,Ed, D,c	3,Ed, D,c	3,Ed, N	3,Ed, N,E	±	±	3,Ed	3,Ed	3,Ed, N	3,Ed, N,E	2,Ed	2,Ed	3,Ed, D,c	3,Ed, N,E,D
6171 F		±	±	1,Ed	1,Ed	3,Ed, N,D	3,Ed, N,D	2,Ed	2,Ed	1,Ed	1	3,Ed, N	3,Ed, N,E	1,Ed	2,Ed	3,Ed, c	3,Ed	3,Ed, N,E	3,Ed, N,E
6172 F		±	±	±,Ed	1,Ed	3,Ed, N,D	3,Ed, N,D,E	1	0	0	0,D	3,Ed, D,c	3,Ed, N,D	1,Ed	2,Ed	2,Ed	3,Ed, N,D	2,Ed	2,Ed
6173 F		0	±	1	±	2,Ed, D	2,Ed, D	3,Ed, N	3,Ed, N	0	0	2,Ed	2,Ed, D	3,Ed, N	3,Ed, N,E	1	±	3,Ed, D	3,Ed, D

[a]Scored according to scale presented in Appendix B.
[b]Due to signs of severe irritation and tissue damage seen in some animals, beginning after the third induction exposure, the location of the dosing site was adjusted so that patches were not placed over damaged skin for subsequent inductions.
[c]Small area or foci of necrosis.

Ed=Edema E=Eschar
N=Necrosis M=Male
D=Desquamation F=Female

TABLE III

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

INCIDENCE OF DERMAL RESPONSE AT CHALLENGE

Group	Material	Conc[b]	Interval Hr	Dermal Scores[a] 0	±	1	2	3	Ed	N	Total No. of Animals
IA	Acetone	100%	24	10	0	0	0	0	0	0	10
			48	10	0	0	0	0	0	0	10
IB	Acetone (Irritation Control)[c]	100%	24	10	0	0	0	0	0	0	10
			28	10	0	0	0	0	0	0	10
IIA	DNCB	0.3%	24	0	0	0	7	3	10	1[d]	10
			48	0	0	0	7	3	10	2	10
IIB	DNCB (Irritation Control)[c]	0.3%	24	7	3	0	0	0	0	0	10
			48	9	1	0	0	0	0	0	10
CHALLENGE											
IIIA	Diethylphenyl Azomethine	1%	24	7	2	1	0	0	0	0	10
			48	7	3	0	0	0	0	0	10
IIIB	Diethylphenyl Azomethine (Irritation Control)[c]	1%	24	10	0	0	0	0	0	0	10
			48	10	0	0	0	0	0	0	10
RE-CHALLENGE											
IIIA	Diethylphenyl Azomethine	1%	24	6	4	0	0	0	0	0	10
			48	8	2	0	0	0	0	0	10
IIIB	Diethylphenyl Azomethine (Irritation Control)[c]	1%	24	10	0	0	0	0	0	0	10
			48	10	0	0	0	0	0	0	10

[a]Scored using the scale presented in Appendix B.
[b]Conc.=Concentration administered at challenge.
[c]Irritation control groups were treated at challenge or re-challenge only.
[d]Areas of necrosis; entire test site not necrotic.
Ed=Edema; N=Necrosis

TABLE IV

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

INDIVIDUAL DERMAL SCORES[a] AT CHALLENGE

GROUP: I MATERIAL: Acetone
INDUCTION CONCENTRATION: 100%
CHALLENGE CONCENTRATION: 100%

GROUP IA Animals Treated During Induction			GROUP IB Irritation Control Animals[b]		
Animal No. and Sex	Interval 24 Hr	48 Hr	Animal No. and Sex	Interval 24 Hr	48 Hr
6037 M	0	0	6086 M	0	0
6038 M	0	0	6087 M	0	0
6039 M	0	0	6088 M	0	0
6042 M	0	0	6089 M	0	0
6049 M	0	0	6090 M	0	0
6143 F	0	0	6185 F	0	0
6160 F	0	0	6186 F	0	0
6161 F	0	0	6187 F	0	0
6162 F	0	0	6188 F	0	0
6163 F	0	0	6189 F	0	0

[a]Scored using the scale presented in Appendix B.
[b]Irritation control animals were treated at challenge only.
M=Male; F=Female

TABLE IV (cont.)

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

INDIVIDUAL DERMAL SCORES[a] AT CHALLENGE

GROUP: II MATERIAL: DNCB
INDUCTION CONCENTRATION: 0.5%
CHALLENGE CONCENTRATION: 0.3%

GROUP IIA Animals Treated During Induction			GROUP IIB Irritation Control Animals[b]		
Animal No. and Sex	Interval 24 Hr	48 Hr	Animal No. and Sex	Interval 24 Hr	48 Hr
6050 M	3,Ed	2,Ed	6086 M	0	0
6067 M	2,Ed	2,Ed	6087 M	±	0
6068 M	2,Ed	2,Ed	6088 M	0	0
6069 M	2,Ed,c	2,Ed	6089 M	±	0
6070 M	2,Ed	3,Ed	6090 M	0	0
6164 F	2,Ed	3,Ed	6185 F	0	0
6165 F	3,Ed	3,Ed,N	6186 F	0	±
6166 F	2,Ed	2,Ed,S	6187 F	0	0
6167 F	2,Ed	2,Ed	6188 F	±	0
6168 F	3,Ed,d	2,Ed	6189 F	0	0

[a]Scored using the scale presented in Appendix B.
[b]Irritation control animals were treated at challenge only.
[c]Patch not intact at end of 6-hour exposure.
[d]Areas of necrosis; entire test site not necrotic.
M=Male; F=Female; Ed=Edema; N=Necrosis; S=Superficial necrosis

TABLE IV (cont.)

CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

INDIVIDUAL DERMAL SCORES[a] AT CHALLENGE

GROUP: III

MATERIAL: Diethylphenyl Azomethine
INDUCTION CONCENTRATION: 5%
CHALLENGE CONCENTRATION: 1%
RE-CHALLENGE CONCENTRATION: 1%

Group IIIA Animals Treated During Induction

Animal No. and Sex	Challenge		Re-Challenge	
	24 Hours	48 Hours	24 Hours	48 Hours
6071 M	+	0	+	0
6072 M	$\overline{0}$	+	$\overline{0}$	0
6073 M	+	$\overline{0}$	0	0
6074 M	$\overline{0}$	0	0	0
6075 M	0	0	+	0
6169 F	0	0	$\overline{0}$	0
6170 F	0	0	+	+
6171 F	0	+	$\overline{0}$	$\overline{0}$
6172 F	1	$\overline{+}$	0	+
6173 F	0	$\overline{0}$	$\overline{+}$	$\overline{0}$

Irritation Control Animals[b]

Group IIIB

Animal No. and Sex	Challenge	
	24 Hours	48 Hours
6086 M	0	0
6087 M	0	0
6088 M	0	0
6089 M	0	0
6090 M	0	0
6185 F	0	0
6186 F	0	0
6187 F	0	0
6188 F	0	0
6189 F	0	0

Group IIIC

Animal No. and Sex	Re-Challenge	
	24 Hours	48 Hours
6113 M	0	0
6114 M	0	0
6115 M	0	0
6116 M	0	0
6112 M	0	0
6210 F	0	0
6211 F	0	0
6212 F	0	0
6213 F	0	0
6214 F	0	0

[a]Scored using scale presented in Appendix B.
[b]Irritation control animals treated at challenge or re-challenge only.
M=Male; F=Female

APPENDIX A

A CLOSED-PATCH REPEATED INSULT DERMAL SENSITIZATION STUDY IN GUINEA PIGS WITH Diethylphenyl Azomethine

RANGE-FINDING STUDY - INDIVIDUAL DERMAL SCORES[a]

Animal No. and Sex	Concentration Interval	100%		50%[b]		25%[b]		10%[b]	
		24 Hours	48 Hours	24 Hours	48 Hours	24 Hours	48 Hours	24 Hours	48 Hours
6055 M		3,Ed,N	3,Ed,N	3,Ed,N	3,Ed,N	2	2	1	1
6056 M		3,Ed,N	3,Ed,N	3,Ed,N	3,Ed,N	3,Ed	3,Ed	1	±
6057 M		3,Ed,N	3,Ed,N	3,Ed,N	3,Ed,N	3,Ed	3,Ed	2	2
6147 F		3,Ed,N	3,Ed,N	3,Ed,N	3,Ed,N	1	1	2	1
6148 F		3,Ed,N	3,Ed,N	3,Ed,N	3,Ed,N	3,Ed	3,Ed	±	±
6149 F		3,Ed,N	3,Ed,N	3,Ed,N	3,Ed,N	3,Ed	3,Ed	2,Ed	2,Ed

Animal No. and Sex	Concentration Interval	5%		1%		0.5%		0.1%	
		24 Hours	48 Hours	24 Hours	48 Hours	24 Hours	48 Hours	24 Hours	48 Hours
6058 M		1	1	0	0	0	0	0	0
6059 M		2,Ed	1	0	0	0	0	0	0
6060 M		1	1	0	0	0	0	0	0
6150 F		1	1	0	0	0	0	0	0
6151 F		1	1,Ed	0	0	0	0	0	0
6152 F		1,Ed	1	0	0	0	0	0	0

[a]Scored using scale presented in Appendix B.
[b]Vehicle=acetone
M=Male; F=Female

MASTER FILE
PROJECT NO. SR-85-150

CLIENT PRIVATE

EVALUATION OF THE POTENTIAL OF DIETHYLPHENYL AZOMETHINE TO INDUCE UNSCHEDULED DNA SYNTHESIS IN PRIMARY RAT HEPATOCYTE CULTURES

Final Report

January 7, 1986

By:

James P. Bakke

James P. Bakke, Project Leader
Cell Biologist, DNA Damage and Repair Program

and

Jon C. Mirsalis, Ph.D., Study Director
Director, DNA Damage and Repair Program
Cellular & Genetic Toxicology Department
Toxicology Laboratory

Prepared for:

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, MO 63167

Attention: Dr. Joel Kronenberg

Monsanto Study No. SR-85-150
SRI Project LSC-8747-1

Approved by:

Jon B. Reid, Ph.D., Director
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W. A. Skinner, Vice President
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CLIENT PRIVATE

EXAMINATION OF MONSANTO CHEMICAL DIETHYLPHENYL AZOMETHINE IN THE IN VITRO HEPATOCYTE DNA REPAIR ASSAY

Monsanto Study No. SR-85-150

IN VITRO HEPATOCYTE DNA REPAIR ASSAY

STATEMENT OF PURPOSE

The purpose of this study is to evaluate the ability of diethylphenyl azomethine to induce unscheduled DNA synthesis (UDS) in the in vitro hepatocyte DNA repair assay.

SPONSOR

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, MO 63167

TESTING FACILITY (CONTRACT LABORATORY)

Cellular & Genetic Toxicology Department
Toxicology Laboratory
SRI International
333 Ravenswood Avenue
Menlo Park, CA 94025

PROPOSED SCHEDULE

Proposed starting date: 6/15/85

Proposed completion date: 9/1/85

Proposed draft final report submission date: 9/1/85

APPROVALS:

Jon Mirsalis 5/31/85

Jon Mirsalis, Ph.D. Date
Study Director
Cellular & Genetic Toxicology Dept.
SRI International
(415) 859-5382

Joel Kronenberg 6/5/85

Name: Joel Kronenberg Date
Title: Sr Prod Toxicologist
Monsanto Company
Telephone: 314/694-8832

THE *IN VITRO* HEPATOCYTE DNA REPAIR ASSAY

BACKGROUND

The measurement of DNA repair as unscheduled DNA synthesis (UDS) following chemically induced DNA damage has been shown to be a valuable tool in assessing the genotoxic activity of chemicals. Several *in vitro* assays for the measurement of UDS have been described (Martin et al., 1978; San and Stich, 1975; Trosko and Yager, 1974); however, these assays often do not provide a means to metabolize chemicals to an active form.

A substantial advance was made by the development of an assay that employs primary rat hepatocytes (Williams, 1977). This system offers many advantages over other *in vitro* UDS systems: (1) the low level of DNA replication in the adult rat liver ($< 0.1\%$) precludes the need for inhibitors of DNA replication; (2) the same cells serve as both activator and target; and (3) a more accurate profile of metabolism is obtained than with liver microsomal preparations. This system has been shown to detect a wide variety of genotoxic agents, including polycyclic aromatic hydrocarbons, nitrosamines, mycotoxins, and aromatic amines.

METHODS

Primary Cell Cultures

Primary rat liver cell cultures derived from the livers of adult male Fischer-344 rats will be used for all experiments. Hepatocytes will be isolated according to the procedure of Williams (1977) and inoculated into culture dishes containing coverslips in Williams' Medium E supplemented with 2 mM l-glutamine, 50 μg/ml gentamicin sulfate, and 10% fetal bovine serum. After 1.5 to 2.0 hours of incubation at 37°C, the nonviable cells (those not attached to the coverslips) will be washed out of the cultures, and the viable cells will be used immediately for the UDS assay. All subsequent steps will be performed in serum-free medium.

Dilution of Test Articles

Immediately before each assay, test articles will be diluted in an appropriate solvent (water, ethanol, acetone, or dimethylsulfoxide) to form a series of concentrations that, when diluted into culture medium, will yield the appropriate set of test concentrations. The final concentration of solvent will be maintained at 1% or less to preclude the possibility of a cytotoxic effect in response to the solvent.

Controls

Three controls will be incorporated into each UDS assay: a positive control, a negative (solvent) control, and an untreated medium control. The positive control will be 2-acetylaminofluorene (2-AAF), which is known to induce UDS after metabolic conversion to its active form. Two concentrations of 2-AAF will be tested in each experiment; one concentration will be scored and reported in the Final Report. The negative control will be solvent diluted in culture medium.

Test Protocol

For the preliminary UDS assay, three cultures will be used for each of 8 to 10 dilutions of the test article, for the positive control, for the negative control, and for the untreated medium control. The maximum test article concentration tested will be the highest soluble concentration or 5000 μg/ml, whichever is lower. Cultures will be exposed simultaneously to the test material and to 10 μCi/ml ^{3}H-thymidine (specific activity, 40 to 80 Ci/mmole) for 17 to 21 hours at 37°C. After exposure, all cultures will be washed, swelled in a 1% sodium citrate, fixed in 1:3 glacial acetic acid/ethanol, and washed with deionized water. The coverslips will be mounted to slides, dipped in Kodak NTB-2 emulsion, and exposed at -20°C for 7 to 12 days prior to development. Cells will be stained in methyl-green Pyronin Y. The UDS assay will be repeated for at least three of the highest noncytotoxic test concentrations to ensure reproducibility. These concentrations will be selected by the Project Leader and the Sponsor.

Measurement of UDS

Quantitative autoradiographic grain counting will be accomplished using an ARTEK Model 880 or 980 colony counter interfaced with a Zeiss Universal Microscope via an ARTEK TV camera. Data will be fed directly into a VAX 11/782 computer via an ARTEK BCD-RS232 Omni-Interface. Fifty morphologically unaltered cells on a randomly selected area of the slide will be counted. The highest count from two nuclear-sized areas over the most heavily labeled cytoplasmic areas adjacent to the nucleus will be subtracted from the nuclear count to give the net grains/nucleus (NG). The percent of cells in repair will be calculated as the percentage of cells with at least +5 NG. One hundred and fifty cells will be scored for each concentration reported for each experiment.

ANALYSIS OF RESULTS

Data Collected

All collection of data and pooling of slides will be done by programs in the VAX 11/782 computer. Frequency distributions of grain counts for each test concentration as well as average and median grain counts will be calculated and compared with control values. No other statistical methods will be used for analysis of the data.

Criteria for Interpretation

Positive. A test article will be considered positive if UDS (amount of incorporated ^{3}H-thymidine) is markedly elevated above that in the solvent control. The presence of a dose-response, changes in the frequency distribution of cellular responses, increases of the percentage of cells in repair and reproducibility of data will all be considered in classifying the test article as a "positive" or "negative."

Negative. A material will be considered negative if testing has been performed to the limits of solubility and if UDS is not markedly elevated above that in the solvent control.

SAMPLE AND TIME REQUIREMENTS

Sample Requirements

Three grams of the test article will be needed to complete the testing. The client will be responsible for the stability, melting point determination, and the purity analysis of the test article.

Time Requirements

Approximately twelve weeks will be required to complete testing of a test article.

QUALITY ASSURANCE AND REPORTING OF RESULTS

Quality Assurance

This study will be conducted in accordance with the Good Laboratory Practice Regulations promulgated by the Environmental Protection Agency (EPA) on 29 November 1983 (40 CFR Part 160 and 40 CFR Part 792). The duties of SRI's Quality Assurance Unit will include verifying the calculations, inspecting laboratory work and reviewing the Final Report.

Reporting of Results

A draft report will be submitted following completion of the study. A final report will be submitted after approval of the draft report by the sponsor.

REFERENCES

Martin, C. N., A. C. McDermid, and R. C. Garner. 1978. Testing of known carcinogens and noncarcinogens for their ability to induce unscheduled DNA synthesis in HeLa cells. Cancer Res. 38, 2621-2627.

San, R.H.C., and H. F. Stich. 1975. DNA repair synthesis of cultured human cells as a rapid bioassay for chemical carcinogens. Int. J. Cancer 16, 284-291.

Trosko, J. E., and J. D. Yager. 1974. A sensitive method to measure physical and chemical carcinogen-induced "unscheduled DNA synthesis" in rapidly dividing eukaryotic cells. Expt. Cell Res. 88, 47-55.

Williams, G. M. 1977. Detection of chemical carcinogens by unscheduled DNA synthesis in rat liver primary cell cultures. Cancer Res. 37, 1845-1851.

QUALITY ASSURANCE UNIT

Final Report Statement

SRI International assures the quality and integrity of this study, Evaluation Of The Potential Of Diethylphenyl Azomethine To Induce Unscheduled DNA Synthesis In Primary Rat Hepatocyte Cultures, for the Monsanto Company.

The study was inspected on July 16, 1985 and July 17, 1985 during the perfusion and washdown phases. The findings of the Quality Assurance Unit inspections were reported at the time of the inspection to the Study Director. SRI management was informed of the inspection results on July 24, 1985 and August 5, 1985. A data audit was performed on September 23, 1985 and January 10, 1986. The Study Director and SRI management were informed of the audit results on September 24, 1985 and January 13, 1986.

The final report was audited and reviewed on January 10, 1986. The results of the final report review were communicated to the Study Director and SRI management on January 13, 1986. The final report accurately describes the methods and standard operating procedures and reflects the raw data of the study. Any deviations from the approved protocol and standard operating procedures were made with proper authorization and documentation.

Manager of Regulatory Affairs
and Quality Assurance

Date

SUMMARY

SRI International examined diethylphenyl azomethine for Monsanto Company by conducting unscheduled DNA synthesis (UDS) tests with primary cultures of rat hepatocytes. Laboratory work was initiated on 12 June 1985, and tabulation of data was completed on 5 September 1985. An appreciable increase in UDS above that of the solvent control level was not observed after treatment of the hepatocytes with diethylphenyl azomethine. Therefore, based on our criteria for a significant response, diethylphenyl azomethine was negative in this assay. This study (SRI Project LSC 8747-1, Monsanto Study No. SR-85-150) was conducted in compliance with the Environmental Protection Agency Good Laboratory Practice (GLP) Standards under Section 4 of TSCA, as set forth in 40 CFR Parts 160 and 792, November 29, 1983.

ACKNOWLEDGMENTS

Erica Loh, Carol Hamilton, and Marilyn Ramsey contributed substantially to the completion of this study.

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INTRODUCTION

The measurement of DNA repair as unscheduled DNA synthesis (UDS) following chemically induced DNA damage has been shown to be a valuable tool in assessing the genotoxic activity of chemicals. Several *in vitro* assays for the measurement of UDS have been described (Martin et al., 1978; San and Stich, 1975; Trosko and Yager, 1974); however, these assays often do not provide a means to metabolize chemicals to an active form.

A substantial advance was made by the development of an assay that employs primary rat hepatocytes (Williams, 1977). This assay offers many advantages over other *in vitro* UDS systems: (1) the low level of DNA replication in the adult rat liver (< 0.1%) precludes the need for inhibitors of DNA replication; (2) the same cells serve as both activator and target; and (3) a more accurate profile of metabolism is obtained than with microsomal preparations. This assay has been shown to detect a wide variety of genotoxic agents, including polycyclic aromatic hydrocarbons, nitrosamines, mycotoxins, and aromatic amines.

MATERIALS

- Test Article:
  - Identification: Diethylphenyl azomethine; Lot 5-30-85-205.
  - Physical State: Pale yellow liquid.
  - Test Article Purity Analysis: 95.5%.
  - Stability: Stable under normal laboratory conditions.*
  - Storage Conditions: Stored at room temperature.
  - Date Received: 6/10/85.
  - Amount Received: 10 g*
- Animals:
  - Species: Fischer-344 adult male rats.
  - Source: Charles River Laboratories, Inc.
    251 Ballardvale Street
    Wilmington, MA 01887
- Solvent used:
  - Acetone.
  - Source: American Scientific Products
    Sunnyvale, CA 94043
- Positive Control Article:
  - 2-Acetylaminofluorene (2-AAF), 0.5 and 3 µg/ml, CAS No. 53-96-3.
  - Source: Aldrich Chemical Co.
    940 W. St. Paul Avenue
    Milwaukee, WI 53233

*As reported by Sponsor.

METHODS

Primary Cell Cultures

Primary rat liver cell cultures derived from the livers of two adult male Fischer-344 rats weighing 263 and 309 g were used for the preliminary and replicate experiments, respectively. Each rat was anesthetized with 0.2 cc of Nembutal®/100 g body weight prior to each experiment. Hepatocytes were isolated by liver perfusion with a collagenase solution according to the procedure of Williams (1977) and inoculated into culture dishes containing coverslips in Williams' Medium E supplemented with 2 mM glutamine, 50 µg/ml gentamicin, and 10% fetal bovine serum. After 1.5 to 2.0 hours of incubation at 37°C, the nonviable cells (those not attached to the coverslips) were washed out of the cultures and the viable cells were used immediately for the UDS assay. All subsequent steps were performed in serum-free medium.

Dilution of Test Article

Immediately before each assay, the test article and the positive control were diluted in acetone to form a series of concentrations that, when diluted in culture medium, yielded the appropriate set of test concentrations. The final concentration of acetone was maintained at 1% to preclude the possibility of a cytotoxic effect in response to the solvent.

Controls

Three controls were incorporated into each UDS assay: a positive control, a negative (solvent) control, and an untreated medium control. The positive control was 2-acetylaminofluorene, which is known to induce UDS after metabolic conversion to its active form. Two concentrations of 2-AAF were tested in each experiment; one

concentration from each experiment was scored and the results are included in the final report. The negative control was the solvent diluted in culture medium.

Test Protocol

For the preliminary UDS assay, three cultures were used for each of eight dilutions of diethylphenyl azomethine, for the positive control, for the negative control, and for the untreated medium control. The maximum concentration of diethylphenyl azomethine tested was 5000 µg/ml in medium, which was found to be the limit of solubility of the test article. Cultures were exposed simultaneously to the test material and to 10 µCi/ml ^{3}H-thymidine (specific activity, approximately 80 Ci/mmole) for 19 to 20 hours at 37°C. After exposure, all cultures were washed with medium, swelled in a hypotonic solution, fixed, and washed with water. The coverslips were mounted on slides, dipped in Kodak NTB-2 emulsion, and exposed at -20°C for 7 days prior to development. Cells were stained in methyl-green Pyronin Y. The UDS assay was repeated at eight concentrations of diethylphenyl azomethine selected by the Project Leader and the Sponsor. The highest concentration tested in the replicate experiment was 5000 µg/ml.

Measurement of UDS

Quantitative autoradiographic grain-counting was accomplished using an ARTEK Model 880 or 980 colony counter interfaced with a Zeiss Universal Microscope via an ARTEK TV camera. Data were fed directly into a VAX 11/782 computer via an ARTEK BCD-RS232 Omni-Interface. Fifty morphologically unaltered cells on a randomly selected area of the slide were counted. The highest count from two nuclear-size areas over the most heavily labeled cytoplasmic areas adjacent to the nucleus was subtracted from the nuclear count to give the net grains/nucleus (NG). The percentage of cells in repair was calculated as the percentage of cells with at least 5 NG. One hundred and fifty cells were scored for each concentration reported for each experiment.

Analysis of Results

Data Collected

All collection of data and pooling of slides were done by programs in the VAX 11/782 computer. Frequency distributions of grain counts for each test concentration as well as average and median grain counts were calculated and compared with control values. No other statistical methods were used for analysis of the data.

Criteria for Interpretation

Positive. A test article is considered positive if UDS (amount of incorporated ^{3}H-thymidine) is markedly elevated above that in the solvent control. The presence of a dose response, a change in the frequency distribution of cellular responses, an increase in the percentage of cells in repair, and reproducibility of data are all considered in classifying the test article as a "positive" or "negative." If the data warrant, a test article is classified as a "weak positive."

Negative. A material is considered negative if testing has been performed to the limits of solubility or cytotoxicity, or at 5000 μg/ml, and if UDS is not significantly elevated above that in the solvent control.

Data Storage

Notebook #12166 and the Final Report will be stored for one year in Room 205-19, then transferred to SRI's Records Center. Microscopic slides will be stored in Room 103B-19 for one year and then transferred to Room 108-73 for at least nine additional years. The chemical specimen will be maintained in the Chemical Repository, Room M-217, until Monsanto requests that the remaining portion of the sample be returned or discarded.

RESULTS AND DISCUSSION

Diethylphenyl azomethine was examined for genotoxicity in the in vitro rat hepatocyte DNA repair assay. Results of the UDS assays with diethylphenyl azomethine are presented in Table 1. Cytotoxicity was observed in both the preliminary and replicate experiments at 500, 1000, and 5000 µg/ml. A precipitate was observed at 5000 µg/ml in both experiments. UDS was measured at concentrations of the test compound between 1 and 100 µg/ml in both assays.

The net grain counts were negative at each concentration of the test compound, in the solvent control, and in the medium control, in contrast to the strong positive response produced in both experiments by the positive control, 2-acetylaminofluorene (18.7 and 32.6 net grains). An increase in the percent of cells in repair (21% compared to 0% in the solvent control) was observed at the highest non-cytotoxic concentration (100 µg/ml) in the replicate assay. A slight increase was also observed in the preliminary assay (8%). Examination of the frequency distribution of cellular responses reveals a small population of cells exhibiting significant increases in UDS. This suggests that genotoxicity may be induced in a small population of hepatocytes; however, the fact that NG never exceeds 0 indicates that this does not represent a significant genotoxic response and may be an artifact of the system.

These results indicate that diethylphenyl azomethine is not a genotoxic agent in the in vitro rat hepatocyte DNA repair assay.

TABLE 1

ASSAY FOR INDUCTION OF UNSCHEDULED DNA SYNTHESIS BY DIETHYLPHENYL AZOMETHINE
IN THE IN VITRO HEPATOCYTE DNA REPAIR ASSAY

Treatment	Concentration [µg/ml]	Preliminary Assay N.G.	Preliminary Assay S.E.	Preliminary Assay Median	Preliminary Assay % IR	Replicate Assay N.G.	Replicate Assay S.E.	Replicate Assay Median	Replicate Assay % IR
CONTROL/MEDIUM	---	-18.9	2.1	-18.6	1	-15.4	3.0	-14.0	0
CONTROL/ACETONE	1%	-17.1	2.9	-16.7	1	-12.6	3.3	-11.6	0
2-ACETYLAMINOFLUORENE	0.5	N.S.				32.6	3.7	31.6	90
	3	18.7	3.4	18.6	77	N.S.			
DIETHYLPHENYL AZOMETHINE	1	-15.4	3.2	-14.9	0	-17.6	3.4	-17.7	1
	5	-14.1	2.3	-12.6	0	-15.2	1.5	-15.4	0
	10	-12.1	2.0	-11.2	2	-13.3	1.6	-13.0	0
	50	-11.4	2.9	-10.2	3	-13.9	3.2	-13.0	0
	100	-8.0	2.7	-7.9	8	-2.0	1.2	-2.8	21
	500	toxic				toxic			
	1000	toxic				toxic			
	5000	toxic				toxic			

Standard errors (S.E.) represent slide-to-slide variation.
% IR = Percentage of cells in repair.
N.G. = net grains/nucleus.
toxic = Cytotoxicity observed; slides unscorable.
N.S. = Not scored at this concentration.

CLIENT PRIVATE

REFERENCES

Martin, C. N., A. C. McDermid, and R. C. Garner. 1978. Testing of known carcinogens and noncarcinogens for their ability to induce unscheduled DNA synthesis in HeLa cells. Cancer Res. 38, 2621-2627.

San, R.H.C., and H. F. Stich. 1975. DNA repair synthesis of cultured human cells as a rapid bioassay for chemical carcinogens. Int. J. Cancer 16, 284-291.

Trosko, J. E., and J. D. Yager. 1974. A sensitive method to measure physical and chemical carcinogen-induced "unscheduled DNA synthesis" in rapidly dividing eukaryotic cells. Exp. Cell Res. 88, 47-55.

Williams, G. M. 1977. Detection of chemical carcinogens by unscheduled DNA synthesis in rat liver primary cell cultures. Cancer Res. 37, 1845-1851.

Monsanto

DEPARTMENT OF MEDICINE & ENVIRONMENTAL HEALTH
SAMPLE SUBMISSION

STUDY NO. SR-85-150

PLEASE TYPE OR PRINT

I. SAMPLE IDENTIFICATION

PRODUCT NAME(S)	CHEMICAL NAME
Diethyl phenylazomethine	Benzene amine 2,6-diethyl N-methylene

CP NO.	CHEM. ABSTRACTS REG. NO.	LOT OR I.D. NO., NOTE BOOK REF.
34721	35203-[illegible]-8	5-30-85-205 *

SAMPLE SIZE	PURITY	SAMPLE DISPOSITION	
10 g	95.5%	☒ DISCARD ☐ RETURN	☐ HOLD, NOTIFY BEFORE DISCARDING

II. CHEMICAL AND PHYSICAL PROPERTIES

STRUCTURAL FORMULA (COMPOSITION OF MIXTURE)

*Reference
nbp 2697536

EMPIRICAL FORMULA	MOLECULAR WEIGHT	COLOR/PHYSICAL STATE
$C_{11}H_{15}N$	161.24	light yellow liquid

MELTING POINT	BOILING POINT	VAPOR PRESSURE	SPECIFIC GRAVITY
		4×10^{-3} psia at 100°F	

SOLUBILITY: WATER	ORGANIC SOLVENTS (SPECIFY)	OTHER
insoluble	acetone, chloroform	

PHYSICAL/CHEMICAL HAZARDS

☐ FLAMMABLE ☐ UNSTABLE TO LIGHT ☐ POLYMERIZES READILY ☒ NO SPECIAL PRECAUTIONS
☐ EXPLOSIVE ☐ UNSTABLE TO HEAT ☐ HYGROSCOPIC ☐ OTHER (SPECIFY)
☐ OXIDIZER ☐ UNSTABLE TO WATER ☐ REACTS WITH _____

OTHER PROPERTIES, SPECIAL REQUIREMENTS (SPECIFY)
stable

III. TOXICITY INFORMATION

ORAL LD_{50} 1490 mg/kg
DERMAL LD_{50} _____
EYE IRRITATION ~~4i.5/110~~ severe
SKIN IRRITATION ~~1.3/8.0~~ severe
SINGLE VAPOR INHALATION 0.83 mg/L (nominal), 6 hr, no mortality

____ NO INFORMATION AVAILABLE
____ SEE ATTACHMENT
____ OTHER (SPECIFY)

YO-83-12

IV. DOCUMENTATION

COMPOSITION & PURITY	METHOD OF SYNTHESIS
☒ STATED ABOVE	☐ SEE ATTACHMENT
☐ SEE ATTACHMENT	☐ STAFF TOXICOLOGY FILE
☐ STAFF TOXICOLOGY FILE	☒ OPERATING CO. FILE

SUBMITTED BY: (Name, Location, Phone No., Date)	DMEH CONTACT: (Name, Location, Phone No., Date)
Lydia A. Suba, C2SC, 4-2124 5/30/85	Joel Kronenberg, G2WD, 4-8832 5/30/85

V. EHL USE

STUDY NUMBER(S)	SUBSTANCE IDENTIFICATION CODE

WHITE COPY—LABORATORY COPY; YELLOW COPY—DMEH FILE COPY; PINK COPY—REQUESTOR'S COPY

G-3078 (REV. 1/80)

MAC/Administration/EHL
(CO./DIV./DEPT./LOCATION)

Final REPORT
(TYPE OF REPORT)

REPORT NO.: MSL-7908

JOB/PROJECT NO.: ML-86-360/EHL 86126 and 86127

DATE: May 9, 1988

TITLE: Fertility and Reproduction Inhalation Studies with 2,6-Diethylphenyl Azomethine in Sprague-Dawley Rats

AUTHORS: B. Richard Dudek, Ph.D., D.A.B.T.
F. A. Ruecker, D.V.M., Dipl. A.C.V.P.

ABSTRACT: In a male fertility study, four groups of 25 male rats were exposed to atmospheres of 2,6-diethylphenyl azomethine for 6 hours/day, 5 days/week (except holidays) for approximately 11 weeks (56 exposure days). Exposures continued on a 5 day/week schedule during a two week mating period and for two weeks thereafter. Each male was consecutively cohoused (1:1) with two unexposed females. These females were terminated approximately two weeks after copulation to assess pregnancy status and implantation loss. Mean analytical exposure concentrations were 2.6, 14, and 50 mg 2,6-diethylphenyl azomethine/cubic meter in air. With the exception of red/brown perinasal encrustation seen in high level animals shortly after exposure, there were no significant signs of toxicity. The mean body weight of high level males was significantly reduced compared to controls throughout the study while the mid and low level animals were unaffected. There

(Continued on reverse side)

REPT. NO.: MSL-7908 AUTHORS: B. R. Dudek, F. A. Ruecker
TITLE: Fertility and Reproduction Inhalation Studies with 2,6-Diethylphenyl Azomethine in Sprague-Dawley Rats
COPY NO.:

were no significant differences in any of the mating and fertility parameters measured. There were no gross necropsy findings considered related to exposure.

In a female reproduction study, four groups of 30 female rats received the same treatment as described above for the male fertility study prior to mating. There was a significant decrease in body weights among the high level animals compared to controls throughout the study. Exposures continued on a 5 day/week schedule during the mating period. During the mating period, each female was cohoused with one unexposed male. Once copulation was confirmed, exposures continued (starting on gestation Day 0) on a 7 day/week schedule through gestation Day 20. Mean analytical exposure concentrations were 2.6, 14, and 51 mg/cubic meter in air. Females were then housed in delivery boxes and allowed to deliver their pups. On lactation Day 4, litters were culled to 8 pups, 4 of each sex when possible. High level pup weights were reduced from 2 to 13% during the lactation period. Some of the reductions were statistically significant; Day 4, pre- and post-cull females; Day 7, females; and Days 0 and 4 pre-cull, combined sexes. Reduced high level pup body weights may be a result of maternal toxicity (significant decrease in dam body weights throughout the study relative to controls) and therefore may not be a direct effect of the test material on the offspring. Pups were weaned on lactation Day 21 and necropsied. Selected tissues were removed, fixed, and examined microscopically. No abnormalities were found that were attributed to test material exposure.

In conclusion, the lowest-observed-effect level (LOEL) and the no-observed-effect level (NOEL) for maternal toxicity are 51 and 14 mg/cubic meter in air, respectively, based on reduced body weights of F0 females exposed at 51 mg/cubic meter. The LOEL and NOEL for males similarly exposed are considered to be 50 and 14 mg/cubic meter in air, respectively. Pups from dams exposed to 50 mg/cubic meter had reduced body weights during the lactation period. This difference appeared to be related to the significantly reduced dam weight seen throughout the study and was probably not a direct treatment effect on the offspring.

Monsanto

MAC QUALITY the voice of the customer

FROM (NAME—LOCATION—PHONE) MAC TOXICOLOGY [redacted]/C2SE/4-8890

DATE June 13, 1988

SUBJECT Fertility and Reproduction Inhalation Studies with 2,6-Diethylphenyl Azomethine

REFERENCE ML-86-360; 86126 and 86127

TO B. W. Eley - C2SB

cc. E.J. Brandt /C2SE
E.E. Debus /C2SF
B.R. Dudek/EHL
T.W. Fuhremann /C2SE
G.B. Fuller/C2SF
R.L. Harness /C2SB
R.W. Street /C2SE
L.A. Suba /C2SE
Toxdata /A3NG
S&EH Library /A3NH
MAC Tox File

The final report for the referenced studies with 2,6-diethylphenyl azomethine has been received and is summarized below. This study was conducted at Monsanto's Environmental Health Laboratory.

Purpose

This study was designed to evaluate the effects of 2,6-diethylphenyl azomethine on male and female reproductive function. This project consisted of 2 studies conducted concurrently: (1) a male fertility study and (2) a female fertility/reproduction study.

Methods

Male and female Sprague-Dawley rats were exposed via inhalation to 2,6-diethylphenyl azomethine (lot numbers W.STO 11-10-86 and W.STO 1-16-87, 98.7% and 97% pure, respectively). Target concentrations were 0, 2.5, 15 and 50 mg/m^3. Nominal and analytical concentrations were determined once and 4 times during each exposure, respectively. Distribution of atmospheric concentrations was determined twice during the study. The exposure schedules were as described below.

In the male fertility study, four groups of 25 male rats were exposed for 6 hours/day, 5 days/week, for approximately 11 weeks and then consecutively co-housed (1:1) with 2 unexposed females until copulation was confirmed or 7 days had elapsed. Exposures were continued 5 days/week throughout the mating period and for two weeks thereafter. Females with confirmed copulation were sacrificed on gestation Day 13 and the number and status (live vs dead) of implants, and the number of corpora lutea were determined. Females without confirmed copulation were sacrificed in the second week after co-housing and gross necropsies were performed. Males were discarded without necropsy.

In the female reproduction study, four groups of 30 female rats were exposed 5 days/week, 6 hours/day for approximately 11 weeks. Females were then co-housed (1:1) with one unexposed male until copulation was confirmed or 7 days had elapsed. If copulation was not confirmed, the female was co-housed with a second unexposed male (proven breeder). Exposure was continued 5 days/week throughout the mating period. Once copulation was confirmed, females were exposed on a 7 day/week basis through gestation day 20 and were allowed to deliver the F_1 litters. Females with litters were sacrificed on lactation day 21, non-delivering females were sacrificed in the week following their expected delivery, and females without confirmed copulation were sacrificed within 2 weeks after co-housing. Gross necropsies were performed on all F_0 females.

F_1 animals were examined for the presence of external abnormalities on lactation days 0, 4, 7, 14, and 21. On day 4, litters were culled to 8 pups. Total litter weights were determined by sex on days 0, 4 (pre- and post-culling), 7 and 14 of lactation. Individual weights were obtained on lactation day 21. Gross necropsies were performed on all F_1 animals at scheduled sacrifice (lactation day 21) and approximately 30 tissues (Table I) were obtained from 10 animals/sex/exposure level. Tissues from control and high level F_1 animals were examined microscopically.

In both of these studies, exposed animals were observed during and immediately following each exposure. Mortality checks were conducted twice daily. In the male fertility study, males were weighed and detailed examinations were performed weekly. In the female fertility/reproduction study, F_0 females were weighed and thoroughly examined once a week until copulation was confirmed, then on gestation days 0, 6, 13, 20, and lactation days 0, 4, 7, 14, and 21 or until sacrifice.

Results

Mean analytical exposure levels for the male fertility study and the female reproduction study were 2.6, 14, and 50 mg/m^3; and 2.6, 14, and 51 mg/m^3, respectively. The distribution of 2,6-diethylphenyl azomethine within the chambers was acceptable.

In the male fertility study, the only mortality seen was one control male who died during the mating period. Some of the animals in the high exposure group were not responsive to outside stimulation during the exposures. Red/brown perinasal encrustation was seen frequently in high level animals after exposure. Mean body weights in high level animals were reduced 6 to 13% compared to control animals throughout the study. No differences were seen in any of the mating and fertility parameters measured.

In the female reproduction study, some of the high level animals were not responsive during the exposure. Red/brown perinasal encrustation was seen in mid and high level animals after exposure. Body weights of high level animals were reduced 7-15% relative to controls throughout the study. No significant differences were seen in the fertility or pregnancy indices, or in litter mortality. Pup weights in the high level group were reduced from 2 to 13% relative to controls during the lactation period. Some of these decreases were statistically different from control weights. Differences in pup weights were attributed to decreased dam weights, and not to a direct effect of test material on the offspring. No significant gross or microscopic abnormalities were seen in the weanlings.

Conclusion

The NOEL for animal toxicity was 2.5 mg/m^3. However, the only effect seen at 15 mg/m^3 which may be related to treatment was red/brown perinasal encrustation in a few females in the female reproduction study. Pups from dams exposed to 50 mg/m^3 had reduced body weights during the lactation period, but this decrease was attributed to reduced dam weight and not considered a direct treatment effect. No other effects on reproductive function were seen in either male or females.

Linda Loretz

Linda J. Loretz, Ph.D.
Senior Product Toxicologist
Monsanto Agricultural Company

/jjs

TABLE I

TISSUES RETAINED

- abdominal aorta
- adrenals
- bone and bone marrow (femur)
- brain (longitudinal section)
- diaphragm
- esophagus
- eyes with optic nerve
- gonads
  - ovaries
  - testes with epididymides
- heart
- intestine
  - duodenum
  - colon
  - ileum
- kidneys (2)
- liver (2 sections)
- lung (2 sections, at least 2 lobes and mainstem bronchi)
- lymph nodes
  - mesenteric
  - thymic
- mammary gland
- nasal passages (3 sections)
- pancreas
- pituitary
- prostate
- salivary gland (submaxillary)
- sciatic nerve
- seminal vesicle
- skeletal muscle
- skin
- spinal cord
- spleen
- stomach (longitudinal section)
- thymus
- trachea
- thyroid/parathyroid
- urinary bladder
- uterus (including the cervix)
- vagina
- gross lesions (if determined to be treatment-related by the pathologist)

MONSANTO AGRICULTURAL COMPANY
ENVIRONMENTAL HEALTH LABORATORY
645 S. NEWSTEAD AVENUE
ST. LOUIS, MISSOURI 63110

Fertility and Reproduction Inhalation Studies with 2,6-Diethylphenyl Azomethine in Sprague-Dawley Rats

---

Study Numbers: 86126 and 86127

Project Number: ML-86-360

B. Richard Dudek 9 May 1988

B. Richard Dudek, Ph.D., D.A.B.T. Date
Study Director

F. A. Ruecker 5/9/88

F. A. Ruecker, D.V.M, Dipl. A.C.V.P. Date
Pathologist

SUMMARY/DISCUSSION

In the male fertility study, four groups of 25 male rats were exposed for 6 hours/day, 5 days/week (except holidays) for approximately 11 weeks (56 exposure days). Exposures continued on a 5 day/week schedule during a two week mating period and for two weeks thereafter. Each male was consecutively cohoused (1:1) with two unexposed females. These females were terminated approximately two weeks after copulation to assess pregnancy status and implantation loss. Mean analytical exposure concentrations were 2.6, 14, and 50 mg 2,6-diethylphenyl azomethine/cubic meter in air. With the exception of red/brown perinasal encrustation seen in high level animals shortly after exposure, there were no significant signs of toxicity. The mean body weight of high level males was significantly reduced compared to controls throughout the study while the mid and low level animals were unaffected. There were no significant differences in any of the mating and fertility parameters measured. There were no gross necropsy findings considered related to exposure.

In the female reproduction study, four groups of 30 female rats received the same treatment as described above for the male fertility study prior to mating. There was a significant decrease in body weights among the high level animals compared to controls throughout the study. Exposures continued on a 5 day/week schedule during the mating period. During the mating period, each female was cohoused with one unexposed male. Once copulation was confirmed, exposures continued (starting on gestation Day 0) on a 7 day/week schedule through gestation Day 20. Mean analytical exposure concentrations were 2.6, 14, and 51 mg/cubic meter in air. Females were then housed in delivery boxes and allowed to deliver their pups. On lactation Day 4, litters were culled to 8 pups, 4 of each sex when possible. High level pup weights were reduced from 2 to 13% during the lactation period. Some of the reductions were statistically significant (Dunnett's); Day 4, pre- and post-cull females; Day 7, females; and Days 0 and 4 pre-cull, combined sexes. Reduced high level pup body weights may be a result of maternal toxicity (significant decrease in dam body weights throughout the study relative to controls) and therefore may not be a direct effect of the test material on the offspring. Pups were weaned on lactation Day 21 and necropsied. Selected tissues were removed, fixed, and examined microscopically. No abnormalities were found that were attributed to test material exposure.

In conclusion, the lowest-observed-effect level (LOEL) and the no-observed-effect level (NOEL) for maternal toxicity are 51 and 14 mg/cubic meter in air, respectively, based on reduced body weights of F0 females exposed at 51 mg/cubic meter. The LOEL and NOEL for males similarly exposed are considered to be 50 and 14 mg/cubic meter in air, respectively. Pups from dams exposed to 50 mg/cubic meter had reduced body weights during the lactation period. This difference appeared to be related to the significantly reduced dam weight seen throughout the study and was probably not a direct treatment effect on the offspring.

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TRADEMARKS

The following registered trademark is used in this report:

Item	Registered Trademark of:
RODENT CHOW	Purina Mills, Inc. St. Louis, MO

INTRODUCTION

Purpose: To evaluate the reproductive toxicity of 2,6-diethylphenyl azomethine in male and female Sprague-Dawley rats
Project Design: Consisted of two studies: (1) a male fertility study (EHL 86126) and (2) a female reproduction study (EHL 86127). Animals in these studies were exposed concurrently.
Date Studies Started: November 20, 1986

MATERIALS AND METHODS

Experimental Design

Male Fertility Study:

Four groups of 25 male rats were exposed for 6 hours/day, 5 days/week (except holidays) for approximately 11 weeks (56 exposure days). Males were then consecutively cohoused (1:1) with two unexposed females during a 2 week mating period. Exposures continued on a 5 day/week basis during the mating period and for 2 weeks thereafter. Females were terminated approximately two weeks after copulation to assess pregnancy status and implantation losses.

Female Reproduction Study:

Four groups of 30 female rats were exposed for 6 hours/day, 5 days/week (except holidays) for approximately 11 weeks (56 exposure days). Females were then cohoused (1:1) with unexposed males; exposures continued on a 5 day/week basis during the mating period. Once copulation was confirmed, females were exposed on a 7 day/week basis through gestation Day 20. They were then housed in delivery boxes and allowed to deliver their pups. On lactation Day 4, litters were culled to 8 pups, 4 of each sex when possible. Pups were weaned on lactation Day 21 and necropsied.

Test Material

Name: 2,6-Diethylphenyl azomethine
EHL Substance Identification Codes: T860069 and T870001
Lot Numbers: W.STO 11-10-86 and W.STO 1-16-87 (respectively)
Stated Purity: 98.7% and 97.0% (respectively)
Date Received: 11/11/86 and 1/16/87 (respectively)
Description at Receipt: Light yellow liquid
Source: Monsanto Agricultural Company

Animals

Species: Albino rat
Strain: Sprague-Dawley
Source: Charles River Breeding Laboratory, Portage, MI
Date of Arrival at EHL: November 4, 1986

Number of Adults Used in Studies:
Male Fertility: 300 (100 males, 200 females)
Female Reproduction: 240 (120 males, 120 females)
Test Group Size:
Male Fertility: 25 males, 50 females
Female Reproduction: 30/sex

Method of Assignment: Computer randomization by weight
Method of Identification: Individual eartag, bar-coded cage card

Age at Study Start: 6 weeks
Weight Range at Study Start: Males - 171 to 214 grams
Females - 120 to 185 grams

Type of Housing:
Premating - Individual suspended stainless steel cages over paper bedding. Animals receiving inhalation exposures were housed in all wire cages.
During Mating - Female housed in male's cage
Birth/Lactation - From gestation Day 20 through lactation, females were housed in double-wide cages with solid bottoms and wood shaving bedding.

Water Availability: ad libitum (St. Louis public water supply, conditioned by an ion exchange water softener using sodium zeolite) except during inhalation exposures
Food Availability: Purina RODENT CHOW (5002) ad libitum except during inhalation exposures
Light Cycle: 12 hours daily (on at 6:30 a.m.)
Animal Room Environmental Specifications:
Temperature - 70 to 74 degrees F
Relative Humidity - 35 to 60%
There were no excursions in animal room environmental conditions which had any obvious impact on the results of the study.

Exposure System

Exposure Chamber: Ten cubic meter New York University style stainless steel chambers with pyramidal tops and bottoms (Figure 1)

Test Atmosphere Generation: Test material was metered from a syringe drive through a capillary tube into a Laskin-style nebulizer (1) located in the top of the chamber (Figure 2). The concentration of the test material in the inhalation chamber was controlled by regulating the speed of the pump drive and, consequently, the flowrate of the test material into the nebulizer.

Chamber Airflow, Temperature, Pressure, Relative Humidity: Monitored continuously and recorded approximately every 30 minutes

Animal Placement During Exposure: Animals were positioned on the middle rows of the cage racks. They were rotated weekly through the cage positions.

Procedures for Monitoring Test Material in the Chambers

Nominal Concentration: Routinely calculated once per exposure by determining the total amount of test material delivered to the chamber and dividing this amount by the total air volume passing through the chamber

Test Chamber Analytical Sampling: Routinely sampled at least four times during each exposure

Control Chamber Analytical Sampling: Checked for the presence of test material once during the first week and approximately once every two weeks thereafter

Test Material Sampling Method: Test atmosphere was drawn through an impinger containing iso-octane

Formaldehyde Sampling Method: Measured with Draeger tubes daily and determined analytically on 2 consecutive study days. Analytical samples were obtained by drawing test atmosphere through an impinger containing iso-octane and N-benzyl-ethanolamine.

Sampling Location: Port halfway down on chamber door

Analytical Method: Gas chromatography (test material/Appendix 1, Exhibit 1; formaldehyde/Appendix 1, Exhibit 1A)

Uniformity of Distribution: Determined by analyzing the chamber atmosphere at non-routine sampling sites

Chambers Sampled: All exposure chambers

Frequency: Once during the first two weeks and once during the final two weeks of the study

In-Life Observations

The following observations were performed on animals in both studies:

Checks for Mortality and Moribundity: Twice daily

During Exposure Observations: Performed between second and fifth hour of exposure. Percentage estimates of observable animals exhibiting signs of toxicity were recorded

After Exposure Observations: Immediately after each exposure

Additional observations were made on animals in certain studies and are listed below:

Male Fertility Study:

Body Weights/Detailed Observations:
Males - Once a week
Females - Once during the week preceding cohousing

Female Reproduction Study:

FO Body Weights/Detailed Observations:
Males - Once during the week preceding cohousing
Females - Once a week until copulation confirmed or until sacrifice, then on gestation Days 0 (day copulation confirmed), 6, 13, 20, and lactation Days 0 (day delivery completed), 4, 7, 14 and 21

Litter Observations: Pups were examined for the presence of external abnormalities on lactation Days 0, 4, 7, 14 and 21. On Day 4, litters were culled to 8 pups, 4 of each sex when possible. Total litter weights were determined by sex on Days 0, 4 (pre- and post-culling), 7, and 14 of lactation. Individual weights were obtained on lactation Day 21.

Mating of Animals

Cohousing Schedule - Male Fertility Study:

Initiation of Cohousing: After approximately 11 weeks of exposures, two days after last previous exposure
Age at Initiation of Cohousing: Approximately 18 weeks
Length of Cohousing Periods: Each male was cohoused with one unexposed female until copulation was confirmed or 7 days elapsed (first mating set). Immediately after copulation or 7 unsuccessful cohousing days, each male was cohoused with a second untreated female until copulation was confirmed or 7 days elapsed (second mating set).

Cohousing Schedule - Female Reproduction Study:

Initiation of Cohousing: After approximately 11 weeks of exposures, two days after last previous exposure
Age at Initiation of Cohousing: Approximately 18 weeks
Length of Cohousing Periods: Each female was cohoused with one unexposed male until copulation was confirmed or 7 days elapsed. If copulation was not confirmed, the female was cohoused with another untreated male (proven breeder) for up to 7 additional days.

Determination of Confirmed Copulation - Both Studies:

The area under the cages of cohoused animals was examined each morning for the presence of copulatory plugs. If the location of a plug was ambiguous, a vaginal smear was obtained from the nearby female(s) and examined for the presence of sperm. All remaining females with unconfirmed copulation were examined for the presence of a vaginal copulatory plug. The observation of a copulatory plug or sperm constituted confirmed copulation.

Pathology

Examination of Animals - Male Fertility Study:

Time of Scheduled Termination:
Males - Terminated 2 weeks after the mating period
Females - Those with confirmed copulation were terminated on gestation Day 13 or the next normal working day. Females without confirmed copulation were terminated in the second week after cohousing ended.

Extent of Examination:
Males - None
Females - Fertility assessment on all females, gross necropsy on non-pregnant females.

Examination of Animals - Female Reproduction Study:

Time of Scheduled Termination:
F0 Males - Terminated after the mating period
F0 Females - Females with litters were terminated on lactation Day 21. Non-delivering females were terminated in the week after their expected delivery. Females without confirmed copulation were sacrificed within 2 weeks after the last night of cohousing.
F1 Animals - Lactation Day 21

Extent of Examination:
F0 Males - None
F0 Females - Gross necropsy
F1 Animals Found Dead - Gross necropsy. Lungs and stomachs of pups found dead on lactation Day 0 were examined to determine if breathing/feeding had occurred. This was done to determine if the pups were born alive or dead.
F1 Animals at Scheduled Termination - Given gross necropsy (all animals), and tissues were obtained from 10 animals/sex/level. Tissues from control and high level animals were examined microscopically.

Necropsy Procedures:

Gross Necropsy: Internal and external. Internal cavities (abdominal, thoracic, cranial and scrotal) were opened and the following tissues and organs were removed and fixed from selected F1 animals.

abdominal aorta
adrenals
bone and bone marrow (femur)
brain (longitudinal section)
diaphragm
esophagus
eyes with optic nerve
gonads
  ovaries
  testes with epididymides
heart
intestine
  duodenum
  colon
  ileum
kidneys (2)
liver (2 sections)
lung (2 sections, at least 2 lobes and mainstem bronchi)
lymph nodes
  mesenteric
  thymic
mammary gland
nasal passages (3 sections)
pancreas
pituitary
prostate
salivary gland (submaxillary)
sciatic nerve
seminal vesicle
skeletal muscle
skin
spinal cord
spleen
stomach (longitudinal section)
thymus
trachea
thyroid/parathyroid
urinary bladder
uterus (including the cervix)
vagina
gross lesions (if determined to be treatment-related by the pathologist)

Fertility Assessment: Uteri were examined to determine pregnancy status. The following determinations were made in pregnant animals: the number and status (live vs. dead) of implants, and the number of corpora lutea.

Histopathology Procedures:

Fixative: Eyes - glutaraldehyde in 10% neutral buffered formalin
All other tissues - 10% neutral buffered formalin

Tissue Preparation: Fixed tissues (above) scheduled for microscopic examination were washed, dehydrated, embedded in paraffin, sectioned at approximately 5 microns, and stained with hematoxylin and eosin

Examination: Light microscopy

Statistics

The following statistical procedures were used to detect statistically significant differences between treated animals and their respective controls:

Dunnett's Multiple Comparison Test (2): adult body weights, pups weights (mean litter weights)

Mann-Whitney Test (3): numbers of live, dead, and total implants, and corpora lutea (expressed per pregnant female); numbers of live and dead implants (expressed per corpora lutea per pregnant female); pre- and postimplantation losses

Mann-Whitney Test with Bonferroni Inequality Procedure (4): precoital and gestational lengths, pup survival (when sample size $\geq$ 20)

Fisher's Exact Test with Bonferroni Inequality Procedure (5): incidence of microscopic lesions

Uncorrected Chi-square Test (6) with Bonferroni Inequality Procedure and Fisher's Exact Test with Bonferroni Inequality Procedure: pregnancy and fertility indices

Chi-square test: mating index, numbers of females with $\geq$ 1 and $\geq$ 2 dead implants

Other statistical routines used for some data were:

Bartlett's Test to evaluate homogeneity of variances, Analysis of Variance to determine if the sample (group) means could be considered as an estimate of a common population, and Grubb's Test (7) to detect outliers

RESULTS - CHAMBER ATMOSPHERE ANALYSIS

Test material stability was monitored during the study and was found to be acceptable. A discussion of the stability assessment is given in Appendix 1, Exhibit 3.

Mean nominal and analytical values for the three exposure levels of 2,6-diethylphenyl azomethine over the entire study period were:

Study	Concentration (mg/cubic meter)		
Level (target)	Low (2.5)	Mid (15)	High (50)
86126 - Male Fertility			
Nominal (N)	4.0	24	112
Analytical (A)	2.6	14	50
N/A Ratio	1.5	1.7	2.2

(Continued on following page)

Study	Concentration (mg/cubic meter)		
Level (target)	Low (2.5)	Mid (15)	High (50)
86127 - Female Reproduction			
Nominal (N)	4.0	23	110
Analytical (A)	2.6	14	51
N/A Ratio	1.5	1.6	2.2

Daily individual and mean analytical chamber concentration data are presented in Appendix 1, Exhibit 3, Tables 1 and 2, respectively. Study mean analytical chamber concentrations are given in Appendix 1, Exhibit 3, Tables 3 and 4. Daily and mean nominal concentrations are given in Appendix 1, Exhibit 4, Tables 1 and 2.

Formaldehyde, a product of test material breakdown, was detected in the exposure chambers throughout the studies using semi-quantitative Draeger tube analysis and was determined analytically on 2 consecutive study days. Draeger tube determinations (means) for the low, mid, and high levels were 1, 5, and greater than 10 mg/cubic meter in air of formaldehyde. Analytical determinations (averages) were 1.6, 7.9 and 31 mg/cubic meter in air of formaldehyde, respectively (Appendix 1, Exhibit 3, Table 9).

Distribution of Test Material in Test Chambers

The distribution of the test material in the exposure chambers was determined during the course of the study and was found to be acceptable. Chamber distribution data is presented in Appendix 1, Exhibit 5.

Chamber Environmental Conditions

A summary of chamber environmental conditions for both studies can be found in Appendix 1, Exhibit 6.

RESULTS - MALE FERTILITY STUDY (86126)

Inlife Observations

Some of the animals of the high level appeared not responsive during the exposures (Table 1, Text). Red/brown perinasal encrustation was seen frequently during the study in high level animals after exposure and is considered related to the irritant properties of the test material (Table 2, Text). There were no other clinical observations considered related to treatment (Appendix 2, Table 2). The mean body weight of high level animals was significantly reduced (approximately 6 to 13% from corresponding controls) throughout the study (Table 3, Text; Appendix 2, Table 1). The body weights of mid and low level males were not affected by exposure to test compound.

One control male died during the mating period. This death was apparently due to renal dysfunction (multiple, bilateral kidney calculi, and multiple urinary bladder calculi) (Table 4, Text). Animal termination history is presented in Appendix 4.

A summary of body weight data for females used in the fertility study is presented in Appendix 2, Table 3.

Mating and Fertility Results

There were no significant differences in any of the mating and fertility parameters measured (Table 5, Text; Appendix 2, Tables 4, 5, and 6) when treated groups were compared to the control group.

RESULTS - FEMALE REPRODUCTION STUDY (86127)

Inlife Observations

There were no deaths among animals exposed to the test material. During the exposure period some of the high level animals appeared not responsive to stimulation (ex., tapping on outside of chamber) (Table 6, Text). The most frequent sign recorded after exposure was red/brown perinasal encrustation which occurred in mid and high level animals (Table 7, Text). This sign is apparently due to the irritant properties of the test material. There were no clinical signs noted during the weekly observation period that could be related to test material exposure (Appendix 3, Table 2). There was a significant reduction (7 to 15%) in body weight compared to controls among the high level animals throughout the premating phase of the study (Table 8, Text; Appendix 3, Table 1). This difference is attributed to test material exposure. The body weights of mid and low level animals were unaffected by exposure to the test material.

A summary of body weight data for males used in the reproduction study is presented in Appendix 3, Table 3.

Mating, Fertility, Reproduction Results

There were no significant differences in the numbers of animals with confirmed copulation, the fertility and pregnancy indices (Table 9, Text; Appendix 3, Table 4), and litter mortality (Appendix 3, Tables 5-7). Gestational length (Appendix 3, Table 8) for high level animals was statistically shorter (2%); this minimal difference does not appear to be directly related to test material exposoure.

Gestation and Lactation Body Weights

Body weights of high level dams were significantly reduced during both the gestation (12 to 19%, Table 10, Text; Appendix 3, Table 9) and lactation period (9 to 18%, Table 11, Text; Appendix 3, Table 10). This difference is considered to be related to test material exposure and appears to be a continuation of the reduction seen during the premating phase of the study. F1, high level, pup weights were reduced from 2 to 9% (males) and from 5 to 13% (females) compared to controls during the lactation period (Tables 12-14, Text). These decreases were statistically different (Dunnett's Test) from control weights on Day 4, pre- and post-cull females; Day 7, females; and Days 0, and Day 4 pre-cull, combined sexes. At Day 21 the weight differences from controls were 3 and 6% for high level male and female pups, respectively. The high level pups weight differences were probably due to the decreased dam weights measured throughout the study and were not likely a direct effect of the test material on the offspring.

Gross and Microscopic Pathology

There were no gross abnormalities in the dams (Table 15, Text) or gross or microscopic pathological abnormalities in their weanlings (Tables 16 and 17, Text, respectively) that were considered related to exposure to the test material. Animal termination history is presented in Appendix 4.

REFERENCES

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SUPPLEMENTAL STUDY INFORMATION

Study Performed at: Environmental Health Laboratory (EHL)
645 S. Newstead Ave., St. Louis, MO 63110
Date Protocol Signed by Study Director: November 20, 1986
Date Protocol (Amended) Signed by Study Director: March 2, 1987
Date of Study Start: November 20, 1986
Date of Last Necropsy: April 8, 1987
Location of Study Protocol, Original Data, Tissue Specimens and Final Report: Environmental Health Laboratory Archives

Supervisory Personnel:

M. V. Roloff, Ph.D.
Inhalation Toxicology Consultant

M. W. Dietrich, Ph.D.
Group Leader, Analytical Chemistry

F. A. Ruecker, D.V.M., Dipl. A.C.V.P.
Manager, Pathology (Pathologist)

L. D. Stout, D.V.M., M.S.
Manager, Toxicology Studies

R. M. Folk, Ph.D.
Director, Environmental Health Laboratory

S&EH QUALITY ASSURANCE AUDIT STATEMENT

Study Number:	86126 and 86127 ML-86-360
Protocol Amendments:	One - March 2, 1987
Study Title:	Fertility and Reproduction Inhalation Studies with 2, 6-Diethylphenyl Azomethine in Sprague-Dawley Rats
Dates of Inspections and Communication of Findings:	November 19, 25, 1986 December 3, 1986 January 8, 21, 1987 February 19, 1987 March 3, 31, 1987 May 4, 1987 June 1, 10, 11, 12, 18, 1987 July 7, 16, 20, 21, 24, 27, 29, 1987 August 5, 10, 13, 1987 November 11, 1987 December 16, 1987
Quality Assurance Review Conducted by:	K. M. Blowers D. E. Brock S. M. Haag S. R. Lee B. M. Pappacena/Williamson C. K. Russell K. E. Segall M. L. Taff
Results:	The Quality Assurance review indicates the final report accurately presents the raw data as developed during the study. There appears to be no significant deviation from applicable GLP regulations that adversely affected study quality or integrity.

Gretchen F Uelner
Manager, Quality Assurance

DECEMBER 17, 1987
Date

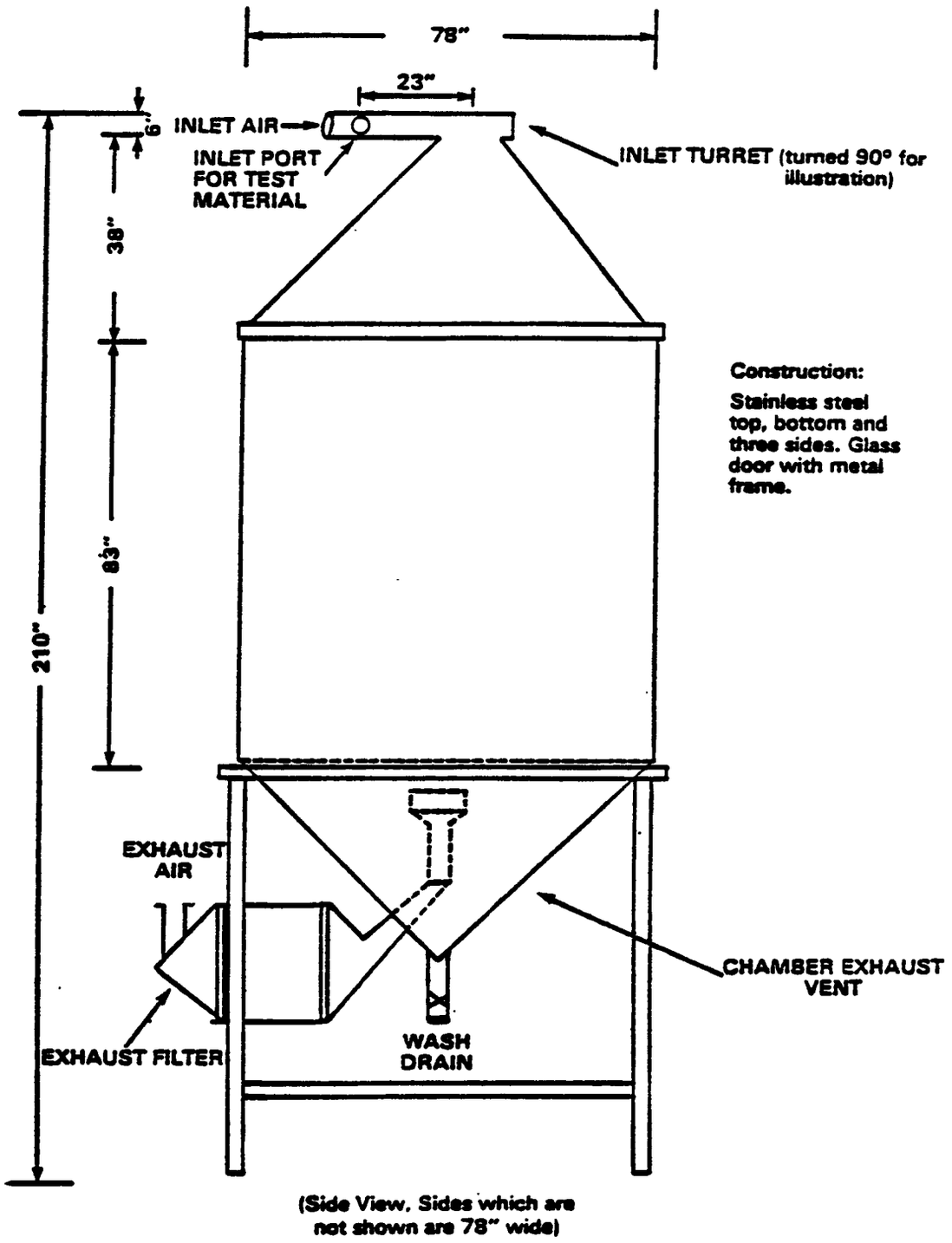
STATEMENT OF COMPLIANCE

To the best of our knowledge, studies EHL 86126 and EHL 87127 (ML-87-360) were conducted in general conformance with the Environmental Protection Agency Good Laboratory Practice Standards.

B. R. Dudek

Study Director

FIGURE 1. CHRONIC INHALATION CHAMBER



(Side View. Sides which are not shown are 78" wide)

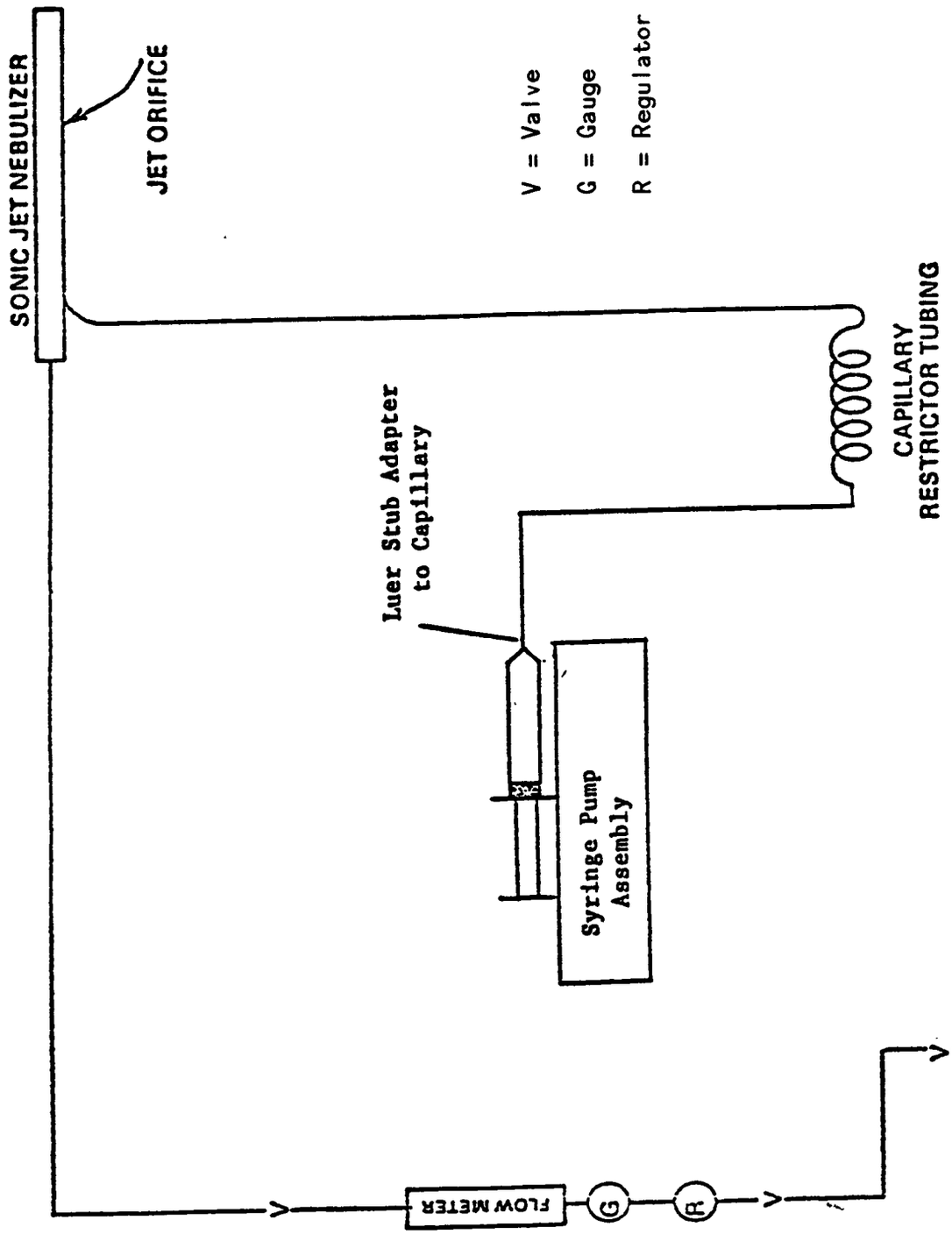


FIGURE 2

GENERATION SYSTEM

Table 1

EHL 86126 - SIGNS OF TOXICITY DURING EXPOSURE

EXPOSURE NO.	OBSERVATION			
	NOT RESPONSIVE			
	N	1	2	3
9-10, 12-21, 23-30, 32-33, 40-80				E
11				D
22, 31, 34-39				F

D = Approximately 51-75% of the animals observable have this effect.
E = Approximately 76-99% of the animals observable have this effect.
F = Approximately 100% of the animals observable have this efect.

Table 2

EHL 86126 - WEEKLY OCCURRENCES OF SIGNS OF TOXICITY

OBSERVED AFTER EXPOSURE

WEEK NO.	OBSERVATION			
	RED/BROWN PERINASAL ENCRUSTATION			
	MALES			
	N	1	2	3
3				4
4				7
5			1	7
6				14
7				5
8 - 10				6
11				7
12				8
13				9
14				12
15				10
16				11
17				12

	PERIORBITAL ENCRUSTATION			
	MALES			
	N	1	2	3
12 - 13		1		
15				1
17				1

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

Table 3

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

SEX: MALE

GROUP	TARGET DOSE	DATE (1986): DAY OF STUDY:	PRE-TEST	26-NOV 7	3-DEC 14	10-DEC 21	17-DEC 28	23-DEC 34	30-DEC 41	7-JAN 49
MN		MEAN	192.7	257.0	300.6	338.5	373.6	390.4	418.4	438.4
NEGATIVE CONTROL		STD. DEV.	10.39	13.45	16.13	19.71	22.68	26.46	30.33	34.10
		SAMPLE SIZE	25	25	25	25	25	25	25	25
M1	2.500 MG/M3	MEAN	192.9	255.9	301.5	334.7	372.0	393.4	421.9	447.4
TEST GROUP		STD. DEV.	10.83	15.57	18.57	28.98	23.58	24.30	27.00	29.07
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	25	25	25	25	25	25	25	25
M2	15.00 MG/M3	MEAN	192.9	252.1	291.7	326.9	361.5	377.5	402.8	425.8
TEST GROUP		STD. DEV.	10.65	15.52	18.70	21.83	25.94	27.46	30.61	31.15
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	25	25	25	25	25	25	25	25
M3	50.00 MG/M3	MEAN	192.8	243.2**	286.7*	314.4**	343.9**	358.0**	381.3**	399.2**
TEST GROUP		STD. DEV.	10.71	17.52	22.52	28.69	32.02	36.25	38.99	43.47
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	25	25	25	25	25	25	25	25

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .05$)
** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

SEX: MALE

GROUP	TARGET DOSE	DATE (1987): DAY OF STUDY:	14-JAN 56	21-JAN 63	28-JAN 70	4-FEB 77	11-FEB 84	18-FEB 91	25-FEB 98	4-MAR 105
MN		MEAN	453.1	464.0	479.8	493.5	504.3	511.0	522.0	532.5
NEGATIVE CONTROL		STD. DEV.	36.49	41.68	43.88	46.16	51.11	53.11	53.60	54.66
		SAMPLE SIZE	25	25	25	25	25	25	24	24
M1	2.500 MG/M3	MEAN	468.1	481.2	500.5	508.9	519.9	524.8	533.0	547.4
TEST GROUP		STD. DEV.	31.30	35.29	38.18	45.28	43.53	45.07	43.11	45.03
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	25	25	25	25	25	25	25	25
M2	15.00 MG/M3	MEAN	444.0	454.2	472.3	483.6	495.4	499.6	506.3	518.3
TEST GROUP		STD. DEV.	32.29	35.10	37.81	40.20	43.73	43.09	43.42	44.70
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	25	25	25	25	25	25	25	25
M3	50.00 MG/M3	MEAN	411.0**	421.5**	435.9**	444.0**	456.9**	459.1**	467.5**	474.4**
TEST GROUP		STD. DEV.	45.69	48.93	52.62	54.74	55.94	56.56	57.20	58.68
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	25	25	25	25	25	25	25	25

- - - L E G E N D - - -

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NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

SEX: MALE

GROUP	TARGET DOSE	DATE (1987): DAY OF STUDY:	11-MAR 112	18-MAR 119	25-MAR 126
MN		MEAN	540.8	545.1	559.4
NEGATIVE CONTROL		STD. DEV.	57.27	61.72	63.28
		SAMPLE SIZE	24	24	24
M1	2.500 MG/M3	MEAN	554.6	555.0	571.6
TEST GROUP		STD. DEV.	48.29	51.92	52.05
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	25	25	25
M2	15.00 MG/M3	MEAN	528.1	530.8	549.1
TEST GROUP		STD. DEV.	46.30	47.39	49.96
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	25	25	25
M3	50.00 MG/M3	MEAN	478.9**	480.9**	508.4**
TEST GROUP		STD. DEV.	60.26	63.84	60.55
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	25	25	25

- - - L E G E N D - - -

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** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 15-JUN-87

Table 4

STUDY NO: 86126 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
PATHOLOGY SECTION
STUDY TYPE: RE SPECIES: RAT SUBSTANCE: 2,6-DIETHYLPHENYL AZOMETHINE PRINTED: 24-AUG-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **

SELECTION CRITERIA: ALL DEATHS REPORTED
GENERATION FØ : ADULTS

	MALE			
	MN	M1	M2	M3
NO. IN GROUP AT RISK:	1	Ø	Ø	Ø
KIDNEY(S)				
-CALCULUS	1	Ø	Ø	Ø
-ENLARGED	1	Ø	Ø	Ø
URINARY BLADDER				
-CALCULUS	1	Ø	Ø	Ø
-ENLARGED/DILATED	1	Ø	Ø	Ø

Table 5

SUMMARY OF MATING, FERTILITY AND NIDATION DATA - 86126 - FØa

GENERATION: FØa	CONTROL	LOW	MID	HIGH
NUMBER CO-HOUSED	25	25	25	25
NUMBER WITH CONFIRMED COPULATION	2Ø	23	23	22
NUMBER PREGNANT	19	21	2Ø	21
FERTILITY INDEX (%)	76	84	8Ø	84
PREGNANCY INDEX (%)	95	91	87	95
IMPLANTS/DAM	14.8 (2.Ø)	14.Ø (4.1)	13.2 (4.4)	15.4 (2.2)
VIABLE EMBRYOS/DAM	14.2 (2.3)	13.1 (4.4)	12.6 (4.4)	14.Ø (2.2)
VIABLE EMBRYOS/ CORPORA LUTEA (%)	87 (14)	8Ø (25)	8Ø (26)	87 (1Ø)
RESORPTIONS/DAM	Ø.7 (Ø.9)	Ø.9 (1.3)	Ø.6 (Ø.8)	1.4 (1.5)
RESORPTIONS/CORPORA LUTEA (%)	4 (6)	5 (8)	4 (5)	8 (9)
CORPORA LUTEA/DAM	16.3 (1.7)	16.4 (2.1)	15.8 (1.9)	16.1 (2.Ø)
% PREIMPLANTATION LOSS	9 (12)	14 (23)	16 (27)	4 (6)
% POSTIMPLANTATION LOSS	5 (7)	1Ø (23)	5 (6)	9 (9)
DAMS WITH > 1 RESORPTION (%)	42	43	45	71
DAMS WITH > 2 RESORPTIONS (%)	21	19	15	29

VALUES EXPRESSED AS MEAN (S.D.)
SIGNIFICANTLY DIFFERENT FROM CONTROL VALUE: * p<Ø.Ø5, ** p<Ø.Ø1
FERTILITY INDEX = NO. PREGNANT/NO. CO-HOUSED; PREGNANCY INDEX = NO. PREGNANT/NO. WITH CONFIRMED COPULATION

SUMMARY OF MATING, FERTILITY AND NIDATION DATA - 86126 - FØb

GENERATION: FØb	CONTROL	LOW	MID	HIGH
NUMBER CO-HOUSED	25	25	25	25
NUMBER WITH CONFIRMED COPULATION	2Ø	22	25	24
NUMBER PREGNANT	2Ø	21	22	23
FERTILITY INDEX (%)	8Ø	84	88	92
PREGNANCY INDEX (%)	1ØØ	95	88	96
IMPLANTS/DAM	14.2 (2.4)	14.5 (2.4)	13.9 (1.6)	14.Ø (1.7)
VIABLE EMBRYOS/DAM	13.2 (2.5)	13.8 (2.3)	13.2 (1.7)	13.Ø (1.8)
VIABLE EMBRYOS/ CORPORA LUTEA (%)	85 (17)	91 (9)	84 (15)	89 (11)
RESORPTIONS/DAM	1.Ø (1.Ø)	Ø.7 (Ø.8)	Ø.7 (Ø.9)	1.Ø (1.3)
RESORPTIONS/CORPORA LUTEA (%)	6 (6)	5 (5)	4 (5)	6 (9)
CORPORA LUTEA/DAM	15.7 (2.5)	15.2 (2.3)	16.1 (2.6)	14.8 (1.5)
% PREIMPLANTATION LOSS	9 (14)	5 (8)	12 (15)	5 (8)
% POSTIMPLANTATION LOSS	7 (7)	5 (5)	5 (6)	7 (9)
DAMS WITH > 1 RESORPTION (%)	65	52	5Ø	61
DAMS WITH > 2 RESORPTIONS (%)	25	19	9	17

VALUES EXPRESSED AS MEAN (S.D.)
SIGNIFICANTLY DIFFERENT FROM CONTROL VALUE: * p<Ø.Ø5, ** p<Ø.Ø1
FERTILITY INDEX = NO. PREGNANT/NO. CO-HOUSED; PREGNANCY INDEX = NO. PREGNANT/NO. WITH CONFIRMED COPULATION

Table 6

EHL 86127 - SIGNS OF TOXICITY DURING EXPOSURE

EXPOSURE NO.	OBSERVATION			
	NOT RESPONSIVE			
	N	1	2	3
9-10, 12-21, 23-33, 35-37, 40-80				E
11				D
34, 38-39				F

D = Approximately 51-75% of the animals observable have this effect.
E = Approximately 76-99% of the animals observable have this effect.
F = Approximately 100% of the animals observable have this efect.

Table 7

EHL 86127 - WEEKLY OCCURRENCES OF SIGNS OF TOXICITY

OBSERVED AFTER EXPOSURE

WEEK NO.	OBSERVATION

RED/BROWN PERINASAL ENCRUSTATION

	FEMALES		
	N	1	2	3
2				3
3 - 4				10
5				15
6				13
7			2	9
8			2	11
9				8
10			1	9
11				8
12			2	11
13			2	11
14			3	16
15			3	16
16				14
17				1

PERIORBITAL ENCRUSTATION

	FEMALES		
	N	1	2	3
15				1

FOCAL LOSS OF HAIR

	FEMALES		
	N	1	2	3
5 - 6	1			

Table 8

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

SEX: FEMALE

GROUP	TARGET DOSE	DATE (1986): DAY OF STUDY:	PRE-TEST	26-NOV 7	3-DEC 14	10-DEC 21	17-DEC 28	23-DEC 34	30-DEC 41	7-JAN 49
FN		MEAN	152.0	193.8	216.4	232.6	248.6	261.8	276.6	286.4
NEGATIVE CONTROL		STD. DEV.	16.35	18.46	21.29	22.87	26.33	27.16	31.67	33.21
		SAMPLE SIZE	30	30	30	30	30	30	30	30
F1	2.500 MG/M3	MEAN	151.8	192.3	213.2	230.4	246.8	261.8	274.3	286.2
TEST GROUP		STD. DEV.	16.06	20.64	21.66	22.51	25.78	27.91	29.52	30.70
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	30	30	30	30	30	30	30	30
F2	15.00 MG/M3	MEAN	152.1	188.8	213.5	230.2	246.4	259.0	272.4	279.5
TEST GROUP		STD. DEV.	16.26	20.57	22.42	24.40	26.48	26.70	30.21	30.05
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	30	30	30	30	30	30	30	30
F3	50.00 MG/M3	MEAN	151.9	181.5*	202.1*	214.6*	230.5*	237.7**	251.2**	256.6**
TEST GROUP		STD. DEV.	15.89	19.86	22.65	26.48	23.08	24.07	25.99	25.68
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	30	30	30	30	30	30	30	30

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .05$)
** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

SEX: FEMALE

GROUP	TARGET DOSE	DATE (1987): DAY OF STUDY:	14-JAN 56	21-JAN 63	28-JAN 70	4-FEB 77	11-FEB 84	18-FEB 91	25-FEB 98	4-MAR 105
FN		MEAN	293.1	298.0	303.6	309.8	316.9	326.4	346.0	371.8NA
NEGATIVE CONTROL		STD. DEV.	33.77	37.92	38.18	38.17	40.81	40.60	56.38	70.53
		SAMPLE SIZE	30	30	30	30	30	11	5	4
F1	2.500 MG/M3	MEAN	291.9	296.7	302.7	305.8	310.3	308.9	283.4	286.5NA
TEST GROUP		STD. DEV.	31.28	32.48	33.17	33.55	35.71	39.30	0.00	0.00
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	30	30	30	30	30	12	1	1
F2	15.00 MG/M3	MEAN	291.4	295.1	302.9	305.2	312.6	323.8	334.7	0.0NA
TEST GROUP		STD. DEV.	30.72	32.62	36.82	36.65	37.44	46.14	0.00	0.00
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	30	30	30	30	30	10	1	0
F3	50.00 MG/M3	MEAN	262.4**	261.9**	266.1**	269.4**	277.3**	284.0	305.6	298.5NA
TEST GROUP		STD. DEV.	25.50	25.23	25.72	26.92	27.56	20.67	2.40	4.95
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	30	30	30	30	30	8	2	2

- - - L E G E N D - - -

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NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

Table 9

SUMMARY OF MATING, FERTILITY AND LITTER DATA - 86127

GENERATION: F0a	CONTROL	LOW	MID	HIGH
NUMBER CO-HOUSED	30	30	30	30
NUMBER WITH CONFIRMED COPULATION	28	29	30	28
NUMBER PREGNANT	21	24	26	23
FERTILITY INDEX (%)	70	80	87	77
PREGNANCY INDEX (%)	75	83	87	82
NUMBER OF LIVE PUPS				
DAY 0	10.8 (4.6)	13.0 (2.8)	12.4 (3.7)	13.4 (2.3)
DAY 4 (PRE-CULL)	10.8 (3.9)	12.7 (2.6)	12.2 (3.8)	13.0 (2.6)
DAY 7	7.4 (1.4)	8.0 (0.2)	7.5 (1.5)	8.0 (0.2)
DAY 14	7.4 (1.4)	8.0 (0.2)	7.5 (1.5)	8.0 (0.2)
DAY 21	7.3 (1.4)	7.9 (0.3)	7.5 (1.5)	8.0 (0.2)

VALUES EXPRESSED AS MEAN (S.D.)
SIGNIFICANTLY DIFFERENT FROM CONTROL VALUE: * $p<0.05$, ** $p<0.01$
FERTILITY INDEX = NO. PREGNANT/NO. CO-HOUSED; PREGNANCY INDEX = NO. PREGNANT/NO. WITH CONFIRMED COPULATION

Table 10

SUMMARY OF GESTATION BODY WEIGHTS - 86127

GROUP	PARAMETER	BODY WEIGHT MEANS (GMS) AND STANDARD ERRORS OF THE MEANS			
		GESTATION DAY 0	GESTATION DAY 6	GESTATION DAY 13	GESTATION DAY 20
N	MEAN	319.2	343.7	370.5	432.4
	S.E.M.	(10.2)	(10.9)	(11.8)	(12.3)
	NO. OF ANIMALS	19	19	19	19
1	MEAN	312.2	339.3	365.5	438.7
	S.E.M.	(6.6)	(7.5)	(8.0)	(10.1)
	NO. OF ANIMALS	24	24	24	24
2	MEAN	311.9	336.6	366.2	438.9
	S.E.M.	(7.2)	(8.1)	(9.1)	(11.5)
	NO. OF ANIMALS	26	26	26	26
3	MEAN	267.9**	291.5**	319.4**	384.0**
	S.E.M.	(5.8)	(6.3)	(6.9)	(8.1)
	NO. OF ANIMALS	23	23	23	23

* INDICATES P < .05 BY DUNNETT'S TEST (ONE-SIDED)
** INDICATES P < .01 BY DUNNETT'S TEST (ONE-SIDED)

Table 11

SUMMARY OF LACTATION BODY WEIGHTS - 86127

GROUP	PARAMETER	BODY WEIGHT MEANS (GMS) AND STANDARD ERRORS OF THE MEANS				
		LACTATION DAY 0	LACTATION DAY 4	LACTATION DAY 7	LACTATION DAY 14	LACTATION DAY 21
N	MEAN	351.9	351.7	356.4	370.6	353.5
	S.E.M.	(12.7)	(10.9)	(10.6)	(11.1)	(11.0)
	NO. OF ANIMALS	19	17	17	17	17
1	MEAN	343.8	357.5	360.7	367.1	346.7
	S.E.M.	(7.8)	(7.9)	(8.1)	(7.6)	(7.7)
	NO. OF ANIMALS	24	24	24	24	24
2	MEAN	344.8	351.5	356.7	363.6	345.9
	S.E.M.	(9.5)	(8.6)	(8.6)	(8.6)	(7.7)
	NO. OF ANIMALS	26	26	26	26	26
3	MEAN	298.9**	317.2*	325.1*	338.8*	321.2*
	S.E.M.	(6.9)	(7.4)	(7.0)	(6.8)	(6.5)
	NO. OF ANIMALS	23	22	22	22	22

* INDICATES P < .05 BY DUNNETT'S TEST (ONE-SIDED)
** INDICATES P < .01 BY DUNNETT'S TEST (ONE-SIDED)

Table 12

LITTER REPORT - STUDY 86127 - MALE PUPS

MALE PUPS DAM	FOUND DEAD	FOUND LIVE	TOTAL SURVIVING PRE CULL LAC. DAY 4	TOTAL SURVIVING POST CULL LAC. DAY 4	TOTAL SURVIVING LAC. DAY 7	TOTAL SURVIVING LAC. DAY 14	TOTAL SURVIVING LAC. DAY 21	MEAN LIVE PUP WEIGHTS (GM) PRE CULL LAC. DAY Ø	MEAN LIVE PUP WEIGHTS (GM) POST CULL LAC. DAY 4	MEAN LIVE PUP WEIGHTS (GM) LAC. DAY 7	MEAN LIVE PUP WEIGHTS (GM) LAC. DAY 14	MEAN LIVE PUP WEIGHTS (GM) MEAN (STD) LAC. DAY 21
FØa CONTROL												
NF001	Ø	11	6	4	4	4	4	5.2	7.1	6.9	11.7	27.7	45.5 (2.9)
NF002	Ø	7	Ø	Ø	Ø	Ø	Ø	6.1	----	----	----	----	---- (---)
NF003	Ø	2	2	2	2	2	2	6.5	11.4	11.4	18.2	38.5	65.4 (9.5)
NF004	Ø	8	8	4	4	4	4	6.9	11.4	11.3	18.1	38.3	61.Ø (2.2)
NF005	Ø	1	Ø	Ø	Ø	Ø	Ø	6.1	----	----	----	----	---- (---)
NF006	Ø	5	5	4	4	4	4	6.4	11.7	11.5	18.3	35.9	59.8 (3.Ø)
NF007	Ø	3	3	3	3	3	3	6.9	11.8	11.8	19.4	36.9	63.5 (4.6)
NF008	Ø	2	2	2	2	2	2	8.4	15.6	15.6	22.Ø	40.2	64.8 (3.2)
NF009	Ø	6	6	4	4	4	4	5.8	7.5	7.7	14.4	31.9	54.8 (2.Ø)
NF013	Ø	8	8	4	4	4	4	7.2	11.Ø	1Ø.5	18.8	38.6	59.1 (4.5)
NF014	Ø	11	11	4	4	4	4	6.4	11.1	11.3	19.6	4Ø.5	68.2 (3.7)
NF016	Ø	7	7	5	5	5	5	7.6	12.6	12.5	19.5	36.4	6Ø.4 (2.7)
NF017	Ø	2	2	2	2	2	2	7.3	12.7	12.7	2Ø.3	41.2	67.2 (3.4)
NF019	Ø	2	2	2	2	2	2	7.6	13.6	13.6	2Ø.1	35.8	59.9 (Ø.8)
NF020	Ø	11	11	6	6	6	6	6.3	8.5	8.4	13.7	29.8	49.3 (1.8)
NF023	Ø	2	2	2	2	2	2	6.4	11.Ø	11.Ø	17.6	34.2	56.Ø (Ø.1)
NF024	Ø	3	3	3	3	3	3	7.2	12.Ø	12.Ø	18.7	34.6	56.8 (1.2)
NF025	Ø	8	8	4	4	4	4	6.4	8.9	9.1	15.1	28.4	49.4 (4.Ø)
NF029	Ø	8	8	4	4	4	4	6.1	9.8	9.7	16.3	33.6	56.3 (1.1)
MEANS	Ø.Ø	5.6	5.5	3.5	3.5	3.5	3.5	6.7	11.Ø	11.Ø	17.7	35.4	58.7
STD	Ø.Ø	3.5	3.2	1.2	1.2	1.2	1.2	Ø.8	2.2	2.2	2.7	4.1	6.4
N	19	19	17	17	17	17	17	19	17	17	17	17	17

LITTER REPORT - STUDY 86127 - MALE PUPS (CONT)

MALE PUPS DAM	FOUND DEAD	FOUND LIVE	TOTAL SURVIVING PRE CULL LAC. DAY 4	TOTAL SURVIVING POST CULL LAC. DAY 4	7	14	21	MEAN LIVE PUP WEIGHTS (GM) PRE CULL LAC. DAY 0	MEAN LIVE PUP WEIGHTS (GM) POST CULL LAC. DAY 4	7	14	MEAN (STD) 21
F0a LOW												
1F002	0	6	6	4	4	4	4	5.9	9.4	9.3	14.9	30.9	50.7 (2.4)
1F003	0	9	9	4	4	4	4	6.9	11.7	11.7	19.9	41.6	66.8 (3.0)
1F004	0	6	6	4	4	4	4	6.8	11.1	11.1	17.4	34.4	57.7 (2.1)
1F005	1	7	7	4	4	4	4	6.6	10.6	10.9	19.8	39.8	67.4 (2.7)
1F006	0	10	10	4	4	4	4	7.2	10.3	9.6	15.7	34.7	58.3 (2.7)
1F007	0	9	8	4	4	4	4	6.1	9.5	9.5	15.4	34.8	57.4 (2.6)
1F008	0	7	5	4	4	4	3	5.8	9.3	9.6	15.9	34.3	55.1 (7.9)
1F009	0	5	4	4	4	4	4	7.2	11.9	11.9	19.4	39.2	66.6 (3.4)
1F011	0	11	11	4	4	4	4	6.2	9.2	9.3	15.0	34.0	56.5 (3.3)
1F012	0	6	6	4	4	4	4	6.6	10.8	10.8	16.2	33.9	53.9 (3.9)
1F013	0	6	6	4	4	4	4	5.2	8.5	8.4	14.3	31.0	49.4 (3.2)
1F014	0	5	5	4	4	4	4	6.4	10.7	10.7	18.2	39.9	64.4 (2.6)
1F015	0	4	4	4	4	4	4	5.8	10.0	10.0	14.6	29.1	49.5 (2.6)
1F018	0	5	5	4	4	4	4	8.0	12.2	12.1	20.3	40.2	68.0 (1.4)
1F019	0	10	10	4	4	4	4	7.5	11.9	11.8	20.4	43.2	68.8 (3.4)
1F022	0	8M	9	4	4	4	4	7.1	10.9	10.7	17.7	35.2	59.2 (2.5)
1F023	0	4	4	4	4	4	4	6.1	9.7	9.7	15.1	30.9	48.4 (2.1)
1F024	0	9	9	4	4	4	4	5.7	8.4	8.6	15.2	32.3	51.2 (3.5)
1F025	1	12	12	5	5	5	5	6.7	10.5	10.4	17.3	35.9	59.0 (4.6)
1F026	0	7	7	6	6	6	6	6.9	10.8	10.8	16.3	33.0	52.7 (3.7)
1F027	0	4	4	4	4	4	4	5.7	8.9	8.9	14.9	32.3	52.8 (3.9)
1F028	0	2	2	2	2	2	2	6.7	11.7	11.7	16.8	34.0	60.2 (0.6)
1F029	0	9	9	4	4	4	4	5.8	9.3	9.4	16.9	35.5	57.9 (1.6)
1F030	0	9	9	5	5	5	5	6.4	11.2	11.1	19.3	40.6	62.6 (5.0)
MEANS	0.1	7.0	7.0	4.1	4.1	4.1	4.0	6.5	10.3	10.3	17.0	35.4	58.1
STD	0.3	2.6	2.6	0.7	0.7	0.7	0.7	0.7	1.1	1.1	2.0	3.8	6.4
N	24	23	24	24	24	24	24	23	24	24	24	24	24

'M' : INDICATES MISSEXING OF PUPS. COUNT AND WEIGHT DATA EXCLUDED FROM SEPARATE SEX ANALYSES.

LITTER REPORT - STUDY 86127 - MALE PUPS (CONT)

MALE PUPS	FOUND		TOTAL SURVIVING					MEAN LIVE PUP WEIGHTS (GM)						
			PRE CULL	POST CULL				PRE CULL	POST CULL				MEAN (STD)	
DAM	DEAD	LIVE	LAC. DAY 4		7	14	21	LAC. DAY 0	4	7	14	21		
F0a MID														
2F001	0	4	4	4	4	4	4	6.8	11.6	11.6	17.1	34.0	55.7	(4.3)
2F002	0	6	6	4	4	4	4	8.1	13.4	13.5	22.0	41.5	70.2	(0.9)
2F003	0	6	6	4	4	4	4	6.4	9.9	10.3	16.2	34.3	58.3	(3.0)
2F005	0	8	8	4	4	4	4	6.6	9.2	9.3	15.2	34.9	56.7	(6.1)
2F006	0	6	6	4	4	4	4	6.4	10.9	10.7	18.0	37.6	63.4	(0.8)
2F007	0	4	4	4	4	4	4	6.9	10.8	10.8	17.5	35.9	53.6	(1.5)
2F008	0	7	7	4	4	4	4	6.8	10.3	10.3	17.0	34.5	56.5	(2.0)
2F009	0	6	6	4	4	4	4	7.1	11.7	11.7	18.5	36.4	60.4	(1.0)
2F010	0	6	6	4	4	4	4	6.7	11.5	11.5	19.5	37.7	57.7	(2.5)
2F011	0	12	12	6	6	6	6	6.9	10.6	10.6	17.9	40.0	65.5	(2.7)
2F012	0	8	8	4	4	4	4	7.2	11.7	11.4	20.1	40.9	66.7	(3.0)
2F013	0	5	5	4	4	4	4	5.6	8.4	8.1	12.9	30.8	48.0	(7.8)
2F014	1	2	2	2	2	2	2	5.9	9.3	9.3	15.7	32.2	54.6	(3.3)
2F015	0	7	7	4	4	4	4	6.5	9.5	9.4	15.9	35.7	56.4	(5.3)
2F016	0	5	5	4	4	4	4	6.4	9.0	8.9	14.5	30.0	51.6	(2.9)
2F017	0	5	4	4	4	4	4	7.6	14.6	14.6	24.2	45.7	72.2	(4.3)
2F018	0	4	4	4	4	4	4	8.1	14.7	14.7	22.4	44.0	71.9	(1.8)
2F020	0	8	8	4	4	4	4	6.7	10.0	10.1	16.0	32.6	54.1	(1.3)
2F021	0	6	3	3	3	3	3	5.7	11.9	11.9	16.7	33.0	49.8	(1.3)
2F022	0	8	8	4	4	4	4	5.5	8.9	9.3	14.6	30.0	48.0	(2.2)
2F024	0	1	1	1	1	1	1	7.7	13.8	13.8	20.8	38.0	62.6	(---)
2F025	0	9	9	4	4	4	4	6.3	8.8	9.2	15.7	34.3	58.3	(3.4)
2F026	0	9	9	4	4	4	4	6.1	9.8	9.2	15.9	33.5	56.8	(5.6)
2F027	0	5	5	4	4	4	4	6.2	10.2	10.4	17.3	35.8	57.4	(1.9)
2F029	0	0	0	0	0	0	0	----	----	----	----	----	----	(---)
2F030	0	9	9	4	4	4	4	6.4	10.0	9.9	17.0	36.8	58.1	(3.7)
MEANS	0.0	6.2	6.1	3.8	3.8	3.8	3.8	6.7	10.8	10.8	17.5	36.0	58.6	
STD	0.2	2.4	2.5	0.9	0.9	0.9	0.9	0.7	1.8	1.8	2.7	4.0	6.7	
N	26	25	25	25	25	25	25	25	25	25	25	25	25	

LITTER REPORT - STUDY 86127 - MALE PUPS (CONT)

MALE PUPS DAM	FOUND DEAD	FOUND LIVE	TOTAL SURVIVING PRE CULL LAC. DAY 4	TOTAL SURVIVING POST CULL LAC. DAY 4	7	14	21	MEAN LIVE PUP WEIGHTS (GM) PRE CULL LAC. DAY 0	PRE CULL LAC. DAY 4	POST CULL LAC. DAY 4	7	14	MEAN (STD) 21
F0a HIGH													
3F001	0	8	0	0	0	0	0	5.8	----	----	----	----	---- (---)
3F002	0	10	10	4	4	4	4	5.7	8.9	9.0	16.3	33.8	52.1 (2.6)
3F003	0	4	4	4	4	4	4	6.4	11.1	11.1	15.7	32.8	56.1 (1.8)
3F004	0	11	10	4	4	4	4	6.0	9.0	9.6	17.5	39.2	61.9 (2.7)
3F005	0	9	8	4	4	4	4	6.3	9.0	9.3	15.4	33.2	57.0 (2.7)
3F006	1	6	6	4	4	4	4	7.0	12.6	12.6	21.6	43.6	73.7 (3.2)
3F008	0	6	6	4	4	4	4	6.8	10.9	11.3	18.1	36.3	60.3 (1.8)
3F009	0	5	4	4	4	4	4	7.5	12.6	12.6	18.5	35.5	59.9 (1.1)
3F012	0	4	4	4	4	4	4	6.4	10.6	10.6	17.5	34.3	60.3 (1.5)
3F013	0	5	5	4	4	4	4	6.4	9.3	9.4	15.5	32.6	52.0 (2.3)
3F014	0	5	5	4	4	4	4	6.4	10.7	10.8	18.6	38.5	60.8 (2.0)
3F015	0	4	4	4	4	4	4	5.7	8.9	8.9	14.5	30.2	51.7 (5.0)
3F017	0	4	4	4	4	4	4	6.3	9.6	9.6	16.0	32.8	53.0 (4.1)
3F019	0	4	4	4	4	4	4	6.3	10.3	10.3	17.5	37.2	64.9 (4.2)
3F020	0	5	5	4	4	4	4	6.6	10.2	10.2	17.0	35.0	55.2 (1.4)
3F021	0	6	6	4	4	4	4	6.0	9.1	9.7	17.3	35.9	55.1 (1.7)
3F022	0	6	6	4	4	4	4	6.6	10.5	10.6	17.9	36.8	60.7 (2.4)
3F023	0	6	6	4	4	4	4	6.8	11.2	11.4	17.5	38.1	62.1 (7.0)
3F024	0	9	9	4	4	4	4	6.0	8.5	8.8	13.7	28.9	48.0 (7.4)
3F025	0	6	6	4	4	4	4	5.6	8.9	8.6	14.4	30.1	48.5 (7.8)
3F027	1	4	3	3	3	3	3	5.2	9.4	9.4	15.6	33.9	54.5 (1.8)
3F028	0	7	4	4	4	4	4	5.2	9.6	9.6	14.8	27.5	45.9 (3.2)
3F030	0	5	5	4	4	4	4	6.5	10.8	10.8	18.6	39.8	63.4 (2.6)
MEANS	0.1	6.0	5.6	4.0	4.0	4.0	4.0	6.2	10.1	10.2	16.8	34.8	57.1
STD	0.3	2.1	2.0	0.2	0.2	0.2	0.2	0.5	1.2	1.1	1.8	3.8	6.5
N	23	23	22	22	22	22	22	23	22	22	22	22	22

Table 13

LITTER REPORT - STUDY 86127 - FEMALE PUPS

FEMALE PUPS	FOUND		TOTAL SURVIVING					MEAN LIVE PUP WEIGHTS (GM)						
			PRE CULL	POST CULL				PRE CULL	POST CULL				MEAN (STD)	
DAM	DEAD	LIVE	LAC. DAY 4		7	14	21	LAC. DAY 0	4		7	14	21	
F0a CONTROL														
NF001	0	4	4	4	4	4	4	4.7	7.1	7.1	12.2	27.5	45.8	(1.4)
NF002	0	7	0	0	0	0	0	5.5	----	----	----	----	----	(---)
NF003	0	2	2	2	2	2	2	6.3	10.5	10.5	17.1	38.2	61.9	(7.1)
NF004	0	4	4	4	4	4	4	6.1	10.2	10.2	16.9	35.6	56.8	(5.2)
NF005	2	0	0	0	0	0	0	----	----	----	----	----	----	(---)
NF006	0	5	5	4	4	4	4	5.9	9.8	9.7	16.2	33.3	55.7	(1.1)
NF007	0	10	10	5	5	5	5	6.8	11.9	11.9	19.0	35.9	61.4	(1.5)
NF008	0	4	4	4	4	4	4	7.9	14.7	14.7	21.7	39.6	64.1	(1.2)
NF009	0	12	11	4	4	4	4	5.5	7.7	7.8	13.7	30.7	51.2	(3.4)
NF013	0	6	5	4	4	4	4	6.3	10.4	10.4	18.2	36.7	57.0	(3.9)
NF014	0	4	4	4	4	4	4	6.0	10.2	10.2	18.3	38.6	62.9	(2.5)
NF016	0	3	3	3	3	3	3	7.1	11.9	11.9	18.9	37.0	59.3	(1.2)
NF017	0	5	5	5	5	5	5	6.7	11.7	11.7	18.5	38.0	60.9	(2.4)
NF019	0	2	2	2	2	2	2	7.2	13.1	13.1	19.8	35.5	59.0	(0.8)
NF020	0	2	2	2	2	2	1	5.7	8.1	8.1	13.1	28.0	45.8	(---)
NF023	0	9	9	6	6	6	6	6.2	10.8	10.8	17.5	32.5	55.4	(1.5)
NF024	0	6	6	5	5	5	5	6.7	10.8	11.1	17.5	34.1	56.7	(2.7)
NF025	0	8	8	4	4	4	4	5.9	8.4	8.4	13.5	26.6	44.4	(6.8)
NF029	0	5	5	4	4	4	4	5.7	9.0	9.0	15.3	32.1	52.4	(4.1)
MEANS	0.1	5.4	5.2	3.9	3.9	3.9	3.8	6.2	10.4	10.4	16.9	34.1	55.9	
STD	0.5	2.8	2.8	1.1	1.1	1.1	1.2	0.7	2.0	2.0	2.6	4.0	6.1	
N	19	18	17	17	17	17	17	18	17	17	17	17	17	

FEMALE PUPS DAM	FOUND DEAD	FOUND LIVE	TOTAL SURVIVING PRE CULL LAC. DAY 4	TOTAL SURVIVING POST CULL LAC. DAY 4	TOTAL SURVIVING LAC. DAY 7	TOTAL SURVIVING LAC. DAY 14	TOTAL SURVIVING LAC. DAY 21	MEAN LIVE PUP WEIGHTS (GM) PRE CULL LAC. DAY Ø	MEAN LIVE PUP WEIGHTS (GM) POST CULL LAC. DAY 4	MEAN LIVE PUP WEIGHTS (GM) LAC. DAY 7	MEAN LIVE PUP WEIGHTS (GM) LAC. DAY 14	MEAN LIVE PUP WEIGHTS (GM) MEAN (STD) LAC. DAY 21
F0a LOW												
1F002	0	5	5	4	4	4	4	5.5	8.7	8.7	14.1	29.4	48.1 (1.5)
1F003	0	5	5	4	4	4	4	6.5	10.6	10.3	17.8	38.4	61.4 (3.1)
1F004	0	5	5	4	4	4	4	6.4	10.7	11.1	17.5	32.8	54.9 (3.4)
1F005	0	8	7	4	4	4	4	6.3	9.7	9.7	17.8	36.3	60.1 (3.5)
1F006	1	6	6	4	4	4	4	7.0	9.1	9.0	15.1	32.4	54.8 (3.6)
1F007	0	7	7	4	4	4	4	6.0	9.2	9.4	15.4	34.5	55.1 (3.0)
1F008	0	7	7	4	4	4	4	5.7	9.8	9.9	16.9	34.8	59.4 (2.1)
1F009	0	5	5	4	4	4	4	6.6	11.5	11.4	18.4	36.7	59.3 (3.8)
1F011	0	7	6	4	4	4	4	5.6	7.7	7.9	12.6	30.6	51.4 (4.1)
1F012	0	7	7	4	4	4	4	6.1	9.9	9.6	14.1	31.4	50.0 (1.0)
1F013	0	7	6	4	4	4	4	5.0	8.4	8.4	14.1	30.6	48.8 (2.8)
1F014	0	11	11	4	4	4	4	6.1	9.7	9.2	16.4	37.7	59.8 (3.0)
1F015	0	4	4	4	4	4	4	5.4	9.6	9.6	14.0	27.9	45.8 (2.5)
1F018	0	8	8	4	4	4	4	7.3	10.9	10.9	18.9	38.2	63.0 (2.2)
1F019	0	5	5	4	4	4	4	6.9	11.2	11.1	19.4	40.2	63.8 (2.5)
1F022	0	5M	4	4	4	4	4	6.9	10.2	10.2	16.2	32.1	54.2 (4.9)
1F023	0	7	7	4	4	4	4	6.0	9.5	9.5	14.9	30.3	48.1 (2.9)
1F024	0	4	4	4	4	4	4	5.1	7.7	7.7	13.9	29.3	46.6 (3.3)
1F025	1	4	3	3	3	3	3	6.0	10.3	10.3	16.9	36.4	58.4 (3.2)
1F026	0	2	2	2	2	2	2	6.6	10.9	10.9	16.2	32.9	52.0 (2.9)
1F027	0	10	10	4	4	4	4	5.4	8.3	8.4	14.1	30.5	49.9 (1.0)
1F028	0	5	5	5	5	5	5	6.7	11.2	11.2	17.1	33.6	57.5 (2.3)
1F029	0	6	6	4	4	4	4	5.4	8.8	8.7	15.8	33.2	53.1 (1.4)
1F030	0	3	3	3	3	3	3	6.1	10.8	10.8	18.8	39.0	61.4 (4.0)
MEANS	0.1	6.0	5.8	3.9	3.9	3.9	3.9	6.1	9.8	9.8	16.1	33.7	54.9
STD	0.3	2.1	2.1	0.5	0.5	0.5	0.5	0.6	1.1	1.1	1.9	3.5	5.5
N	24	23	24	24	24	24	24	23	24	24	24	24	24

'M' : INDICATES MISSEXING OF PUPS. COUNT AND WEIGHT DATA EXCLUDED FROM SEPARATE SEX ANALYSES.

LITTER REPORT - STUDY 86127 - FEMALE PUPS (CONT)

FEMALE PUPS	FOUND		TOTAL SURVIVING					MEAN LIVE PUP WEIGHTS (GM)						
			PRE CULL	POST CULL				PRE CULL	POST CULL				MEAN (STD)	
DAM	DEAD	LIVE	LAC. DAY 4		7	14	21	LAC. DAY 0	4	7	14	21		
FØa MID														
2F001	Ø	2	2	2	2	2	2	6.8	11.7	11.7	17.3	33.2	56.Ø	(3.3)
2F002	Ø	6	6	4	4	4	4	7.6	12.7	12.5	2Ø.3	38.6	63.6	(1.Ø)
2F003	Ø	11	11	4	4	4	4	6.Ø	8.9	9.1	14.5	3Ø.2	52.1	(6.5)
2F005	Ø	8	8	4	4	4	4	6.2	8.6	9.Ø	14.9	34.8	56.4	(3.Ø)
2F006	Ø	7	7	4	4	4	4	6.Ø	1Ø.6	1Ø.4	18.Ø	36.8	6Ø.7	(4.Ø)
2F007	Ø	8	8	4	4	4	4	6.6	1Ø.8	1Ø.6	17.3	35.9	54.4	(2.Ø)
2F008	Ø	6	6	4	4	4	4	6.2	9.2	9.3	15.3	32.Ø	51.6	(2.Ø)
2F009	1	4	4	4	4	4	4	6.4	1Ø.6	1Ø.6	16.9	33.Ø	54.3	(4.Ø)
2F010	Ø	6	6	4	4	4	4	6.5	11.2	11.2	18.9	36.9	57.9	(2.Ø)
2F011	Ø	2	2	2	2	2	2	6.6	1Ø.3	1Ø.3	17.6	37.5	63.1	(2.1)
2F012	1	6	6	4	4	4	4	6.6	1Ø.8	11.1	19.4	39.8	65.5	(3.Ø)
2F013	Ø	9	8	4	4	4	4	5.5	8.6	8.3	12.7	3Ø.9	49.2	(6.Ø)
2F014	Ø	12	12	6	6	6	6	5.5	8.5	8.9	14.8	31.1	5Ø.2	(2.7)
2F015	Ø	7	7	4	4	4	4	6.Ø	8.6	8.3	14.Ø	32.3	49.7	(4.8)
2F016	1	1Ø	1Ø	4	4	4	4	6.2	8.7	8.9	14.9	31.2	52.Ø	(1.8)
2F017	Ø	9	9	4	4	4	4	7.1	13.1	13.1	21.5	42.2	68.7	(1.9)
2F018	Ø	5	5	4	4	4	4	8.1	14.8	14.9	22.7	44.5	73.9	(6.Ø)
2F020	Ø	5	5	4	4	4	4	6.3	1Ø.1	9.8	15.2	3Ø.6	51.Ø	(3.Ø)
2F021	Ø	3	3	3	3	3	3	6.4	1Ø.9	1Ø.9	16.6	31.1	47.6	(2.2)
2F022	Ø	6	6	4	4	4	4	5.3	8.5	9.1	14.4	3Ø.8	47.8	(1.2)
2F024	Ø	5	5	5	5	5	5	6.5	12.Ø	12.Ø	17.8	34.7	58.Ø	(1.5)
2F025	Ø	8	8	4	4	4	4	5.7	7.5	7.6	13.1	29.9	51.3	(4.2)
2F026	Ø	4	4	4	4	4	4	5.3	9.1	9.1	15.4	32.4	53.8	(3.9)
2F027	Ø	1Ø	1Ø	4	4	4	4	6.Ø	9.9	9.9	16.1	33.3	54.5	(2.7)
2F029	Ø	1	1	1	1	1	1	6.4	1Ø.8	1Ø.8	16.2	35.9	59.2	(---)
2F030	1	7	6	4	4	4	4	5.6	9.4	9.7	16.6	35.8	56.8	(3.6)
MEANS	Ø.2	6.4	6.3	3.8	3.8	3.8	3.8	6.3	1Ø.2	1Ø.3	16.6	34.4	56.1	
STD	Ø.4	2.8	2.8	Ø.9	Ø.9	Ø.9	Ø.9	Ø.6	1.7	1.7	2.5	3.8	6.6	
N	26	26	26	26	26	26	26	26	26	26	26	26	26	

LITTER REPORT - STUDY 86127 - FEMALE PUPS (CONT)

FEMALE PUPS	FOUND		TOTAL SURVIVING					MEAN LIVE PUP WEIGHTS (GM)						
			PRE CULL	POST CULL				PRE CULL	POST CULL			MEAN (STD)		
DAM	DEAD	LIVE	LAC. DAY 4		7	14	21	LAC. DAY Ø	4	7	14	21		
F0a HIGH														
3F001	Ø	6	Ø	Ø	Ø	Ø	Ø	5.7	----	----	----	----	----	(---)
3F002	Ø	6	6	4	4	4	4	5.3	8.1	8.4	15.1	31.6	48.1	(Ø.9)
3F003	Ø	3	3	3	3	3	3	5.2	8.2	8.2	11.9	26.Ø	44.5	(6.8)
3F004	Ø	7	7	4	4	4	4	5.6	8.Ø	8.1	14.7	35.1	56.Ø	(1.5)
3F005	1	4	4	4	4	4	4	6.1	8.6	8.6	14.5	31.6	54.4	(1.3)
3F006	Ø	8	8	4	4	4	4	6.6	11.8	11.6	20.2	40.8	69.Ø	(5.5)
3F008	Ø	7	7	4	4	4	4	6.4	10.7	10.6	17.Ø	35.Ø	56.2	(3.Ø)
3F009	Ø	6	6	4	4	4	4	6.7	11.3	11.Ø	16.8	34.2	56.2	(2.8)
3F012	Ø	8	8	4	4	4	4	6.3	10.3	10.1	17.Ø	34.Ø	59.6	(1.4)
3F013	Ø	11	11	4	4	4	4	5.8	8.8	9.Ø	15.1	32.5	51.6	(1.4)
3F014	Ø	8	8	4	4	4	4	5.6	9.8	10.3	17.8	37.1	57.9	(2.4)
3F015	Ø	7	7	4	4	4	4	5.6	8.6	8.6	14.1	29.Ø	49.9	(1.2)
3F017	Ø	11	11	4	4	4	4	5.7	8.5	8.6	14.4	30.4	49.3	(3.Ø)
3F019	Ø	11	11	4	4	4	4	5.9	9.2	9.8	16.5	35.3	60.Ø	(1.4)
3F020	Ø	7	7	4	4	4	4	6.4	10.2	10.Ø	16.9	34.7	56.9	(1.3)
3F021	Ø	9	9	4	4	4	4	5.5	8.2	8.4	14.1	31.6	47.7	(3.7)
3F022	Ø	7	7	4	4	4	4	6.3	9.9	9.6	16.3	33.7	53.7	(5.9)
3F023	Ø	9	9	4	4	4	4	6.Ø	9.8	9.5	14.4	32.3	52.5	(9.Ø)
3F024	Ø	5	5	4	4	4	4	5.7	8.2	8.2	12.4	26.6	43.3	(2.8)
3F025	Ø	8	8	4	4	4	4	5.1	8.1	7.8	13.4	29.6	47.2	(5.6)
3F027	Ø	7	7	5	5	5	5	5.Ø	8.9	8.5	14.3	31.9	50.5	(2.1)
3F028	Ø	5	4	4	4	4	4	5.Ø	8.8	8.8	12.Ø	25.1	41.5	(6.8)
3F030	Ø	9	9	4	4	4	4	6.1	9.9	9.5	16.9	37.Ø	56.2	(3.2)
MEANS	Ø.Ø	7.3	7.4	4.Ø	4.Ø	4.Ø	4.Ø	5.8	9.3*	9.2*	15.3*	32.5	52.8	
STD	Ø.2	2.1	2.2	Ø.3	Ø.3	Ø.3	Ø.3	Ø.5	1.1	1.Ø	2.Ø	3.8	6.3	
N	23	23	22	22	22	22	22	23	22	22	22	22	22	

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .05$)

Table 14

LITTER REPORT - STUDY 86127 - MALE AND FEMALE PUPS COMBINED

MALE AND FEMALE PUPS COMBINED	FOUND		TOTAL SURVIVING					MEAN LIVE PUP WEIGHTS (GM)						
			PRE CULL	POST CULL				PRE CULL	POST CULL				MEAN (STD)	
DAM	DEAD	LIVE	LAC. DAY 4		7	14	21	LAC. DAY 0	4	7	14	21		
F0a CONTROL														
NF001	0	15	10	8	8	8	8	5.0	7.1	7.0	12.0	27.6	45.6	(2.1)
NF002	0	14	0	0	0	0	0	5.8	----	----	----	----	----	(---)
NF003	0	4	4	4	4	4	4	6.4	11.0	11.0	17.7	38.3	63.6	(7.2)
NF004	0	12	12	8	8	8	8	6.6	11.0	10.7	17.5	36.9	58.9	(4.3)
NF005	2	1	0	0	0	0	0	6.1	----	----	----	----	----	(---)
NF006	0	10	10	8	8	8	8	6.1	10.8	10.6	17.2	34.6	57.7	(3.0)
NF007	0	13	13	8	8	8	8	6.8	11.8	11.9	19.1	36.3	62.2	(2.9)
NF008	0	6	6	6	6	6	6	8.1	15.0	15.0	21.8	39.8	64.4	(1.8)
NF009	0	18	17	8	8	8	8	5.6	7.6	7.8	14.0	31.3	53.0	(3.3)
NF013	0	14	13	8	8	8	8	6.8	10.7	10.5	18.5	37.7	58.1	(4.1)
NF014	0	15	15	8	8	8	8	6.3	10.8	10.8	19.0	39.5	65.5	(4.1)
NF016	0	10	10	8	8	8	8	7.4	12.4	12.3	19.3	36.7	60.0	(2.2)
NF017	0	7	7	7	7	7	7	6.9	12.0	12.0	19.0	38.9	62.7	(3.9)
NF019	0	4	4	4	4	4	4	7.4	13.4	13.4	20.0	35.7	59.4	(0.8)
NF020	0	13	13	8	8	8	7	6.2	8.5	8.4	13.6	29.3	48.8	(2.1)
NF023	0	11	11	8	8	8	8	6.2	10.8	10.9	17.5	33.0	55.6	(1.3)
NF024	0	9	9	8	8	8	8	6.8	11.2	11.4	18.0	34.3	56.7	(2.1)
NF025	0	16	16	8	8	8	8	6.1	8.6	8.7	14.3	27.5	46.9	(5.8)
NF029	0	13	13	8	8	8	8	5.9	9.5	9.4	15.8	32.9	54.3	(3.5)
MEANS	0.1	10.8	10.8	7.4	7.4	7.4	7.3	6.5	10.7	10.7	17.3	34.7	57.3	
STD	0.5	4.6	3.9	1.4	1.4	1.4	1.4	0.7	2.0	2.0	2.6	4.0	6.0	
N	19	19	17	17	17	17	17	19	17	17	17	17	17	

LITTER REPORT - STUDY 86127 - MALE AND FEMALE PUPS COMBINED (CONT)

MALE AND FEMALE PUPS COMBINED	FOUND		TOTAL SURVIVING					MEAN LIVE PUP WEIGHTS (GM)						
			PRE CULL	POST CULL				PRE CULL	POST CULL			MEAN (STD)		
DAM	DEAD	LIVE	LAC. DAY 4		7	14	21	LAC. DAY Ø	4	7	14	21		
F0a														
LOW														
1F002	Ø	11	11	8	8	8	8	5.7	9.1	9.0	14.5	30.1	49.4	(2.3)
1F003	Ø	14	14	8	8	8	8	6.8	11.3	11.0	18.9	40.0	64.1	(4.0)
1F004	Ø	11	11	8	8	8	8	6.6	10.9	11.1	17.5	33.6	56.3	(3.0)
1F005	1	15	14	8	8	8	8	6.4	10.2	10.3	18.8	38.0	63.8	(4.9)
1F006	1	16	16	8	8	8	8	7.1	9.8	9.3	15.4	33.5	56.6	(3.5)
1F007	Ø	16	15	8	8	8	8	6.1	9.4	9.5	15.4	34.7	56.3	(2.9)
1F008	Ø	14	12	8	8	8	7	5.8	9.6	9.8	16.4	34.6	57.6	(5.3)
1F009	Ø	10	9	8	8	8	8	6.9	11.7	11.7	18.9	37.9	62.9	(5.2)
1F011	Ø	18	17	8	8	8	8	6.0	8.7	8.6	13.8	32.3	54.0	(4.4)
1F012	Ø	13	13	8	8	8	8	6.3	10.3	10.2	15.2	32.6	51.9	(3.3)
1F013	Ø	13	12	8	8	8	8	5.1	8.4	8.4	14.2	30.8	49.1	(2.8)
1F014	Ø	16	16	8	8	8	8	6.2	10.0	10.0	17.3	38.8	62.1	(3.6)
1F015	Ø	8	8	8	8	8	8	5.6	9.8	9.8	14.3	28.5	47.7	(3.1)
1F018	Ø	13	13	8	8	8	8	7.6	11.4	11.5	19.6	39.2	65.5	(3.2)
1F019	Ø	15	15	8	8	8	8	7.3	11.7	11.4	19.9	41.7	66.3	(3.8)
1F022	Ø	13	13	8	8	8	8	7.0	10.7	10.4	16.9	33.7	56.7	(4.5)
1F023	Ø	11	11	8	8	8	8	6.0	9.6	9.6	15.0	30.6	48.3	(2.3)
1F024	Ø	13	13	8	8	8	8	5.5	8.2	8.2	14.5	30.8	48.9	(4.0)
1F025	2	16	15	8	8	8	8	6.5	10.5	10.4	17.2	36.1	58.8	(3.9)
1F026	Ø	9	9	8	8	8	8	6.9	10.8	10.8	16.3	33.0	52.5	(3.3)
1F027	Ø	14	14	8	8	8	8	5.5	8.4	8.7	14.5	31.4	51.3	(3.1)
1F028	Ø	7	7	7	7	7	7	6.7	11.4	11.4	17.0	33.7	58.3	(2.3)
1F029	Ø	15	15	8	8	8	8	5.6	9.1	9.1	16.3	34.3	55.5	(2.9)
1F030	Ø	12	12	8	8	8	8	6.4	11.1	11.0	19.1	40.0	62.1	(4.4)
MEANS	0.2	13.0	12.7	8.0	8.0	8.0	7.9	6.3	10.1	10.0	16.5	34.6	56.5	
STD	0.5	2.8	2.6	0.2	0.2	0.2	0.3	0.6	1.1	1.1	1.9	3.6	5.8	
N	24	24	24	24	24	24	24	24	24	24	24	24	24	

LITTER REPORT - STUDY 86127 - MALE AND FEMALE PUPS COMBINED (CONT)

MALE AND FEMALE PUPS COMBINED	FOUND		TOTAL SURVIVING					MEAN LIVE PUP WEIGHTS (GM)						
			PRE CULL	POST CULL				PRE CULL	POST CULL				MEAN (STD)	
DAM	DEAD	LIVE	LAC. DAY 4		7	14	21	LAC. DAY Ø	4	7	14	21		
F0a MID														
2F001	Ø	6	6	6	6	6	6	6.8	11.6	11.6	17.2	33.8	55.8	(3.6)
2F002	Ø	12	12	8	8	8	8	7.8	13.1	13.0	21.1	40.1	66.9	(3.6)
2F003	Ø	17	17	8	8	8	8	6.1	9.3	9.7	15.4	32.3	55.2	(5.7)
2F005	Ø	16	16	8	8	8	8	6.4	8.9	9.2	15.1	34.9	56.5	(4.5)
2F006	Ø	13	13	8	8	8	8	6.2	10.7	10.6	18.0	37.2	62.0	(3.1)
2F007	Ø	12	12	8	8	8	8	6.7	10.8	10.7	17.4	35.9	54.0	(1.7)
2F008	Ø	13	13	8	8	8	8	6.5	9.8	9.8	16.1	33.2	54.0	(3.2)
2F009	1	10	10	8	8	8	8	6.8	11.3	11.2	17.7	34.7	57.4	(4.2)
2F010	Ø	12	12	8	8	8	8	6.6	11.4	11.3	19.2	37.3	57.8	(2.1)
2F011	Ø	14	14	8	8	8	8	6.8	10.5	10.5	17.8	39.3	64.9	(2.6)
2F012	1	14	14	8	8	8	8	7.0	11.3	11.2	19.7	40.4	66.1	(2.9)
2F013	Ø	14	13	8	8	8	8	5.5	8.5	8.2	12.8	30.9	48.6	(6.5)
2F014	1	14	14	8	8	8	8	5.6	8.6	9.0	15.0	31.4	51.3	(3.3)
2F015	Ø	14	14	8	8	8	8	6.2	9.1	8.8	14.9	34.0	53.0	(5.9)
2F016	1	15	15	8	8	8	8	6.2	8.8	8.9	14.7	30.6	51.8	(2.3)
2F017	Ø	14	13	8	8	8	8	7.3	13.5	13.8	22.8	44.0	70.4	(3.6)
2F018	Ø	9	9	8	8	8	8	8.1	14.8	14.8	22.5	44.3	72.9	(4.2)
2F020	Ø	13	13	8	8	8	8	6.5	10.0	10.0	15.6	31.6	52.5	(2.7)
2F021	Ø	9	6	6	6	6	6	6.0	11.4	11.4	16.1	32.0	48.7	(2.0)
2F022	Ø	14	14	8	8	8	8	5.4	8.7	9.2	14.5	30.4	47.9	(1.7)
2F024	Ø	6	6	6	6	6	6	6.7	12.3	12.3	18.3	35.3	58.8	(2.3)
2F025	Ø	17	17	8	8	8	8	6.0	8.2	8.4	14.4	32.1	54.8	(5.1)
2F026	Ø	13	13	8	8	8	8	5.8	9.6	9.1	15.7	33.0	55.3	(4.7)
2F027	Ø	15	15	8	8	8	8	6.0	10.0	10.1	16.7	34.5	55.9	(2.7)
2F029	Ø	1	1	1	1	1	1	6.4	10.8	10.8	16.2	35.9	59.2	(---)
2F030	1	16	15	8	8	8	8	6.1	9.8	9.8	16.8	36.3	57.4	(3.4)
MEANS	Ø.2	12.4	12.2	7.5	7.5	7.5	7.5	6.4	10.5	10.5	17.0	35.2	57.3	
STD	Ø.4	3.7	3.8	1.5	1.5	1.5	1.5	Ø.6	1.7	1.6	2.5	3.8	6.5	
N	26	26	26	26	26	26	26	26	26	26	26	26	26	

LITTER REPORT - STUDY 86127 - MALE AND FEMALE PUPS COMBINED (CONT)

MALE AND FEMALE PUPS COMBINED	FOUND		TOTAL SURVIVING					MEAN LIVE PUP WEIGHTS (GM)						
			PRE CULL	POST CULL				PRE CULL	POST CULL					
DAM	DEAD	LIVE	LAC. DAY 4		7	14	21	LAC. DAY 0	4	7	14	21	MEAN	(STD)
F0a HIGH														
3F001	0	14	0	0	0	0	0	5.7	----	----	----	----	----	(---)
3F002	0	16	16	8	8	8	8	5.6	8.6	8.7	15.7	32.7	50.1	(2.8)
3F003	0	7	7	7	7	7	7	5.9	9.8	9.8	14.1	29.9	51.1	(7.4)
3F004	0	18	17	8	8	8	8	5.9	8.6	8.9	16.1	37.1	58.9	(3.8)
3F005	1	13	12	8	8	8	8	6.2	8.9	9.0	15.0	32.4	55.7	(2.4)
3F006	1	14	14	8	8	8	8	6.8	12.1	12.1	20.9	42.2	71.3	(4.9)
3F008	0	13	13	8	8	8	8	6.6	10.8	10.9	17.6	35.6	58.2	(3.2)
3F009	0	11	10	8	8	8	8	7.1	11.8	11.8	17.7	34.9	58.0	(2.8)
3F012	0	12	12	8	8	8	8	6.3	10.4	10.4	17.2	34.1	59.9	(1.4)
3F013	0	16	16	8	8	8	8	6.0	9.0	9.2	15.3	32.6	51.8	(1.8)
3F014	0	13	13	8	8	8	8	5.9	10.2	10.5	18.2	37.8	59.4	(2.6)
3F015	0	11	11	8	8	8	8	5.6	8.7	8.7	14.3	29.6	50.8	(3.5)
3F017	0	15	15	8	8	8	8	5.9	8.8	9.1	15.2	31.6	51.1	(3.8)
3F019	0	15	15	8	8	8	8	6.0	9.5	10.0	17.0	36.3	62.4	(3.9)
3F020	0	12	12	8	8	8	8	6.5	10.2	10.1	17.0	34.8	56.0	(1.5)
3F021	0	15	15	8	8	8	8	5.7	8.5	9.0	15.7	33.8	51.4	(4.8)
3F022	0	13	13	8	8	8	8	6.4	10.2	10.1	17.1	35.2	57.2	(5.6)
3F023	0	15	15	8	8	8	8	6.3	10.4	10.4	15.9	35.2	57.3	(9.0)
3F024	0	14	14	8	8	8	8	5.9	8.4	8.5	13.1	27.8	45.6	(5.7)
3F025	0	14	14	8	8	8	8	5.3	8.4	8.2	13.9	29.9	47.8	(6.3)
3F027	1	11	10	8	8	8	8	5.1	9.0	8.9	14.8	32.7	52.0	(2.8)
3F028	0	12	8	8	8	8	8	5.2	9.2	9.2	13.4	26.3	43.7	(5.4)
3F030	0	14	14	8	8	8	8	6.2	10.2	10.1	17.8	38.5	59.8	(4.7)
MEANS	0.1	13.4	13.0	8.0	8.0	8.0	8.0	6.0*	9.6*	9.7	16.0	33.7	55.0	
STD	0.3	2.3	2.6	0.2	0.2	0.2	0.2	0.5	1.1	1.0	1.9	3.7	6.2	
N	23	23	22	22	22	22	22	23	22	22	22	22	22	

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .05$)

Table 15

STUDY NO: 86127 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: RE SPECIES: RAT SUBSTANCE: 2,6-DIETHYLPHENYL AZOMETHINE PRINTED: 20-AUG-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **

SELECTION CRITERIA: ALL DEATHS REPORTED
GENERATION F0 : ADULTS

	---- F E M A L E ----			
	FN	F1	F2	F3
NO. IN GROUP AT RISK:	30	30	30	30
DIAPHRAGM				
-HERNIA	0	0	0	1
KIDNEY(S)				
-DILATED PELVIS	0	2	0	0
NOSE/TURBINATES				
-CONGESTED / RED	0	0	0	0
TESTIS(ES)				
-ABNORMAL COLOR	0	0	0	0
URINARY BLADDER				
-ABNORMAL CONTENT	0	0	0	0
UTERUS				
-HYDROMETRA	0	1	0	0
GI TRACT				
-ABNORMAL CONTENT	0	0	0	0

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 27-MAY-87

Table 16

STUDY NO: 86127 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
PATHOLOGY SECTION
STUDY TYPE: RE SPECIES: RAT SUBSTANCE: 2,6-DIETHYLPHENYL AZOMETHINE PRINTED: 20-AUG-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **

SELECTION CRITERIA: ALL DEATHS REPORTED
GENERATION F1 : WEANLINGS

	MALE			
	MN	M1	M2	M3
NO. IN GROUP AT RISK:	59	97	96	87
KIDNEY(S)				
-DILATED PELVIS	Ø	Ø	2	2
LIVER				
-FOCUS, BROWN, YELLOW,TAN	Ø	Ø	Ø	Ø

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 27-MAY-87

STUDY NO: 86127 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: RE SPECIES: RAT SUBSTANCE: 2,6-DIETHYLPHENYL AZOMETHINE PRINTED: 20-AUG-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **

SELECTION CRITERIA: ALL DEATHS REPORTED
GENERATION F1 : WEANLINGS

	---- F E M A L E ----			
	FN	F1	F2	F3
NO. IN GROUP AT RISK:	65	93	99	88
KIDNEY(S)				
-DILATED PELVIS	0	8	2	0
LIVER				
-FOCUS, BROWN, YELLOW,TAN	0	1	0	0

THIS REPORT GENERATED FROM DATA LOCKED THRU 10-JUN-87

Table 17

STUDY NO: 86127 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: RE SPECIES: RAT SUBSTANCE: 2,6-DIETHYLPHENYL AZOMETHINE PRINTED: 20-AUG-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***

SELECTION CRITERIA: ALL DEATHS REPORTED
GENERATION F1 : WEANLINGS

T I S S U E S W I T H F I N D I N G S	ANIMAL SEX :	----- N U M B E R O F A N I M A L S A F F E C T E D -------- M A L E S ---------			
	DOSAGE GROUP:	MN	M1	M2	M3
	NO. IN GROUP:	59	97	96	87
ADRENAL(S)		(10)	(0)	(0)	(10)
EYE(S)		(10)	(0)	(0)	(10)
-RETINAL ROSETTE		1			0
KIDNEY(S)		(10)	(0)	(0)	(10)
-TUBULAR EPITHELIAL HYPERPLASIA/REGENERATION		5			4
-TUBULAR DILATATION		0			2
LUNG		(10)	(0)	(0)	(10)
-HEMORRHAGE		1			1
NOSE/TURBINATES		(10)	(0)	(0)	(10)
-INFLAMMATION		0			1
PROSTATE		(10)	(0)	(0)	(10)
-MONONUCLEAR/LYMPHOCYTIC INFILTRATE		0			2
URINARY BLADDER		(10)	(0)	(0)	(10)

STUDY NO: 86127 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 2
P A T H O L O G Y S E C T I O N
STUDY TYPE: RE SPECIES: RAT SUBSTANCE: 2,6-DIETHYLPHENYL AZOMETHINE PRINTED: 20-AUG-87

*** SUMMARY INCIDENCE OF MICROSCOPIC FINDINGS ***

SELECTION CRITERIA: ALL DEATHS REPORTED
GENERATION F1 : WEANLINGS

T I S S U E S W I T H F I N D I N G S	ANIMAL SEX :	----- N U M B E R O F A N I M A L S A F F E C T E D -------- ---- F E M A L E S ---------			
	DOSAGE GROUP:	FN	F1	F2	F3
	NO. IN GROUP:	65	93	99	88
ADRENAL(S)		(10)	(0)	(0)	(10)
-HEMATOPOIESIS		2			0
EYE(S)		(10)	(0)	(0)	(10)
-RETINAL ROSETTE		3			1
KIDNEY(S)		(10)	(0)	(0)	(10)
-TUBULAR EPITHELIAL HYPERPLASIA/REGENERATION		6			4
-TUBULAR DILATATION		2			1
-DILATATION, PELVIS		1			1
LUNG		(10)	(0)	(0)	(10)
NOSE/TURBINATES		(10)	(0)	(0)	(10)
URINARY BLADDER		(10)	(0)	(0)	(10)
-MONONUCLEAR/LYMPHOCYTIC INFILTRATE		1			0
-MUCOSAL HYPERPLASIA		1			0

NOTE: A NUMBER IN PARENTHESES OPPOSITE A TISSUE NAME INDICATES THE TOTAL NUMBER EXAMINED WHEN LESS THAN THE NUMBER OF ANIMALS IN THE GROUP.

** = SIGNIFICANTLY DIFFERENT [P LESS THAN OR EQUAL TO 0.01] FROM CONTROL USING FISHER'S EXACT TEST WITH THE BONFERRONI INEQUALITY.

APPENDIX 1

CHAMBER ATMOSPHERIC AND ENVIRONMENTAL FINDINGS

Exhibit 1

Analytical Procedure for Determination of 2,6-diethylphenyl azomethine in Air

Study Number: 86126 and 86127 Page Number: 1

Description

This GC method is designed to measure 2,6-diethylphenyl azomethine (AZO) in air. It is based upon trapping AZO from about 10-15 l of air in an impinger containing iso-octane. Quantitation is achieved using a gas chromatograph with a nitrogen/phosphorus detector and integration of the chromatographic peaks due to AZO and its major decomposition product diethylaniline (DEA).

Instruments:

Typical GC Operating Parameters

Column: Fused Silica, 15 M x 0.53 mm ID.; wide-bore capillary; 1 um film of DB-17; J & W Scientific

Gas Flows:
He - 10 mL/min
H2 - 30 mL/min
Air - 400 mL/min

Temperatures:
Detector: 350 deg. C
Injector: 150 deg. C
Column: 110 deg. C for 6 minutes

Injection Volume: 2 uL

Chromatograph: Varian 3700 GC modified for wide-bore capillary column with autosampler, Integration by Spectra Physics 4720 integrator

Materials:

2,6-diethylphenyl azomethine: EHL Test Substance Control Number T860069.
Iso-octane: Burdick and Jackson, Inc., HPLC Grade
2,6-diethylaniline: Gold Label; Aldrich Chemical Co.

Note: Keep neat test material refrigerated when not in use.

Required Standard Solutions (AZO)

Study Number: 86126 and 86127 Page Number: 2

Stock Standards (a)

Identification	Approximate Sample Weight (mg) (b)	Volume of Sample Standard (mL)	Approximate Stock Standard Concentration (mg/L)
A	10	100	100
B	50	100	500
QC	10	100	100

Working Standards

Identification	Stock Standard	Volume of Stock Standard (mL)	Volume of Working Standard (mL)	Approximate Concentration of Working Standard (mg/L)
WS-1	A	1	100	1
WS-2	B	1	100	5
WS-3	A	10	100	10
WS-4	B	5	100	25
WS-5	A	25	50	50
WS-6	B	15	100	75
QC-L	QC	2.5	100	2.5
QC-M	QC	15	100	15
QC-H	QC	25	50	50

(a) Prepared using EHL Test Substance T860069

(b) To the nearest 0.1 mg.

Comments: Fresh stock and working standards will be prepared in iso-octane every two weeks.

Additional standards, fewer standards and/or alternate concentrations of standards may be used for the calculation of regression coefficients at the discretion of the chemistry group.

Required Standard Solutions (DEA)

Study Number: 86126 and 86127 Page Number: 3

Stock Standards (a)

Identification	Approximate Sample Weight (mg) (b)	Volume of Sample Standard (mL)	Approximate Stock Standard Concentration (mg/L)
A	10	100	100
B	50	100	500
QC	10	100	100

Working Standards

Identification	Stock Standard	Volume of Stock Standard (mL)	Volume of Working Standard (mL)	Approximate Concentration of Working Standard (mg/L)
WS-1	A	1	100	1
WS-2	B	1	100	5
WS-3	A	10	100	10
WS-4	B	5	100	25
WS-5	A	25	50	50
WS-6	B	15	100	75

(a) Prepared using Aldrich Gold Label 2,6-diethylaniline.

(b) To the nearest 0.1 mg.

Comments: Fresh stock and working standards will be prepared in iso-octane every two weeks.

Additional standards, fewer standards and/or alternate concentrations of standards may be used for the calculation of regression coefficients at the discretion of the chemistry group.

These standards (DEA) will be run only together with the study sample. See section 5 on page 5 for details on their use in calculation.

Calculations

Study Number: 86126 and 86127 Page Number: 4

1. Working Standard Concentrations

$C_w = (C_s * V_s)/V_w$

where: C_w = concentration of working standard (mg/L)

C_s = concentration of stock standard (mg/L)

V_s = volume of stock standard (mL)

V_w = volume of working standard (mL)

Values are reported to three significant figures.

2. Regression Coefficients

A linear regression will be calculated from the standard concentrations C_w (in mg/L) and the corresponding areas A. The A and C_w will be treated as X and Y, respectively. The expression $C_w = a+b*A$ will be used to calculate the concentrations of the impinger solutions.

Standards 1-3 will be used to calculate the regression coefficients for any solution having a peak area less than or equal to WS-3. Standards 1-6 will be used to calculate regression coefficients for samples with area counts greater than WS-3.

3. Net Peak Area

If the blank sample exhibits a peak interfering with the test material with an area exceeding 10% of the area of the lowest standard then a net peak area will be calculated.

$A_N = A_T - A_b$

where: A_N = net area of test material

A_b = area of blank peak at test material retention time

A_T = apparent area of test material peak

Calculations (cont.)

Study Number: 86126 and 86127 Page Number: 5

4. Solution Concentration

The solution concentration C_x will be calculated directly from the regression equation by the labnet computer.

Solution concentrations will be reported to three significant figures. Solution concentrations less than the lowest standard will be reported as NM (not measurable).

5. 2,6-diethylaniline Standards

The major decomposition product of AZO is 2,6-diethylaniline (DEA). A single set of working standards of 2,6-diethylaniline will be analyzed with each days' samples. A linear regression line for DEA may be calculated from these standards and the samples. DEA concentrations will be determined from the DEA peak areas only if the study director and/or product toxicologist or chemistry group professional determines that the samples' DEA concentrations need to be determined. This determination will be made at the conclusion of the study. If DEA concentrations are not independently determined then analytical data will be obtained by summing peak areas of both AZO and DEA.

6. Air Concentration

$$C_{air} = C_x * V_{imp} * 10^{-3} \text{ liter/mL} * 1/V_{air}$$

where:
C_x = Solution concentration (mg/L)
C_{air} = Air concentration of AZO (mg/l air)
V_{imp} = Impinger sample volume (mL)
V_{air} = Volume of air sampled (l)

Air concentrations will be reported to two significant figures.

Comments

Study Number: 86126 and 86127 Page Number: 6

A typical chromatogram of a working standard is attached.

Reserve samples and standards will be refrigerated overnight in case re-analysis is necessary.

It is necessary to re-analyze the QC if the mean value for that sample differs from expected by 10% or greater. The study director, upon comparison of nominal and analytical measurements, may recommend re-analysis of impinger samples.

Two sets of standards will be run for each set of analysis; one set will be run at the start of the samples and the second set will be run at the end of the samples. Unless otherwise directed by a professional of the chemistry group, mean peak areas will be used to calculate the correlation coefficient and the linear regression line and all sample concentrations.

QC samples will be run in duplicate both near the beginning and near the end of each analytical run (thus bracketing all samples for that day.) Unless a professional of the chemistry group determines that analytical, sampling or instrumental condition dictate otherwise, mean peak area for QC samples will be used for concentration calculations. QC sample concentrations may vary during the course of the study to approximately match impinger concentrations.

Different standard weights and volumes of stocks and volumetric flasks may be used as long as the approximate concentrations of the stocks and working standards still correspond to those given on page 2.

Computer generated "interim" data may contain more significant figures than is specified in this analytical method. The final analytical data (in the analytical report) will, however, be rounded to the number of significant figures indicated.

This method was developed by Jim Mueller, Kevin McCune and Mark Holland, Ph.D. The following technician is judged capable of performing this analysis.

Technician	Date Training Completed
Sue Schermes	11/19/86
Jim Mueller	11/6/86
Kevin McCune	11/6/86

Prepared By: Mark E. Holland Date: 11/26/86

Reviewed By: Wm E Hyl II Date: 11/26/86

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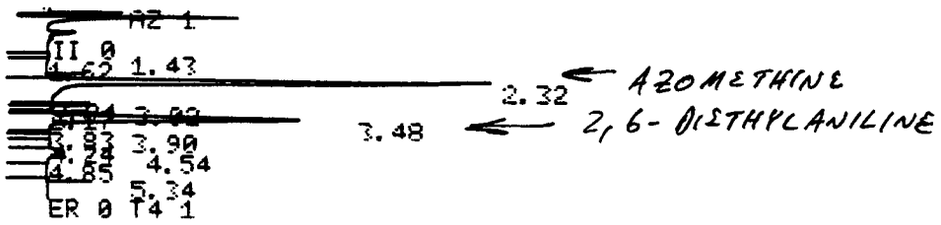

86126-7, AZO, DAY3 11/25/86 15:57:48 CH= "A" PS= 1.

FILE 1. METHOD 5. RUN 4 INDEX 4

ANALYST: MARK HOLLAND

SAMPLE 4 WS-4

SA	IS	XF
0.	0.	1.

NAME	RT	AREA BC	RF
AZO	2.32	184493 09	1.
DEA	3.48	120911 02	1.
3	4.24	2422 02	
4	4.54	11616 03	
TOTALS		319442	

Exhibit 1A

Analytical Procedure for Determination of Formaldehyde in Air

Study Number: 86126 and 86127 Page Number: 1

Description

This GC method is designed to measure formaldehyde in air. It is based upon reacting formaldehyde from about 5-20 L of air in an impinger containing iso-octane and N-benzylethanolamine. Quantitation is achieved using a gas chromatograph with a nitrogen/phosphorus detector and integration of the chromatographic peaks due to 3-benzyloxazolidine, the reaction product of formaldehyde and N-benzylethanolamine.

Instruments:

Typical GC Operating Parameters

Column: Fused Silica, 15M x 0.53 mm; 1 um film of DB-17.
J&W Scientific, Inc.

Gas Flows:
He - 10 mL/min
H2 - 30 mL/min
Air - 300 mL/min

Temperatures:
Detector: 350 deg. C
Injector: 150 deg. C
Column: 100 deg. C for 9 minutes isothermal, then
25 deg. C minute to 200 deg. C, hold for
1 minute

Injection Volume: 2 uL

Chromatograph: Varian 3700 GC with autosampler; Integration by Spectra Physics 4270 integrator

Materials:

N-benzylethanolamine; 98+%, Aldrich Chemical Co., Milwaukee, Wisconsin.
Iso-octane; Burdick and Jackson, Inc., HPLC Grade
3-benzyloxazolidine; Supelco; Bellfonte, PA.

Required Standard Solution

Study Number: 86126 and 86127 Page Number: 2

Stock Standards (a)

Identification	Approximate Sample Weight (mg) (b)	Volume of Sample Standard (mL)	Approximate Stock Standard Concentration (mg/L)
A	50	100	500
B	10	100	100

Working Standards

Identification	Stock Standard	Volume of Stock Standard (mL)	Volume of Working Standard (mL)	Approximate Concentration of Working Standard (mg/L)
WS-1	B	1	100	1.00
WS-2	B	1	50	2.00
WS-3	B	1	25	4.00
WS-4	B	6	100	6.00
WS-5	B	4	50	8.00
WS-6	A	2	100	10.0

(a) Prepared using 3-benzyloxazolidine.
(b) To the nearest 0.1 mg.

Comments: Fresh stock and working standards will be prepared in iso-octane every week.
Additional standards, fewer standards and/or alternate concentrations of standards may be used for the calculation of regression coefficients at the discretion of the chemistry group.

Calculations

Study Number: 86126 and 86127 Page Number: 3

1. Working Standard Concentrations

$C_w = (C_s * V_s)/V_w$

where: C_w = concentration of working standard (mg/L)

C_s = concentration of stock standard (mg/L)

V_s = volume of stock standard (mL)

V_w = volume of working standard (mL)

Values are reported to three significant figures.

2. Regression Coefficients

A linear regression will be calculated from the standard concentratiuons C_w (in mg/L) and the corresponding areas A. The A and C_w will be treated as X and Y, respectively. The expression $C_w = a+b*A$ will be used to calculate the concentrations of the impinger solutions.

Standards 1-4 will be used to calculate the regression coefficients for any solution having a peak area less than or equal to WS-4. Standards 1-6 will be used to calculate regression coefficients for samples with area counts greater than WS-4.

3. Net Peak Area

If the blank sample exhibits a peak interfering with the test material with an area exceeding 10% of the area of the lowest standaard then a net peak will be calculated.

$A_N = A_T - A_b$

where: A_N = net area of test material

A_b = area of blank peak at test material retention time

A_T = apparent area of test material peak

Calculations

Study Number: 86126 and 86127 Page Number: 4

4. Solution Concentration

The solution concentration C_x will be calculated directly from the regression equation by the labnet computer.

Solution concentrations will be reported to three significant figures. Solution concentrations less than the lowest standard will be reported as NM (not measurable).

5. Air Concentration

$$C_{air} = C_x * V_{imp} * 10^{-3} \text{ liter/mL} * 1/V_{air} * 10^3 \text{ L/m}^3$$

where:
C_x = Solution concentration (mg/L)
C_{air} = Air concentration of formaldehyde (ppm air)
V_{imp} = Impinger sample volume (mL)
V_{air} = Volume of air sampled (L)

Air concentrations will be reported to two significant figures.

6. This method is based on the instantaneous and quantitative reaction at room temperature between formaldehyde and N-benzylethanolamine to form 3-benzyloxazolidine. The analyte in this method is 3-benzyloxazolidine. The stock standards and working standards are prepared in iso-octane with 3-benzyloxazolidine. The impinger solution is 0.1% N-benzylethanolamine in iso-octane.

Comments

Study Number: 86126 and 86127 Page Number: 5

A typical chromatogram of a sample is attached.

Unless otherwise directed by a professional of the chemistry group, peak areas will be used to calculate the correlation coefficient and the linear regression line and all sample concentrations.

This method has not been fully validated and is to be used only as an approximate checking procedure for Draeger tube formaldehyde analyses conducted concurrently with these analyses.

Different standard weights and volumes of stocks and volumetric flasks may be used as long as the approximate concentrations of the stocks and working standards still bracket actual study samples' concentrations.

Computer generated "interim" data may contain more significant figures than is specified in this analytical method. The final analytical data (in the analytical report) will, however, be rounded to the number of significant figures indicated.

This method was developed by Mark Holland, Ph.D. The following technicians are judged capable of performing this analysis.

Technician	Date Training Completed
Kevin McCune	2/1/87

Prepared By: Mark E. Holland Date: 5/3/88

Reviewed By: W. E. Hinds II Date: 5/3/88

TOTALS 184371

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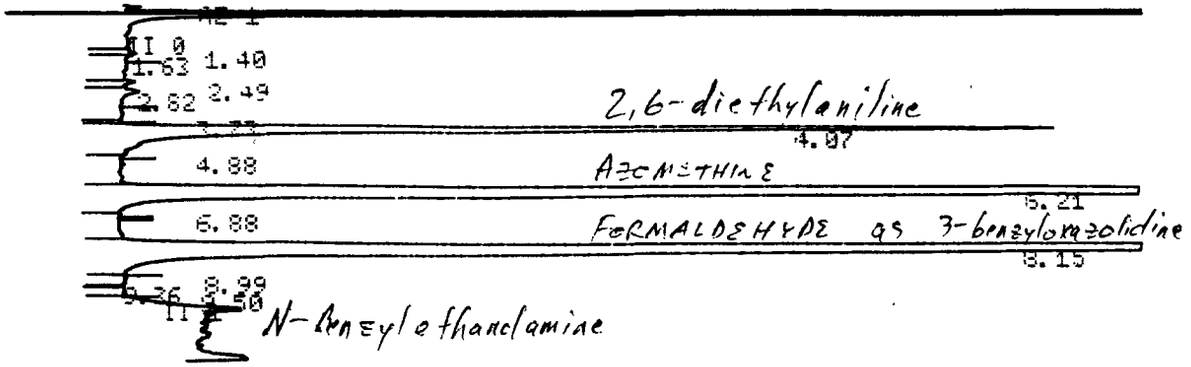


CH20 02/27/87 11:20:27 CH= "A" PS= 1.

FILE 2. METHOD 5. RUN 13 INDEX 3

ANALYST: MARK HOLLAND

SAMPLE 13 H1

SA	IS	XF
1.	0.	1.

NAME	RT	AREA BC	RF
1	1.4	153 02	
2	1.63	148 03	
3	2.49	520 02	
AZO	2.82	1228 03	1.
5	3.73	12 01	
6	4.07	80277 08	
DEA	4.88	29 05	1.
8	6.21	336501 08	
CH20	6.88	27 05	1.
10	8.15	258539 08	
11	8.99	4 05	
12	9.36	10 06	
BEA	9.5	283 07	1.

TOTALS 677731

Exhibit 2

Procedure for Assaying 2,6-diethylphenyl azomethine for Stability Assessment

Study Number: 86126 and 86127 Page: 1

Description

A solution of 2,6-diethylphenyl azomethine (AZO) and indole in iso-octane is analyzed by gas chromatography using a nitrogen/phosphorus detector. The indole is used as an internal standard and its peak area is determined along with sum of the peak areas due to (AZO) and its degradation product, 2,6-diethylaniline (DEA). A ratio of the peak areas of AZO plus DEA vs indole is used as a measure of the stability of the test substance (AZO) over time. The amount of degradation of AZO to DEA is also measured by comparison to standards prepared using pure DEA.

Instrumentation:

Typical GC Operating Parameters

Column: Fused Silica, 15 M x 0.53 mm I.D.; 1 um film of DB-17; J & W Scientific

Gas Flow:
He - 10 ml/min
H2 - 30 ml/min
Air - 300 ml/min

Temperature:
Detector - 350 degrees C
Injector - 150 degrees C
Column - 90 degrees C isothermally for 15 min.

Injection volume: 2 uL

Chromatograph: Varian 3700 G.C. with autosampler, with integration by Spectra-Physics 4270 integrator

Materials:

2,6-diethylphenyl azomethine: EHL Test Substance number T860069

Iso-octane: Burdick and Jackson, HPLC Grade

Indole: Gold Label 99+ % Aldrich Associates, Milwaukee, Wisconsin

2,6-diethylaniline: Gold Label; 99.5%; Aldrich Associates, Milwaukee, Wisconsin

Required Standard Solutions - First Assay

Study Number: 86126 and 86127 Page: 2

Stock Standards

Identification	Sample Used	Approximate Target Sample Weight (mg)	Volume of Stock Standard (mL)	Approximate Target Stock Standard Concentration (mg/L)
A	AZO	100	100	1000
	Indole	100	(same flask)*	1000
B	AZO	100	100	1000
	Indole	100	(same flask)*	1000

Working Standards

Identification	Stock Standards**	Volume of Stock Standards (mL)	Final Volume of Working Standard(mL)	Approximate AZO Concentration of Working Standard(mg/L)	Approximate Indole Concentration of Working Standard(mg/L
WS-1	A	5	100	50	50
WS-2	B	6	100	60	60
WS-3	A	7	100	70	70
WS-4	B	8	100	80	80
Mixed test Solution	A*** or B	7	100	70	70

A relative response ratio is initially calculated from the above prepared solutions as described on page 5 (section 3). Subsequent stability assays are performed using the single solution prepared as described on page 3, from which concentrations are calculated as described on page 6.

* Both substances are prepared in the same solution.
** Both stock standards are used to make each of the four working standards and the mixed test solution according to the dilutions listed above.
*** Note on raw data which stock solution (A or B) is used to make the mixed test solution.

Required Standard Solutions - All Assays

Study Number: 86126 and 86127 Page: 3

Stock Standard

Identification	Sample	Approx. Target Sample Weight (mg)	Volume of Stock Standard (mL)	Approximate Target Stock Standard Concentration mg/L
A	DEA	100	100	1000

Working Standards

Identification	Stock Standard	Volume of Stock Standard (mL)	Final Volume of Standard (mL)	Approximate DEA Concentration in Working Standard (mg/L)
WS-1	A	1	100	10
WS-2	A	2	100	20
WS-3	A	3	100	30
WS-4	A	4	100	40
WS-5	A	5	100	50

Prepare all stocks and working standards fresh for each assay in iso-octane.

Required Standard Solutions - Subsequent Assays

Study Number: 86126 and 86127 Page: 4

Identification	Approximate Target Sample Weight (mg)	Sample Used	Volume of Stock Standard (mL)	Approximate Target Stock Standard Concentration (mg/L)
Mixed Test Solution*	100	AZO	100	1000
	100	Indole	(same flask)	1000

* Both AZO and indole are added to the same 100 mL volumetric flask according to the above directions to prepare the mixed test solution. This solution is used for all subsequent assays of AZO and is prepared freshly for each analysis. It is diluted 7.0 mL to 100 mL with iso-octane before analyses so the approximate target concentratiion of AZO and indole is 70 mg/L.

Stock Standards

Identification	Sample Used	Approximate Target Sample Weight (mg)	Volume of Stock Standard (mL)	Approximate Target Stock Standard Concentration (mg/L)
Indole	Indole	100	100	1000

Working Standards

Identification	Stock Standards*	Volume of Stock Standards (mL)	Final Volume of Working Standard (mL)	Approximate Target Concentration of Working Standard (mg/L)
WS-1	Indole	5	100	50
WS-2	Indole	6	100	60
WS-3	Indole	7	100	70
WS-4	Indole	8	100	80

* Working standards will be used to determine a linear regression line for calculation of indole concentration (C IS) in the mixed test solution. This C IS value will then be used in the equation in part 4; page 7.

First Assay Procedures

Chromatograph the working standards twice and chromatograph the mixed test solution (prepared as directed on page 2) containing test substance and internal standard five times to calculate a mean relative response ratio at time zero according to section 3, page 6.

All Assays

Chromatograph the 5 DEA working standards and calculate the concentration of DEA in the assay samples by a normal linear regresion routine.

Subsequent Assays

At intervals during the study prepare and chromatograph a new mixed test solution and working standards as described on page 3. Then calculate the concentration of the AZO in the mixed test solution and the mean concentration of AZO according to section 4, page 7. The mixed test solution indole mean concentration is then used to calculate the percent recovery of nominal concentration using the previously determined mean response ratio according to section 5, page 7. The percent recovery of nominal concentration is used as a measure of the stability of the test material. A value of 100% indicates no degradation of the test material. The test material will be considered stable for the purposes of the study if all percent recovery values are greater than 95% and less than 105%.

Reporting of Data

Solution concentrations and percent recovery of nominal concentration values will be reported to three significant figures.

Treatment of Data

The test material (AZO) is known to be subject to hydrolysis to form 2,6-diethylaniline (DEA). The sum of the areas for both the DEA and AZO peaks will be used to calculate the AZO linear regresions and to calculate AZO concentrations. A professional of the chemistry group will examine all stability data and if excessive (> 50%) degradation of AZO to DEA is noted at any time he will consult with the study director to decide on appropriate action.

Calculations

Study Number: 86126 and 86127 Page: 6

Concentrations are calculated automatically by a program in the integrator. These calculations are shown for illustration purposes.

1. Working Standard Concentration

$C_w = (C_s * V_s)/V_w$

where: C_w = concentration of working standard (mg/L)
C_s = concentration of stock standard (mg/L)
V_s = volume of stock standard (mL)
V_w = volume of working standard (mL)

Values are reported to three significant figures.

2. Regression Coefficients

A linear regression will be calculated from the working standards conforming to the equation.

$$C_w = a + b * A$$

Where A is the mean peak area due to AZO and DEA of the working standards and C_w the concentration of AZO of the standards. A correlation coefficient greater than 0.98 indicates satisfactory linearity of response over the concentration range used. The working standards are prepared with varying concentrations of the test substance and the regression coefficient is calculated in order to insure that the mixed test solution concentration falls within the linear concentration range of the detector. The narrow concentration ranges for the test substances and internal standard are used in order to obtain regression lines of maximized linearity.

In a similar manner determine the regression coefficients for indole and for DEA.

3. Relative Response Ratio (initial assay only)

The relative response ratio, R, of test material to internal standard is calculated from the expression:

$$R = (A_{IS}/C_{IS})/(A_x/C_x)$$

Where: A_x = Area of the test material
C_x = Concentration of the test material as calculated from linear regression line using AZO plus DEA areas of working standards. (mg/L)
A_{IS} = Area of the internal standard
C_{IS} = Concentration of the internal standard as calculated from linear regression line using indole areas of working standards. (mg/L)

Calculations - Continued

Study Number: 86126 and 86127 Page: 7

Calculate the mean relative response ratio from five replicate injections of the mixed test solution. It is a measure of the relative response of the chromatographic detector to the two materials (AZO plus DEA and indole) and is assumed to be constant.

4. Calculation of Solution Concentrations (subsequent assays only)

The concentration of test material in solution (mg/L) is calculated from the following expression:

$$C\ x = (A\ x/A\ IS) * R * C\ IS$$

Where:
- A x = Area of test material (AZO plus DEA)
- A IS = Area of internal standard
- R = Relative response ratio (previously determined by initial assay)
- C IS = Concentration of internal standard (as calculated from linear regression line prepared from the 5 working standards listed on page 3). (mg/L)

Calculate the mean solution concentration (mean C x) from the initial C x values determined above.

5. Stability Assessment (subsequent assays only)

The stability of the test substance is assessed by comparing the mean test material concentration (mean C x) determined in step 4, above, to the nominal (expected) test material concentration in the mixed test solution. This comparison is then evaluated on a percent basis as "percent recovery":

Percent recovery = (100) (mean C x)/C n

where:
- C x = Calculated concentration from section 4 above
- C n = Nominal concentration of test material in mixed test solution prepared for the stability measurement (p. 3).

Making the assumption that the relative response factor is constant, a percent recovery value less than 100% suggests degradation of the test substance between the time of the initial assay and the time of the subsequent assay.

Comments

Study Number: 86126 and 86127 Page: 8

A typical chromatogram of AZO/DEA and indole and DEA only is attached.

Different standard weights and volumes of stocks and volumetric flasks may be used as long as the approximate concentrations of the stocks and working standards still correspond to those given on page 2.

Because AZO and DEA are known to give different peak area/weight values (peak responses), the concentration of DEA in the assay samples (ie., the amount of degradation) could effect the calculation of R and, thus, the stability determination. A professional of the chemistry group will examine results for determination of degree of AZO degradation to DEA and may modify this procedure if degradation varies a great deal from assay to assay. If the procedure is varied, the AZO degradation to DEA will be taken into account in determining stability.

Computer generated "interim" data may contain more significant figures than is specified in this analytical method. Final analytical data in the analytical report will, however, be rounded to the appropriate number of significant figures.

This method was developed by Kevin McCune and Mark E. Holland, Ph. D. The following technician is judged trained in performing this analysis.

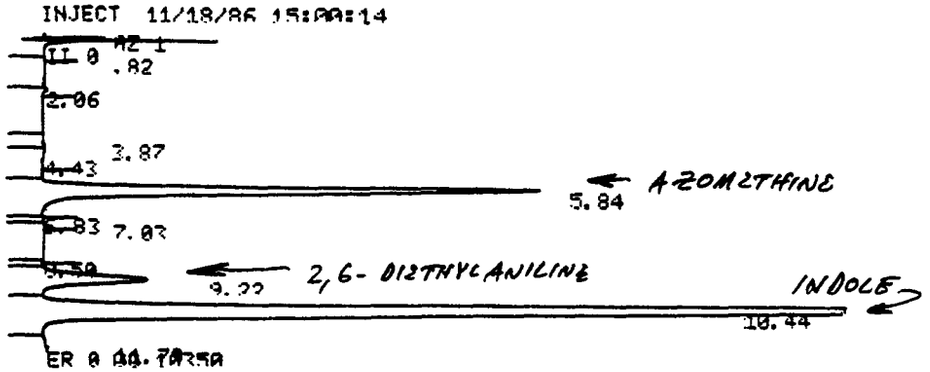
Technician	Date Training Completed
Kevin McCune	11/14/86
Jim Mueller	11/14/86
Sue Schermes	11/14/86
Debbie Detrick	11/14/86

Prepared By: Mark E Holland Date: 11/21/86

Reviewed By: Wm E Hoyle III Date: 11/24/86

.A FAULT 100: AT 10060

CHANNEL A INJECT 11/18/86 15:00:14



86126 & 127 PRE TEST STAR 11/18/86 15:01:14 CH= "A" PS= 1.

FILE 1. METHOD 5. RUN 24 INDEX 26

ANALYST: KEVIN McCUNE

SAMPLE 24 WS-1

SA	IS	XF
0.	0.	1.

NAME	RT	AREA	BC	RF
AZO	5.84	547857	09	1.
DEA	9.22	148687	02	1.
INDOLE	10.44	1654663	09	1.
TOTALS		2350407		

Exhibit 3

Results of the Analysis of 2,6-diethylphenyl azomethine in a Three-Month Inhalation Study

Authors:

K. McCune — 9/14/87 Date

S. Schermes — 9-14-87 Date

J. Mueller — 9-14-87 Date

M. E. Holland, Ph.D. — 9/14/87 Date

Reviewed by:

M. W. Dietrich, Ph.D. — 9/14/87 Date
Chemistry Group Leader

RESULTS AND DISCUSSION

Impinger samples of 2,6-diethylphenyl azomethine (AZO) in iso-octane collected by the inhalation toxicology group over 89 exposure days were analyzed using a gas chromatography procedure. Analytical chemistry laboratory-prepared quality control samples were analyzed together with the study samples to provide a measure of the precision and accuracy of the procedure.

For the pretest exposure days, samples were collected in two impingers connected in series. Both impinger samples were analyzed. Second impinger concentrations of AZO were less than 3% of first impinger and the use of the second impingers was, therefore, discontinued.

Data obtained from the analyses of study samples are found in Tables 1-4. Table 1 shows the daily sample analytical results. Table 2 shows the daily mean chamber concentrations and Table 3 shows the study mean chamber concentrations for the three exposure levels for study 86126 and Table 4 shows the study mean chamber concentrations for the three exposure levels for study 86127. (Animals for study 86126 were not exposed on some study days). Analyses of control chamber samples indicated that no test material was present.

Results of the analyses of quality control samples are given in Table 5 (daily values) and Tables 6 and 7 (study mean values) for studies 86126 and 86127, respectively. The largest percent difference from the expected value on any day was -12.6 and the largest study mean percent difference was -1.3. This showed that the method used had no significant bias and was capable of providing analyses that are both accurate and precise.

Results of the stability assessments of the 2 lots of AZO test substance (T860069 and T870001) are shown in Table 8. The test substance was assayed against an internal standard of indole that was kept in the dark. The test substance is known to degrade to 2,6-diethyaniline (DEA) under normal storage conditions. The extent of this degradation was measured by comparison to standards prepared from high purity (99.5%) DEA. The test material exhibited some degradation (as evidenced by the presence of DEA) throughout the study. This decomposition was closely monitored and was considered to be at acceptable levels. The stability assessments were determined by summing peak areas for both AZO and DEA, its major decomposition product. This was considered an acceptable approach due to the fact that the percent DEA (by peak area) was consistently 15-25%. Most of this degradation is believed to be due to on-column degradation of AZO during the analysis.

This on-column contribution to degradation of the test material could not be eliminated during the study. As a result, it was determined that the most reliable analytical data was obtained by summing peak areas from both the parent test material (AZO) and its decompositon product (DEA). This summation of peak areas was performed for both standards and all samples.

Other potential or likely sources of decomposition of the test material included in-chamber decompositon (due to wet air), in-solution decomposition and storage decomposition of the neat test material (due to polymerization and hydrolysis). Because the individual contributions of these various decomposition pathways cannot be quantified, the analytical data generated during the study relates only to the sum of the concentrations of AZO + DEA in the various standards and samples.

Another decomposition product of AZO is formaldehyde (CH_2O). The inhalation toxicology group measured CH_2O concentrations daily in the inhalation chambers by the use of semi-quantitative Draeger tube analyses. The chemistry group analyzed for CH_2O using a quantitative gas chromatographic method for 2 study days (days 67-68) to confirm the Draeger tube results. Results are shown in Table 9.

Table 1

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
1	8.1	9.9	40
	5.2	12	56
	4.2	12	64
	4.0	12	73
	3.7		
2	1.4	7.7	54
	N.M.	6.4	52
	2.9	7.8	88
	2.2	10	99
3	1.9	6.2	72
	1.7	8.8	66
	1.7	9.7	75
	1.8	11	69
	1.7		
4	2.8	15	51
	2.6	17	55
	2.8	17	51
	2.8	18	51
	2.6		
5	1.5	N.M.	3.9
	0.94	N.M.	2.7
	N.M.	N.M.	16
	N.M.	N.M.	3.3
6	2.4	14	30
	2.3	16	33
	2.3	16	35
	2.4	15	42
	2.2		

N.M. = Not measurable.

Table 1 (cont.)

Daily Analyses of AZO in Chamber

Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
7	2.4	13	25
	2.4	15	27
	2.3	16	31
	2.5	18	32
8	2.5	14	36
	2.5	15	53
	2.5	16	45
	2.8	16	51
9	2.4	8.8	56
	2.2	5.4	58
	2.3	7.9	52
	2.6	10	56
	2.6		
10	2.5	14	59
	2.4	16	69
	2.3	15	76
	2.4	17	73
11	2.4	16	43
	2.4	18	49
	2.4	15	51
	2.3	16	51
	1.3		
12	2.6	14	47
	2.5	16	51
	2.7	17	54
	2.6	17	54
13	2.9	16	40
	3.7	16	41
	3.8	19	44
	3.8	19	47
14	3.0	14	31
	2.6	14	35
	3.0	14	33
	2.8	14	33

Table 1 (cont.)

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
15	4.3	17	50
	3.4	20	53
	3.2	22	58
	3.5	21	60
16	2.1	13	54
	1.9	11	61
	2.0	14	69
	2.0	15	49
17	2.0	12	40
	1.9	13	41
	1.7	13	43
	1.8	14	35
18	2.6	10	34
	2.3	11	34
	2.9	12	36
	2.3	12	38
19	2.4	12	70
	2.4	12	74
	2.7	13	76
	2.1	15	78
20	3.7	12	79
	3.4	13	64
	3.3	13	65
	2.9	13	69
21	2.3	13	44
	2.7	15	49
	2.6	16	52
	2.5	15	56
22	2.8	15	38
	2.6	15	40
	2.7	14	43
	2.5	16	41

Table 1 (cont.)

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
23	2.3	15	48
	2.6	15	50
	2.6	15	52
	2.7	15	52
24	2.3	15	46
	2.2	12	47
	2.4	16	50
	2.6	14	50
25	2.5	13	54
	2.6	13	58
	2.7	14	60
	2.6	15	64
26	1.8	15	55
	2.5	14	58
	2.6	14	65
	2.8	15	62
27	2.3	14	33
	2.1	13	38
	2.1	13	38
	2.2	17	38
28	2.4	14	53
	2.5	14	55
	2.5	16	58
	2.4	15	63
29	2.3	11	49
	2.3	13	52
	2.2	14	56
	2.4	14	55
30	2.6	14	59
	2.5	15	63
	2.6	14	67
	2.4	16	68

Table 1 (cont.)

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
31	9.4	13	34
	1.7	13	38
	2.4	13	39
	2.4	16	38
32	2.6	14	52
	2.4	14	58
	2.4	13	57
	2.6	13	59
33	2.3	14	42
	2.3	14	46
	2.4	14	49
	2.4	15	50
34	2.4	12	44
	2.3	11	47
	2.3	12	48
	2.3	13	54
35	2.3	15	47
	2.5	13	52
	2.5	17	53
	2.4	17	53
36	2.5	14	61
	2.8	15	66
	2.5	15	68
	2.4	16	70
37	2.6	14	39
	2.5	14	46
	2.5	14	50
	2.6	14	56
38	2.5	15	62
	2.7	15	71
	2.6	15	75
	2.7	16	74

Table 1 (cont.)

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
39	2.7	13	51
	2.5	13	54
	2.5	13	57
	2.5	14	56
40	2.7	15	48
	2.7	14	51
	2.7	15	54
	2.7	15	57
41	2.8	12	50
	2.8	12	55
	2.9	13	54
	3.1	14	57
42	2.7	15	37
	2.5	16	42
	2.6	16	44
	2.7	16	45
43	2.7	13	52
	2.5	14	59
	2.4	13	59
	2.4	15	61
44	2.6	14	47
	2.6	16	50
	2.6	16	53
	2.7	16	55
45	2.6	14	49
	2.5	13	55
	2.7	14	57
	2.5	15	61
46	2.7	13	59
	2.5	14	64
	2.6	14	69
	2.7	15	66

Table 1 (cont.)

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
47	2.3	11	50
	2.4	13	53
	2.4	12	56
	2.5	13	59
48	2.5	16	41
	2.5	16	45
	2.7	15	46
	2.6	19	49
49	2.6	14	39
	2.9	15	42
	2.9	16	45
	2.8	16	49
50	2.9	15	59
	2.7	16	67
	2.8	19	67
	3.1	17	70
51	2.7	15	50
	2.5	17	51
	2.8	16	54
	3.0	16	58
52	2.9	16	56
	2.9	18	58
	2.8	18	61
	3.1	17	66
53	2.6	15	52
	2.7	13	63
	2.6	19	71
	3.0	18	71
54	3.1	16	62
	3.0	14	64
	3.0	15	67
	2.9	16	79

Table 1 (cont.)

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
55	2.7	17	62
	2.6	17	63
	2.8	16	62
	2.8	16	72
56	2.8	16	45
	3.0	17	55
	2.7	15	55
	3.1	17	51
57	2.6	14	54
	2.7	15	56
	2.4	17	61
	2.6	17	55
58	2.8	14	57
	3.0	17	62
	2.7	17	64
	2.7	17	64
59	2.7	12	45
	2.8	14	48
	3.0	15	50
	3.0	15	48
60	2.6	14	40
	2.7	14	43
	2.9	16	42
	3.0	16	45
61	3.3	14	33
	2.8	14	36
	2.9	15	36
	2.8	16	37
62*	3.0	14	45
	3.1	16	47
	2.6	16	49
	2.8	15	52

*86127 only

Table 1 (cont.)

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
63*	2.8	14	33
	3.0	15	35
	3.1	17	36
	2.9	16	39
64	3.1	15	36
	2.9	16	39
	3.2	16	40
	3.2	17	42
65	2.8	14	33
	2.8	15	36
	2.8	16	39
	3.1	17	40
66	3.0	16	52
	2.8	14	57
	2.7	16	57
	2.9	16	56
67	2.8	13	44
	2.9	14	50
	2.7	14	52
	2.7	16	53
68	3.0	13	44
	3.0	13	48
	3.0	13	49
	3.1	16	50
69*	2.8	16	28
	2.6	16	29
	3.0	16	31
	3.0	16	31
70*	3.3	15	55
	3.2	17	60
	3.2	15	61
	3.1	15	61

* 86127 only.

Table 1 (cont.)

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
71	2.1	13	32
	2.6	14	38
	2.1	14	42
	2.1	14	39
72	2.7	13	35
	2.4	14	36
	2.5	14	39
	2.3	15	41
73	2.1	13	56
	2.0	13	63
	2.5	14	67
	2.5	16	69
74	2.8	13	37
	1.6	13	40
	3.5	13	40
	2.2	14	42
75	2.4	12	25
	2.4	13	26
	2.4	14	28
	2.5	14	29
76	N.M.	1.6	7.0
	2.2	5.5	35
	3.0	11	24
	3.5	12	44
77	2.3	12	46
	2.7	14	57
	2.3	13	51
	0.66	14	62
78	2.5	14	37
	2.0	13	42
	2.5	14	44
	2.4	14	44

Table 1 (cont.)

Daily Analyses of AZO in Chamber Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
79	2.7	10	28
	2.7	12	31
	2.2	13	33
	2.8	14	34
80	2.5	13	63
	2.5	14	72
	2.5	16	67
	2.6	14	59
81	2.6	11	54
	2.5	13	60
	2.5	13	57
	2.6	13	69
82	2.5	14	30
	2.6	16	31
	2.5	15	40
	2.6	15	45
83*	2.5	13	55
	2.5	14	48
	2.6	16	67
	2.5	13	55
84*	2.6	13	32
	2.5	11	43
	2.4	13	43
	2.6	11	51
85*	-	13	-
		11	
		11	
		11	
86*	-	11	-
		13	
		16	
		17	

*86127 only

Table 1 (cont.)

Daily Analyses of AZO in Chamber

Atmospheres (mg/m^3)

Exposure Day	Low	Mid	High
87*	-	14 15 12 15	-
88*	-	13 14 12 13	-
89*	-	11 12 11 13	-

Note: All air values are obtained by summing peak areas of both AZO and its major decomposition product, 2,6-diethylaniline (DEA).
*86127 only

Table 2

Mean Daily Concentrations and Standard Deviations of AZO in Test Chamber Atmospheres (mg/m^3)

Exposure Day	Low Mean	Low SD	Mid Mean	Mid SD	High Mean	High SD
1	5.0	1.8	11	1.1	58	14.0
2	1.6	1.2	8.0	1.5	73	23.8
3	1.8	0.1	8.9	2.0	71	3.9
4	2.7	0.1	17	1.3	52	2.0
5	0.61	0.7	0.0	0.0	6.5	6.4
6	2.3	0.1	15	1.0	35	5.1
7	2.4	0.1	16	2.1	29	3.3
8	2.6	0.2	15	1.0	46	7.6
9	2.4	0.2	8.0	2.0	56	2.5
10	2.4	0.1	16	1.3	69	7.4
11	2.2	0.5	16	1.3	49	3.8
12	2.6	0.1	16	1.4	52	3.3
13	3.6	0.4	18	1.7	43	3.2
14	2.9	0.2	14	0.0	33	1.6
15	3.6	0.5	20	2.2	55	4.6
16	2.0	0.1	13	1.7	58	8.7
17	1.9	0.1	13	0.8	40	3.4
18	2.5	0.3	11	1.0	36	1.9
19	2.4	0.2	13	1.4	75	3.4
20	3.3	0.3	13	0.5	69	6.8

Table 2 (cont.)

Mean Daily Concentrations and Standard Deviations of AZO in Test Chamber Atmospheres (mg/m^3)

Exposure Day	Low Mean	Low SD	Mid Mean	Mid SD	High Mean	High SD
21	2.5	0.2	15	1.3	50	5.1
22	2.7	0.1	15	0.8	41	2.1
23	2.6	0.2	15	0.0	51	1.9
24	2.4	0.2	14	1.7	48	2.1
25	2.6	0.1	14	1.0	59	4.2
26	2.4	0.4	15	0.6	60	4.4
27	2.2	0.1	14	1.9	37	2.5
28	2.5	0.1	15	1.0	57	4.3
29	2.3	0.1	13	1.4	53	3.2
30	2.5	0.1	15	1.0	64	4.1
31	4.0	3.6	14	1.5	37	2.2
32	2.5	0.1	14	0.6	57	3.1
33	2.4	0.1	14	0.5	47	3.6
34	2.3	0.1	12	0.8	48	4.2
35	2.4	0.1	16	1.9	51	2.9
36	2.6	0.2	15	0.8	66	3.9
37	2.6	0.1	14	0.0	48	7.1
38	2.6	0.1	15	0.5	71	5.9

Table 2 (cont.)

Mean Daily Concentrations and Standard Deviations of AZO in Test Chamber Atmospheres (mg/m^3)

Exposure Day	Low Mean	Low SD	Mid Mean	Mid SD	High Mean	High SD
39	2.6	± 0.1	13	± 0.5	55	± 2.6
40	2.7	± 0.0	15	± 0.5	53	± 3.9
41	2.9	± 0.1	13	± 1.0	54	± 2.9
42	2.6	± 0.1	16	± 0.5	42	± 3.6
43	2.5	± 0.1	14	± 1.0	58	± 3.9
44	2.6	± 0.1	16	± 1.0	51	± 3.5
45	2.6	± 0.1	14	± 0.8	56	± 5.0
46	2.6	± 0.1	14	± 0.8	65	± 4.2
47	2.4	± 0.1	12	± 1.0	55	± 3.9
48	2.6	± 0.1	17	± 1.7	45	± 3.3
49	2.8	± 0.1	15	± 1.0	44	± 4.3
50	2.9	± 0.2	17	± 1.7	66	± 4.7
51	2.8	± 0.2	16	± 0.8	53	± 3.6
52	2.9	± 0.1	17	± 1.0	60	± 4.3
53	2.7	± 0.2	16	± 2.8	64	± 9.0
54	3.0	± 0.1	15	± 1.0	68	± 7.6
55	2.7	± 0.1	17	± 0.6	65	± 4.9
56	2.9	± 0.2	16	± 1.0	52	± 4.7
57	2.6	± 0.1	16	± 1.5	57	± 3.1
58	2.8	± 0.1	16	± 1.5	62	± 3.3

Table 2 (cont.)

Mean Daily Concentrations and Standard Deviations
of AZO in Test Chamber Atmospheres
(mg/m^3)

Exposure Day	Low Mean	Low SD	Mid Mean	Mid SD	High Mean	High SD
59	2.9	0.2	14	1.4	48	2.1
60	2.8	0.2	15	1.2	43	2.1
61	3.0	0.2	15	1.0	36	1.7
62*	2.9	0.2	15	1.0	48	3.0
63*	3.0	0.1	16	1.3	36	2.5
64	3.1	0.1	16	0.8	39	2.5
65	2.9	0.2	16	1.3	37	3.2
66	2.9	0.1	16	1.0	56	2.4
67	2.8	0.1	14	1.3	50	4.0
68	3.0	0.1	14	1.5	48	2.6
69*	2.9	0.2	16	0.0	30	1.5
70*	3.2	0.1	16	1.0	59	2.9
71	2.2	0.3	14	0.5	38	4.2
72	2.5	0.2	14	0.8	38	2.8
73	2.3	0.3	14	1.4	64	5.7
74	2.5	0.8	13	0.5	40	2.1
75	2.4	0.1	13	1.0	27	1.8
76*	2.2	1.5	7.5	4.9	28	15.9

* 86127 only

Table 2 (cont.)

Mean Daily Concentrations and Standard Deviations
of AZO in Test Chamber Atmospheres
(mg/m^3)

Exposure Day	Low Mean	Low SD	Mid Mean	Mid SD	High Mean	High SD
77*	2.0	0.9	13	1.0	54	7.0
78	2.4	0.2	14	0.5	42	3.3
79	2.6	0.3	12	1.7	32	2.6
80	2.5	0.1	14	1.3	65	5.6
81	2.6	0.1	13	1.0	60	6.5
82	2.6	0.1	15	0.8	37	7.2
83*	2.5	0.1	14	1.4	56	7.9
84*	2.5	0.1	12	1.2	42	7.8
85*	-		12	1.0	-	
86*	-		14	2.8	-	
87*	-		14	1.4	-	
88*	-		13	0.8	-	
89*	-		12	1.0	-	

* 86127 only

Table 3

AZO Study Mean Chamber Concentrations
(86126 only)

	Chamber Concentrations (mg/m^3)		
	Low	Mid	High
Target	2.5	15	50
Analytical*	2.6	14	50
Standard Deviation	0.5	2.6	12.5
% Difference from target**	4.0	-6.7	0.0

* From daily mean concentrations.

** % Difference from target = $\frac{(\text{Mean Analytical} - \text{Mean Target})\ (100)}{\text{Mean Target}}$

Table 4

AZO Study Mean Chamber Concentrations
(86127 only)

	Chamber Concentrations (mg/m^3)		
	Low	Mid	High
Target	2.5	15	50
Analytical*	2.6	14	51
Standard Deviation	0.5	2.6	13.3
% Difference from target**	4.0	-6.7	2.0

* From daily mean concentrations.

** % Difference from target = $\frac{(\text{Mean Analytical} - \text{Mean Target})(100)}{\text{Mean Target}}$

Table 5

Daily Quality Control Results (mg/L Solution)*

Exposure Day	QC Low Expected	QC Low Found	QC Low %Diff**	QC Mid Expected	QC Mid Found	QC Mid %Diff**	QC High Expected	QC High Found	QC High %Diff**
1	2.28	2.25	-1.3	13.7	13.3	-2.9	45.5	45.8	0.7
2	2.28	2.17	-4.8	13.7	13.6	-0.7	45.5	46.9	3.1
3	2.28	2.28	0.0	13.7	13.2	-3.6	45.5	45.6	0.2
4	2.28	2.40	5.3	13.7	13.5	-1.5	45.5	45.1	-0.9
5	2.28	2.24	-1.8	13.7	13.3	-2.9	45.5	45.0	-1.1
6	2.28	2.39	4.8	13.7	13.5	-1.5	45.5	46.6	2.4
7	2.28	2.33	2.2	13.7	13.6	-0.7	45.5	46.9	3.1
8	2.28	2.27	-0.4	13.7	13.4	-2.2	45.5	46.3	1.8
9	2.38	2.38	0.0	14.3	13.0	-9.1	47.5	47.4	-0.2
10	2.38	2.16	-9.2	14.3	12.9	-9.8	47.5	47.0	-1.1
11	2.38	2.27	-4.6	14.3	14.4	0.7	47.5	45.5	-4.2
12	2.38	2.15	-9.7	14.3	13.7	-4.2	47.5	45.7	-3.8
13	2.38	2.27	-4.6	14.3	13.5	-5.6	47.5	46.0	-3.2
14	2.38	2.29	-3.8	14.3	13.4	-6.3	47.5	45.6	-4.0
15	2.38	2.39	0.4	14.3	15.7	9.8	47.5	50.8	6.9

* Values are reported in solution concentrations. These solution concentrations correspond to those obtained from samples at the study levels.

** % Difference = $\frac{(\text{Found-Expected})(100)}{\text{Expected}}$

Table 5 (cont.)

Daily Quality Control Results (mg/L Solution)*

Exposure Day	QC Low Expected	QC Low Found	QC Low %Diff**	QC Mid Expected	QC Mid Found	QC Mid %Diff**	QC High Expected	QC High Found	QC High %Diff**
16	2.38	2.28	-4.2	14.3	13.5	-5.6	47.5	44.4	-6.5
17	2.38	2.23	-6.3	14.3	13.6	-4.9	47.5	44.0	-7.4
18	2.38	2.08	-12.6	14.3	13.3	-7.0	47.5	42.6	-10.3
19	2.40	2.36	-1.7	14.4	14.0	-2.8	48.0	47.5	-1.0
20	2.40	2.31	-3.8	14.4	13.8	-4.2	48.0	47.1	-1.9
21	2.40	2.58	7.5	14.4	14.1	-2.1	48.0	47.6	-0.8
22	2.40	2.33	-2.9	14.4	14.1	-2.1	48.0	48.1	0.2
23	2.40	2.31	-3.8	14.4	14.2	-1.4	48.0	47.9	-0.2
24	2.40	2.32	-3.3	14.4	14.3	-0.7	48.0	47.7	-0.6
25	2.40	2.36	-1.7	14.4	14.5	0.7	48.0	48.0	0.0
26	2.40	2.35	-2.1	14.4	14.6	1.4	48.0	47.8	-0.4
27	2.50	2.59	3.6	15.0	15.0	0.0	50.0	50.9	1.8
28	2.50	2.53	1.2	15.0	14.4	-4.0	50.0	49.3	-1.4
29	2.50	2.48	0.8	15.0	14.9	-0.7	50.0	53.0	6.0
30	2.50	2.43	-2.8	15.0	14.5	-3.3	50.0	50.6	1.2

* Values are reported in solution concentrations. These solution concentrations correspond to those obtained from samples at the study levels.

** % Difference = $\frac{(\text{Found}-\text{Expected})(100)}{\text{Expected}}$

Table 5 (cont.)

Daily Quality Control Results (mg/L Solution)*

Exposure Day	QC Low Expected	QC Low Found	QC Low %Diff**	QC Mid Expected	QC Mid Found	QC Mid %Diff**	QC High Expected	QC High Found	QC High %Diff**
31	2.50	2.54	1.6	15.0	14.4	-4.0	50.0	51.1	2.2
32	2.50	2.51	0.4	15.0	14.8	-1.3	50.0	51.5	3.0
33	2.50	2.52	0.8	15.0	14.6	-2.7	50.0	50.9	1.8
34	2.50	2.46	-1.6	15.0	14.4	-4.0	50.0	51.7	3.4
35	2.50	2.50	0.0	15.0	14.9	-0.7	50.0	51.8	3.6
36	2.50	2.51	0.4	15.0	14.8	-1.3	50.0	51.5	3.0
37	2.50	2.56	2.4	15.0	14.4	-4.0	50.0	47.5	-5.0
38	2.50	2.48	-0.8	15.0	14.4	-4.0	50.0	47.9	-4.2
39	2.50	2.36	-5.6	15.0	13.9	-7.3	50.0	47.9	-4.2
40	2.50	2.44	-2.4	15.0	14.0	-6.7	50.0	47.9	-4.2
41	2.50	2.48	-0.8	15.0	14.1	-6.0	50.0	48.6	-2.8
42	2.50	2.43	-2.8	15.0	14.0	-6.7	50.0	48.5	-3.0
43	2.50	2.45	-2.0	15.0	14.2	-5.3	50.0	48.7	-2.6
44	2.50	2.45	-2.0	15.0	15.0	0.0	50.0	52.7	5.4
45	2.50	2.53	1.2	15.0	14.2	-5.3	50.0	49.0	-2.0
46	2.50	2.48	-0.8	15.0	14.4	-4.0	50.0	49.2	-1.6

* Values are reported in solution concentrations. These solution concentrations correspond to those obtained from samples at the study levels.

** % Difference = $\frac{(\text{Found}-\text{Expected})(100)}{\text{Expected}}$

Table 5 (cont.)

Daily Quality Control Results (mg/L Solution)*

Exposure Day	QC Low Expected	QC Low Found	QC Low %Diff**	QC Mid Expected	QC Mid Found	QC Mid %Diff**	QC High Expected	QC High Found	QC High %Diff**
47	2.65	2.66	0.4	15.9	15.8	-0.6	53.0	55.3	4.3
48	2.65	2.66	0.4	15.9	15.5	-2.5	53.0	55.8	5.3
49	2.65	2.66	0.4	15.9	15.8	-0.6	53.0	56.9	7.4
50	2.65	2.66	0.4	15.9	15.7	-1.3	53.0	58.1	9.6
51	2.65	2.47	-6.8	15.9	15.5	-2.5	53.0	56.6	6.8
52	2.65	2.69	1.5	15.9	15.6	-1.9	53.0	55.7	5.1
53	2.65	2.70	1.9	15.9	15.7	-1.3	53.0	55.6	4.9
54	2.65	2.69	1.5	15.9	15.8	-0.6	53.0	56.3	6.2
55	2.65	2.61	-1.5	15.9	15.6	-1.9	53.0	56.0	5.7
56	2.65	2.70	1.9	15.9	15.7	-1.3	53.0	56.3	6.2
57	2.55	2.72	6.7	15.3	15.9	3.9	51.0	55.8	9.4
58	2.55	2.72	6.7	15.3	16.0	4.6	51.0	55.5	8.8
59	2.55	2.67	4.7	15.3	15.9	3.9	51.0	55.3	8.4
60	2.55	2.71	6.3	15.3	15.9	3.9	51.0	55.1	8.0

* Values are reported in solution concentrations. These solution concentrations correspond to those obtained from samples at the study levels.

** % Difference = $\frac{(\text{Found}-\text{Expected})\ (100)}{\text{Expected}}$

Table 5 (cont.)

Daily Quality Control Results (mg/L Solution)*

Exposure Day	QC Low Expected	QC Low Found	QC Low %Diff**	QC Mid Expected	QC Mid Found	QC Mid %Diff**	QC High Expected	QC High Found	QC High %Diff**
61	2.55	2.66	4.3	15.3	15.8	3.3	51.0	55.0	7.8
62***	2.55	2.71	6.3	15.3	15.9	3.9	51.0	55.6	9.0
63***	2.55	2.69	5.5	15.3	15.7	2.6	51.0	54.6	7.1
64	2.55	2.75	7.8	15.3	15.9	3.9	51.0	54.8	7.5
65	2.55	2.69	5.5	15.3	15.7	2.6	51.0	53.5	4.9
66	2.55	2.67	4.7	15.3	16.1	5.2	51.0	54.7	7.3
67	2.55	2.68	5.1	15.3	15.7	2.6	51.0	53.4	4.7
68	2.55	2.71	6.3	15.3	15.9	3.9	51.0	53.5	4.9
69***	2.55	2.74	7.5	15.3	15.7	2.6	51.0	52.7	3.3
70***	2.55	2.72	6.7	15.3	15.9	3.9	51.0	51.9	1.8
71	2.48	2.22	-10.5	14.9	14.9	0.0	49.5	50.2	1.4
72	2.48	2.49	0.4	14.9	15.3	2.7	49.5	48.4	-2.2
73	2.48	2.40	-3.2	14.9	15.4	3.4	49.5	48.7	-1.6
74	2.48	2.38	-4.0	14.9	15.0	0.7	49.5	48.5	-2.0
75	2.48	2.41	-2.8	14.9	15.2	2.0	49.5	48.6	-1.8

* Values are reported in solution concentrations. These solution concentrations correspond to those obtained from samples at the study levels.

** % Difference = $\frac{\text{(Found-Expected) (100)}}{\text{Expected}}$

***86127 only.

Table 5 (cont.)

Daily Quality Control Results (mg/L Solution)*

Exposure Day	QC Low Expected	QC Low Found	QC Low %Diff**	QC Mid Expected	QC Mid Found	QC Mid %Diff**	QC High Expected	QC High Found	QC High %Diff**
76***	2.48	2.52	1.6	14.9	15.0	0.7	49.5	47.9	-3.2
77***	2.48	2.50	0.8	14.9	15.1	1.3	49.5	48.3	-2.4
78	2.48	2.52	1.6	14.9	14.9	0.0	49.5	47.6	-3.8
79	2.48	2.49	0.4	14.9	15.4	3.4	49.5	46.6	-5.9
80	2.48	2.49	0.4	14.9	15.2	2.0	49.5	46.6	-5.9
81	2.48	2.45	-1.2	14.9	15.6	4.7	49.5	45.7	-7.7
82	2.48	2.47	-0.4	14.9	15.4	3.4	49.5	45.4	-8.3
83***	2.48	2.47	-0.4	14.9	16.0	7.4	49.5	45.2	-8.7
84***	2.48	2.53	2.0	14.9	16.2	8.7	49.5	43.8	-11.5
85***	-	-	-	15.0	14.1	-6.0	-	-	-
86***	-	-	-	15.0	14.1	-6.0	-	-	-
87***	-	-	-	15.0	13.9	-7.3	-	-	-
88***	-	-	-	15.0	13.8	-8.0	-	-	-
89***	-	-	-	15.0	13.8	-8.0	-	-	-

* Values are reported in solution concentrations. These solution concentrations correspond to those obtained from samples at the study levels.

** % Difference = $\frac{(\text{Found}-\text{Expected})\ (100)}{\text{Expected}}$

***86127 only.

Note: All values are obtained by summing peak areas from both AZO and its major decomposition product, 2,6-diethylaniline (DEA).

Table 6

Quality Control Mean and Mean % Difference*
(86126 only)

	Concentration (mg/L) Solution*		
	Low	Mid	High
Mean Expected	2.47	14.9	49.4
Mean Found	2.48	14.7	50.0
Mean % Difference**	0.4	-1.3	1.2

* Values are reported in solution concentrations. These solution concentrations correspond to those obtained from samples at the study levels.

** Mean % Difference = $\frac{(\text{Mean Found}-\text{Mean Expected})(100)}{\text{Mean Expected}}$

Table 7

Quality Control Mean and Mean % Difference*
(86127 only)

	Concentration (mg/L) Solution)*		
	Low	Mid	High
Mean Expected	2.48	14.9	49.5
Mean Found	2.46	14.7	50.0
Mean % Difference**	-0.8	-1.3	1.0

* Values are reported in solution concentrations. These solution concentrations correspond to those obtained from samples at the study levels.

** Mean % Difference = $\frac{\text{(Mean Found-Mean Expected) (100)}}{\text{Mean Expected}}$

Table 8

Results of Stability Assessments of 2,6-diethylphenyl azomethine
(2 lots: T860069 and T870001)

Date Assayed	Lot No.	Assay (%)*
11/19/86	T860069	100**
1/19/87	T860069	104
1/19/87	T870001	100**
3/23/87	T870001	95.6

* Assay results are obtained by summing peak areas of both AZO and its major decomposition product, 2,6-diethylaniline (DEA). The percent DEA (by peak area) was typically 15-25%. Five replicate assays were performed and the values reported are the means.

** By definition (pre-study, initial assay).

Table 9

Formaldehyde Chamber Concentrations (PPM)

Study Day	Level	Draeger Tube Procedure	Analytical Determination*
67	Low	1	1.4
	Mid	4	7.1
	High	>8 **	29
68	Low	0.7	1.2
	Mid	4	5.7
	High	>8 **	21
All	Low	1	-
	Mid	4	-
	High	>8 **	-

* Mean of duplicate determinations. (Gas Chromatographic procedure).

** Estimates (above accurate range of Draeger Tubes).

Exhibit 4

EHL 86126 - Daily Nominal Atmospheric Chamber Concentrations

Exp Day	Target Levels (mg/m3) 2.5	15	50
1	4	17	179
2	5	23	198
3	4	25	144
4	5	29	90
5	6	14	17
6	4	36	76
7	4	25	125
8	4	30	152
9	4	26	124
10	5	30	124
11	4	26	97
12	5	25	96
13	7	26	99
14	4	26	102
15	6	29	137
16	3	22	131
17	3	29	97
18	4	22	128
19	4	25	154
20	7	31	120
21	4	28	115
22	4	23	97
23	3	24	114
24	4	24	116
25	4	23	114
26	4	23	115
27	4	24	115
28	4	23	115
29	4	23	115
30	5	24	116
31	4	22	114
32	4	24	115
33	4	24	114
34	4	23	114
35	4	24	115
36	3	24	116
37	4	23	115
38	4	23	115
39	5	23	114
40	4	23	111
41	4	22	115
42	4	24	113
43	4	26	114

EHL 86126 - Daily Nominal Atmospheric Chamber Concentrations

Exp Day	Target Levels (mg/m3) 2.5	15	50
44	4	23	113
45	4	23	114
46	4	24	114
47	4	24	115
48	4	24	116
49	4	23	114
50	4	23	114
51	4	24	114
52	4	24	115
53	4	23	114
54	5	23	115
55	4	23	116
56	4	23	96
57	4	23	95
58	4	23	96
59	5	22	77
60	4	21	80
61	5	21	78
64	4	21	89
65	4	21	90
66	5	21	111
67	4	22	102
68	4	22	102
71	4	20	102
72	4	21	101
73	4	22	111
74	4	21	100
75	4	21	100
78	4	21	100
79	4	22	101
80	4	21	130
81	5	21	126
82	4	21	123
MEAN :	4	24	112
STD DEV :	1	3	22
HIGH VALUE:	7	36	198
LOW VALUE :	3	14	17
NUMBER :	76	76	76

EHL 86127 - Daily Nominal Atmospheric Chamber Concentrations

Exp Day	Target Levels (mg/m3) 2.5	15	50
1	4	17	179
2	5	23	198
3	4	25	144
4	5	29	90
5	6	14	17
6	4	36	76
7	4	25	125
8	4	30	152
9	4	26	124
10	5	30	124
11	4	26	97
12	5	25	96
13	7	26	99
14	4	26	102
15	6	29	137
16	3	22	131
17	3	29	97
18	4	22	128
19	4	25	154
20	7	31	120
21	4	28	115
22	4	23	97
23	3	24	114
24	4	24	116
25	4	23	114
26	4	23	115
27	4	24	115
28	4	23	115
29	4	23	115
30	5	24	116
31	4	22	114
32	4	24	115
33	4	24	114
34	4	23	114
35	4	24	115
36	3	24	116
37	4	23	115
38	4	23	115
39	5	23	114
40	4	23	111
41	4	22	115
42	4	24	113
43	4	26	114
44	4	23	113
45	4	23	114
46	4	24	114
47	4	24	115
48	4	24	116

EHL 86127 - Daily Nominal Atmospheric Chamber Concentrations

Exp Day	Target Levels (mg/m3) 2.5	15	50
49	4	23	114
50	4	23	114
51	4	24	114
52	4	24	115
53	4	23	114
54	5	23	115
55	4	23	116
56	4	23	96
57	4	23	95
58	4	23	96
59	5	22	77
60	4	21	80
61	5	21	78
62	4	21	80
63	4	21	80
64	4	21	89
65	4	21	90
66	5	21	111
67	4	22	102
68	4	22	102
69	4	21	102
70	5	23	102
71	4	20	102
72	4	21	101
73	4	22	111
74	4	21	100
75	4	21	100
76	6	16	57
77	3	21	104
78	4	21	100
79	4	22	101
80	4	21	130
81	5	21	126
82	4	21	123
83	5	22	131
84	5	22	130
85		20	
86		23	
87		22	
88		22	
89		21	
MEAN :	4	23	110
STD DEV :	1	3	23
HIGH VALUE:	7	36	198
LOW VALUE :	3	14	17
NUMBER :	84	89	84

Exhibit 5

EHL 86126,86127 - CHAMBER DISTRIBUTION

	Analytical Concentration (mg/m^3)			
Sample Location	Low (2.5) 12/02/86	Low (2.5) 03/12/87	Mid (15) 12/03/86	Mid (15) 03/10/87
Routine Sampling Port	2.4	2.5	15	12
Top Left Front of Animal Area	2.3	2.1	16	13
Middle of Animal Area	2.0	2.3	12	12
Back Right Bottom of Animal Area	2.5	2.1	17	8.1
Top Right Middle of Animal Area	2.8	2.1	16	12
Routine Sampling Port	2.7	2.4	16	13
Mean Concentration (all locations)	2.5	2.3	15	12
Standard Deviation	0.3	0.2	1.8	1.8
% Range	32	17	33	41

EHL 86126,86127 - CHAMBER DISTRIBUTION

	Analytical Concentration (mg/m^3)	
	High (50) 12/09/86	High (50) 03/11/87
Sample Location		
Routine Sampling Port	51	72
Top Left Front of Animal Area	NM	74
Middle of Animal Area	50	67
Back Right Bottom of Animal Area	53	58
Top Right Middle of Animal Area	51	68
Routine Sampling Port	53	72
Mean Concentration (all locations)	52	69
Standard Deviation	1.3	5.8
% Range	5.8	23

NM = Non-measurable; therefore omitted from the mean.

% Range = (High Value - Low Value)/Mean x 100

Exhibit 6

SUMMARY OF INDIVIDUAL CHAMBER ENVIRONMENTAL MEASUREMENTS

STUDY NUMBER 86126 FROM: 20-NOV-1986
TO: 13-MAR-1987

NUMBER OF EXPOSURE DAYS: 76

		PRESS (IN.H20)	FLOW (L/M)	RH (%)	TEMP (DEG C)
GROUP 1	MEAN	-0.8	2704.5	30.1	22.0
	STD DEV	0.1	27.5	9.5	0.6
	STD ERR	0.0	0.9	0.3	0.0
	MINIMUM	-1.0	2395.5	12.0	20.5
	MAXIMUM	-0.6	2792.5	57.0	24.1
GROUP 2	MEAN	-0.4	2196.0	31.3	23.7
	STD DEV	0.6	122.8	10.0	1.0
	STD ERR	0.0	3.9	0.3	0.0
	MINIMUM	-0.6	1993.2	15.0	21.0
	MAXIMUM	1.5	2456.1	61.0	26.5
GROUP 3	MEAN	-0.7	2349.3	32.9	21.5
	STD DEV	0.2	208.9	9.6	0.7
	STD ERR	0.0	6.6	0.3	0.0
	MINIMUM	-7.0	2029.7	7.0	19.7
	MAXIMUM	-0.4	2766.1	62.0	23.7
GROUP N	MEAN	-1.6	2094.0	31.8	22.7
	STD DEV	0.1	15.3	11.4	0.7
	STD ERR	0.0	0.5	0.4	0.0
	MINIMUM	-1.8	2029.7	7.0	20.8
	MAXIMUM	-1.1	2169.9	81.0	25.0

SUMMARY OF DAILY MEAN CHAMBER ENVIRONMENTAL MEASUREMENTS

STUDY NUMBER 86126 FROM: 20-NOV-1986
TO: 13-MAR-1987

NUMBER OF EXPOSURE DAYS: 76

		PRESS (IN.H2O)	FLOW (L/M)	RH (%)	TEMP (DEG C)
GROUP 1	MEAN	-0.8	2704.5	30.1	22.0
	STD DEV	0.0	24.3	9.3	0.6
	STD ERR	0.0	2.8	1.1	0.1
	MINIMUM	-1.0	2559.5	13.6	20.8
	MAXIMUM	-0.7	2716.5	52.2	23.5
GROUP 2	MEAN	-0.4	2196.0	31.3	23.7
	STD DEV	0.6	123.4	9.7	0.8
	STD ERR	0.1	14.2	1.1	0.1
	MINIMUM	-0.6	2024.1	17.2	22.0
	MAXIMUM	1.5	2428.3	58.1	25.2
GROUP 3	MEAN	-0.7	2349.3	32.9	21.5
	STD DEV	0.1	208.7	9.3	0.6
	STD ERR	0.0	23.9	1.1	0.1
	MINIMUM	-1.2	2035.3	11.2	20.0
	MAXIMUM	-0.4	2712.4	59.8	23.1
GROUP N	MEAN	-1.6	2094.0	31.8	22.7
	STD DEV	0.1	7.5	11.0	0.6
	STD ERR	0.0	0.9	1.3	0.1
	MINIMUM	-1.7	2073.8	10.2	21.2
	MAXIMUM	-1.2	2106.3	75.8	24.3

SUMMARY OF INDIVIDUAL CHAMBER ENVIRONMENTAL MEASUREMENTS

STUDY NUMBER 86127 FROM: 20-NOV-1986
TO: 20-MAR-1987

NUMBER OF EXPOSURE DAYS: 89

		PRESS (IN.H2O)	FLOW (L/M)	RH (%)	TEMP (DEG C)
GROUP 1	MEAN	-0.8	2704.8	30.6	22.0
	STD DEV	0.1	26.4	9.4	0.6
	STD ERR	0.0	0.8	0.3	0.0
	MINIMUM	-1.1	2395.5	12.0	20.5
	MAXIMUM	-0.6	2792.5	57.0	24.1
GROUP 2	MEAN	-0.4	2214.6	32.6	23.7
	STD DEV	0.5	124.6	10.3	1.0
	STD ERR	0.0	3.7	0.3	0.0
	MINIMUM	-0.6	1993.2	15.0	21.0
	MAXIMUM	1.5	2456.1	61.0	26.5
GROUP 3	MEAN	-0.7	2354.4	33.6	21.4
	STD DEV	0.2	209.5	9.8	0.7
	STD ERR	0.0	6.3	0.3	0.0
	MINIMUM	-7.0	2029.7	7.0	19.7
	MAXIMUM	-0.4	2766.1	62.0	23.7
GROUP N	MEAN	-1.6	2094.6	33.0	22.5
	STD DEV	0.1	14.6	11.5	0.7
	STD ERR	0.0	0.4	0.3	0.0
	MINIMUM	-1.8	2029.7	7.0	20.8
	MAXIMUM	-1.1	2169.9	81.0	25.0

SUMMARY OF DAILY MEAN CHAMBER ENVIRONMENTAL MEASUREMENTS

STUDY NUMBER 86127 FROM: 20-NOV-1986
TO: 20-MAR-1987

NUMBER OF EXPOSURE DAYS: 89

		PRESS (IN.H2O)	FLOW (L/M)	RH (%)	TEMP (DEG C)
GROUP 1	MEAN	-0.8	2704.8	30.6	22.0
	STD DEV	0.0	23.1	9.2	0.6
	STD ERR	0.0	2.5	1.0	0.1
	MINIMUM	-1.0	2559.5	13.6	20.8
	MAXIMUM	-0.7	2716.5	52.2	23.5
GROUP 2	MEAN	-0.4	2214.6	32.6	23.7
	STD DEV	0.5	124.8	10.1	0.8
	STD ERR	0.1	13.2	1.1	0.1
	MINIMUM	-0.6	2024.1	17.2	22.0
	MAXIMUM	1.5	2428.3	58.1	25.2
GROUP 3	MEAN	-0.7	2354.4	33.6	21.4
	STD DEV	0.1	208.8	9.4	0.6
	STD ERR	0.0	22.8	1.0	0.1
	MINIMUM	-1.2	2035.3	11.2	20.0
	MAXIMUM	-0.4	2712.4	59.8	23.1
GROUP N	MEAN	-1.6	2094.6	33.0	22.5
	STD DEV	0.1	7.2	11.2	0.7
	STD ERR	0.0	0.8	1.2	0.1
	MINIMUM	-1.7	2073.8	10.2	21.2
	MAXIMUM	-1.2	2106.3	75.8	24.3

APPENDIX 2

FERTILITY STUDY (86126) DATA

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86126 INDIVIDUAL BODY WEIGHT DATA (GM)
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: MALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE (1986): 26-NOV	3-DEC	10-DEC	17-DEC	23-DEC	30-DEC	7-JAN	14-JAN	21-JAN	28-JAN	4-FEB	11-FEB
	DAY OF STUDY: 7	14	21	28	34	41	49	56	63	70	77	84
86126MN 001	280.0	325.8	368.3	401.9	423.9	455.9	475.0	484.8	494.1	507.7	524.2	538.8
86126MN 002	278.4	317.8	347.6	379.5	378.7	401.2	419.6	432.9	446.8	462.8	474.0	486.1
86126MN 003	246.2	287.8	328.6	367.8	378.7	410.2	424.2	442.6	454.4	472.0	491.7	506.4
86126MN 004	263.7	309.4	346.4	376.5	389.5	414.7	439.0	456.4	472.8	485.1	501.9	508.8
86126MN 005	276.7	332.1	377.2	427.0	463.7	505.1	540.8	565.4	590.8	615.1	635.0	662.6
86126MN 006	245.4	287.4	325.7	360.8	367.0	402.4	427.5	437.0	443.3	464.3	471.5	474.6
86126MN 007	248.7	294.7	328.3	367.6	382.3	414.4	420.8	431.7	448.5	457.6	471.6	478.9
86126MN 008	249.5	309.4	358.5	405.3	429.9	463.3	484.2	479.0	513.4	536.3	549.4	557.7
86126MN 009	235.7	288.5	325.2	366.6	391.3	415.2	431.8	450.9	464.5	495.8	511.7	530.9
86126MN 010	246.4	280.8	317.6	345.3	354.1	380.7	392.2	409.0	408.5	419.6	435.9	442.6
86126MN 011	261.3	305.3	333.9	368.5	386.3	411.8	425.4	438.8	449.5	465.0	479.2	483.4
86126MN 012	225.5	258.2	283.9	318.4	335.4	361.2	375.3	385.0	385.7	399.0	405.0	417.3
86126MN 013	264.8	302.4	333.9	368.1	382.1	404.2	428.1	434.1	444.4	458.2	470.5	474.6
86126MN 014	255.8	295.2	336.7	363.6	388.8	406.6	426.5	435.5	436.9	455.9	465.1	461.2
86126MN 015	266.2	320.1	361.3	402.3	426.3	466.3	489.4	514.6	531.3	550.8	558.4	585.9
86126MN 016	262.2	308.0	352.0	366.9	384.3	402.9	425.8	438.2	447.4	462.4	471.1	483.6
86126MN 017	256.6	301.8	340.5	368.7	386.1	411.0	425.7	442.5	454.8	474.6	491.1	504.6
86126MN 018	252.8	293.9	331.9	370.2	384.1	412.3	433.7	452.8	458.3	475.0	483.0	497.9
86126MN 019	253.4	305.0	343.3	377.8	393.2	415.0	439.1	453.1	464.8	477.4	495.0	493.4
86126MN 020	238.4	277.4	306.1	330.9	353.3	373.8	389.3	398.3	406.0	416.1	423.2	429.7
86126MN 021	262.3	298.0	338.7	380.0	389.9	416.0	442.9	461.8	467.7	473.1	490.7	505.9
86126MN 022	266.4	299.2	336.8	379.7	389.9	424.3	446.6	462.7	469.7	479.4	494.4	502.9
86126MN 023	257.9	307.7	349.1	386.3	399.6	432.9	466.2	489.2	509.3	517.3	546.1	564.5
86126MN 024	274.3	315.9	358.7	392.1	414.2	441.3	452.9	471.1	478.1	495.3	500.4	508.4
86126MN 025	255.7	292.2	332.1	368.4	388.2	418.4	438.6	459.4	460.1	478.5	498.2	506.5

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: MALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE (1987): 18-FEB	25-FEB	4-MAR	11-MAR	18-MAR	25-MAR
	DAY OF STUDY: 91	98	105	112	119	126
86126MN 001	544.2	558.3	564.1	581.8	591.4	613.2
86126MN 002	500.1	502.4	508.1	514.9	523.7	539.1
86126MN 003	518.6	526.3	535.2	543.1	552.5	565.9
86126MN 004	512.0	526.7	536.5	548.8	555.6	565.9
86126MN 005	671.4	696.1	714.2	731.2	737.6	761.5
86126MN 006	483.6	501.8	518.2	528.1	528.9	541.3
86126MN 007	508.6	517.2	521.6	520.5	528.3	533.1
86126MN 008	572.8	583.0	582.9	594.3	605.8	628.9
86126MN 009	550.9	554.2	568.3	580.3	592.0	590.8
86126MN 010	455.3	458.3	468.8	476.9	469.2	489.8
86126MN 011	488.6	501.0	513.2	515.2	512.6	526.4
86126MN 012	416.8	434.4	442.3	447.4	458.2	473.1
86126MN 013	480.6	484.4	498.5	507.4	509.8	525.8
86126MN 014	457.7					
86126MN 015	580.1	587.8	601.7	608.5	616.0	634.9
86126MN 016	474.8	491.6	503.9	509.3	513.7	530.0
86126MN 017	518.9	518.1	521.2	523.3	535.9	553.8
86126MN 018	498.5	502.7	496.2	498.0	511.0	530.2
86126MN 019	500.7	515.5	529.8	534.1	533.1	546.3
86126MN 020	427.7	450.6	458.8	466.5	433.1	444.7
86126MN 021	498.0	511.4	524.2	530.4	528.7	539.2
86126MN 022	509.7	521.4	526.4	538.5	547.2	562.3
86126MN 023	578.9	577.6	592.2	602.4	618.6	630.6
86126MN 024	521.7	519.9	527.2	536.9	534.3	543.5
86126MN 025	505.5	486.4	527.4	541.0	545.5	556.2

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE (1986): 26-NOV	3-DEC	10-DEC	17-DEC	23-DEC	30-DEC	7-JAN	14-JAN	21-JAN	28-JAN	4-FEB	11-FEB
	DAY OF STUDY: 7	14	21	28	34	41	49	56	63	70	77	84
86126M1 001	259.6	297.6	324.7	353.0	366.0	404.6	433.8	451.7	470.5	499.8	523.7	543.4
86126M1 002	254.3	299.3	340.2	389.6	398.4	428.4	463.2	489.2	502.3	533.5	555.2	563.9
86126M1 003	262.8	314.2	355.9	403.8	419.1	443.2	470.4	496.7	515.7	530.6	549.5	554.0
86126M1 004	248.6	296.6	323.1	354.6	369.6	402.1	433.6	449.3	442.1	469.0	409.8	430.0
86126M1 005	251.9	282.3	314.3	343.0	368.9	394.2	416.8	439.5	450.1	476.8	484.7	493.2
86126M1 006	259.9	310.7	352.0	375.2	390.2	420.9	433.1	446.9	459.0	467.6	476.1	474.5
86126M1 007	283.7	336.3	375.7	414.1	422.9	454.9	476.6	492.8	515.4	538.8	551.5	570.0
86126M1 008	278.5	332.7	243.3	359.4	405.1	441.4	456.4	490.2	508.3	536.6	559.8	547.4
86126M1 009	228.9	270.4	304.4	347.0	368.8	394.8	417.1	437.4	448.9	466.8	474.0	490.9
86126M1 010	261.9	310.4	342.1	378.4	398.8	431.5	456.5	471.0	479.4	504.4	513.8	524.5
86126M1 011	244.4	292.6	336.1	365.7	382.4	404.5	430.3	454.9	463.0	484.5	495.0	508.0
86126M1 012	241.1	286.7	327.9	372.2	397.8	428.5	459.7	479.5	494.5	510.0	521.4	538.0
86126M1 013	252.6	292.0	330.9	359.3	379.8	404.7	430.0	441.3	448.6	461.4	467.5	488.8
86126M1 014	254.3	292.9	321.2	355.3	379.7	408.1	432.9	457.1	466.6	474.7	489.3	500.2
86126M1 015	275.4	317.4	375.1	414.7	445.5	479.5	500.4	518.8	539.4	567.3	570.3	573.4
86126M1 016	240.2	290.6	331.5	370.5	398.6	429.4	462.0	484.2	497.3	507.2	514.5	533.3
86126M1 017	267.0	326.0	365.5	403.1	428.3	451.8	494.8	512.8	531.0	552.4	563.9	574.9
86126M1 018	239.1	283.1	319.5	350.3	372.8	391.2	414.0	429.6	440.7	451.4	460.6	472.3
86126M1 019	282.0	322.0	363.1	391.4	406.5	437.5	452.1	478.2	494.2	507.2	510.7	528.5
86126M1 020	243.4	287.1	332.0	357.0	373.7	393.9	423.7	439.6	449.6	469.8	476.9	485.4
86126M1 021	228.5	271.2	301.9	331.7	348.8	376.1	399.5	423.6	430.9	445.1	448.1	465.9
86126M1 022	245.4	301.5	342.9	385.0	409.4	439.5	469.4	495.7	509.7	523.5	541.8	559.3
86126M1 023	268.4	319.4	373.4	401.1	424.6	465.8	491.0	523.4	544.2	565.1	578.6	588.9
86126M1 024	274.5	322.0	359.5	396.6	414.8	438.1	472.6	491.9	506.3	535.3	543.6	544.1
86126M1 025	250.9	283.3	310.7	347.0	365.3	382.2	394.3	408.3	421.7	434.9	441.2	445.1

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86126 INDIVIDUAL BODY WEIGHT DATA (GM)
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE (1987): 18-FEB	25-FEB	4-MAR	11-MAR	18-MAR	25-MAR
	DAY OF STUDY: 91	98	105	112	119	126
86126M1 001	552.8	521.1	534.8	559.8	570.4	583.1
86126M1 002	562.5	576.6	598.2	617.6	606.2	618.4
86126M1 003	552.3	559.6	580.8	570.1	570.3	576.6
86126M1 004	439.9	469.8	490.2	497.2	500.3	513.8
86126M1 005	505.0	514.9	532.2	526.2	534.3	559.0
86126M1 006	487.3	498.8	508.9	517.1	512.7	532.9
86126M1 007	580.2	576.4	595.8	595.5	595.8	613.6
86126M1 008	547.0	559.1	589.1	603.2	602.8	612.3
86126M1 009	482.7	489.7	501.2	498.0	498.7	515.7
86126M1 010	526.3	534.1	551.6	565.3	571.4	587.0
86126M1 011	502.0	516.0	529.9	535.1	549.6	566.9
86126M1 012	547.5	557.1	563.7	574.1	593.0	618.0
86126M1 013	492.6	496.7	508.1	516.4	518.9	536.3
86126M1 014	497.9	505.6	526.2	526.3	525.2	551.7
86126M1 015	582.2	596.3	615.5	637.0	637.8	660.7
86126M1 016	544.4	553.0	568.3	563.8	575.3	589.9
86126M1 017	585.6	584.9	581.0	583.0	601.7	632.5
86126M1 018	464.7	484.4	489.4	495.5	498.4	505.4
86126M1 019	531.2	537.9	557.5	566.8	551.8	561.9
86126M1 020	492.2	496.3	511.3	527.2	488.7	509.7
86126M1 021	469.1	479.1	485.3	478.5	449.3	467.4
86126M1 022	568.5	579.0	586.3	592.1	592.9	601.1
86126M1 023	591.8	607.3	623.8	639.6	644.2	658.4
86126M1 024	564.5	574.1	591.2	606.0	603.2	618.9
86126M1 025	450.8	456.0	464.2	472.7	481.6	498.8

STUDY NUMBER: 86126 INDIVIDUAL BODY WEIGHT DATA (GM)
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL		DATE (1986): 26-NOV	3-DEC	10-DEC	17-DEC	23-DEC	30-DEC	7-JAN	14-JAN	21-JAN	28-JAN	4-FEB	11-FEB
		DAY OF STUDY: 7	14	21	28	34	41	49	56	63	70	77	84
86126M2	001	247.6	288.9	323.9	354.4	371.5	393.3	418.3	431.0	444.4	466.1	471.7	467.9
86126M2	002	255.0	292.8	332.2	369.3	384.9	408.7	436.4	456.9	461.8	482.9	499.3	519.3
86126M2	003	258.6	292.9	319.8	350.5	360.9	386.7	405.5	421.3	427.6	440.8	453.9	468.8
86126M2	004	239.8	282.0	319.5	364.9	375.1	403.2	422.0	451.0	468.4	491.8	502.2	520.9
86126M2	005	255.8	293.5	326.2	354.4	370.5	393.0	409.6	423.2	431.9	452.0	469.2	476.4
86126M2	006	234.5	274.4	307.8	330.7	343.6	366.9	393.1	407.9	415.8	430.2	439.7	452.0
86126M2	007	281.4	330.2	372.1	414.2	437.3	467.9	479.7	492.7	514.6	549.4	570.0	592.3
86126M2	008	261.2	309.1	347.6	379.9	402.5	429.0	454.9	469.0	486.2	503.1	512.3	526.0
86126M2	009	266.4	308.9	347.8	382.1	398.0	431.9	453.0	477.7	481.1	502.0	514.6	535.8
86126M2	010	240.3	281.2	315.3	354.8	369.6	389.2	414.5	425.4	434.3	453.2	458.0	463.7
86126M2	011	242.7	276.5	296.4	321.5	339.4	368.0	384.2	400.2	399.3	419.3	436.1	452.7
86126M2	012	255.2	301.0	344.3	378.5	393.5	418.9	439.5	453.2	467.1	485.4	493.6	498.2
86126M2	013	256.0	298.1	332.3	366.0	370.6	400.2	424.7	442.5	449.5	462.4	477.8	478.7
86126M2	014	241.8	277.7	317.4	348.0	366.9	385.0	404.7	416.5	425.4	439.0	447.8	448.6
86126M2	015	239.1	274.6	307.9	340.6	352.6	379.7	408.8	434.6	444.0	461.0	469.6	481.7
86126M2	016	242.2	277.9	326.8	359.2	379.4	405.5	425.4	441.7	460.7	475.7	482.9	490.9
86126M2	017	223.4	263.7	296.7	330.0	346.6	364.4	384.5	399.9	410.5	422.0	428.9	436.0
86126M2	018	271.6	325.2	363.7	408.1	425.7	456.5	479.5	491.7	509.1	524.6	544.8	555.5
86126M2	019	270.4	317.1	357.9	406.6	424.1	463.5	491.7	514.8	526.5	541.4	559.5	580.9
86126M2	020	223.6	260.0	290.6	327.0	355.1	384.0	425.5	454.6	468.3	500.8	512.4	529.4
86126M2	021	260.0	311.0	342.4	386.6	410.1	440.3	465.1	486.6	494.4	516.2	525.0	534.1
86126M2	022	267.2	297.6	331.1	358.2	364.2	386.0	407.6	435.6	435.7	452.7	443.6	450.1
86126M2	023	244.7	275.8	305.8	338.3	348.6	374.6	394.0	413.4	422.9	437.4	451.7	472.3
86126M2	024	245.4	274.7	302.2	332.2	348.0	364.0	380.7	394.2	400.9	412.6	426.0	436.9
86126M2	025	279.0	307.6	344.6	380.6	398.9	408.8	441.3	464.1	475.0	486.2	500.4	514.9

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE (1987): 18-FEB	25-FEB	4-MAR	11-MAR	18-MAR	25-MAR
	DAY OF STUDY: 91	98	105	112	119	126
86126M2 001	464.1	475.6	491.2	503.5	503.1	514.8
86126M2 002	513.6	524.7	537.6	546.1	556.4	569.7
86126M2 003	473.2	481.4	486.3	484.0	491.8	506.9
86126M2 004	524.5	541.3	543.9	553.0	568.4	597.6
86126M2 005	489.9	493.1	497.6	512.3	515.2	530.5
86126M2 006	468.9	473.0	475.9	492.6	493.6	509.3
86126M2 007	607.7	605.2	618.7	634.0	654.6	670.8
86126M2 008	521.4	525.9	534.1	549.3	557.5	577.2
86126M2 009	543.9	545.1	551.6	569.9	577.1	603.8
86126M2 010	466.0	442.7	473.2	469.2	472.8	483.3
86126M2 011	469.7	448.5	477.5	484.0	493.9	516.4
86126M2 012	492.0	506.0	523.1	530.6	536.8	559.2
86126M2 013	488.5	506.7	506.3	512.6	519.9	542.5
86126M2 014	441.1	448.0	462.6	471.3	469.5	488.4
86126M2 015	488.6	499.2	509.6	521.2	531.0	544.6
86126M2 016	498.4	504.0	513.3	520.4	518.1	531.0
86126M2 017	446.0	459.5	455.5	461.7	468.2	480.0
86126M2 018	546.5	537.8	565.5	571.7	559.1	588.4
86126M2 019	579.6	589.3	609.5	622.9	628.2	648.9
86126M2 020	541.1	546.7	569.7	580.6	552.0	582.8
86126M2 021	535.8	549.3	564.6	571.8	552.8	569.4
86126M2 022	447.6	470.2	480.5	495.1	490.8	502.1
86126M2 023	478.4	493.5	499.5	510.0	504.4	522.9
86126M2 024	445.5	455.8	466.0	482.6	485.5	503.2
86126M2 025	516.9	533.8	543.8	552.6	568.8	584.4

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL		DATE (1986): 26-NOV	3-DEC	10-DEC	17-DEC	23-DEC	30-DEC	7-JAN	14-JAN	21-JAN	28-JAN	4-FEB	11-FEB
		DAY OF STUDY: 7	14	21	28	34	41	49	56	63	70	77	84
86126M3	001	237.8	276.2	300.6	329.1	341.1	365.4	387.5	403.6	411.7	429.2	437.8	447.6
86126M3	002	216.0	247.7	268.5	290.3	303.7	322.4	332.3	334.4	341.2	350.5	348.4	359.9
86126M3	003	226.2	268.4	297.8	329.8	338.7	359.1	374.7	391.0	398.6	409.9	417.2	420.5
86126M3	004	241.8	283.9	318.3	352.1	370.3	396.0	414.9	434.6	445.7	467.6	481.8	491.6
86126M3	005	247.5	296.5	325.6	356.5	356.1	380.2	409.3	420.2	433.9	450.9	464.0	479.5
86126M3	006	229.7	275.7	303.0	333.5	344.7	367.4	379.6	391.2	402.3	420.4	430.5	438.5
86126M3	007	250.3	290.2	312.6	350.9	365.1	390.4	400.4	407.3	427.0	441.9	460.2	466.2
86126M3	008	284.4	342.2	387.5	426.4	457.6	492.1	523.6	534.7	550.5	576.3	580.0	600.4
86126M3	009	257.2	303.8	340.2	372.2	392.3	418.7	439.1	449.7	465.5	476.7	488.5	504.0
86126M3	010	266.9	305.3	341.1	374.6	391.8	409.3	440.4	460.9	469.1	484.9	486.4	495.5
86126M3	011	240.3	290.2	334.4	367.3	386.9	403.5	422.6	436.5	442.9	461.0	467.2	477.4
86126M3	012	221.8	262.6	292.7	321.1	337.6	355.0	365.2	378.7	381.7	389.0	393.0	408.4
86126M3	013	255.0	301.5	311.7	334.1	344.9	373.9	389.6	396.5	409.7	425.3	426.5	440.0
86126M3	014	262.6	315.3	336.9	368.8	382.9	403.8	424.8	442.7	464.1	483.7	493.6	514.3
86126M3	015	234.3	273.7	298.4	323.7	333.8	355.3	379.3	392.4	397.4	414.7	422.5	445.6
86126M3	016	241.1	284.8	320.3	348.1	367.3	388.8	404.1	422.8	434.3	452.1	467.8	481.5
86126M3	017	204.7	240.9	244.2	267.7	273.6	292.1	300.9	303.5	309.3	316.4	318.0	331.4
86126M3	018	265.9	325.0	357.8	392.8	414.1	443.8	461.7	468.9	487.4	503.3	519.0	532.7
86126M3	019	247.2	292.2	319.1	355.4	370.4	398.1	419.6	431.2	444.0	459.4	458.3	473.2
86126M3	020	239.7	279.1	307.3	333.5	343.5	363.6	378.3	388.0	385.1	395.1	402.6	426.9
86126M3	021	237.3	278.4	304.3	332.2	348.7	374.2	390.4	408.8	433.9	452.9	459.8	467.4
86126M3	022	247.7	294.6	325.8	350.4	365.2	387.5	412.4	424.9	427.9	436.3	454.4	470.5
86126M3	023	241.8	278.6	295.4	317.6	329.5	347.6	360.0	369.2	375.4	382.7	387.1	404.3
86126M3	024	256.4	296.7	329.7	354.0	362.8	394.5	408.2	420.1	427.7	437.8	451.2	458.1
86126M3	025	226.6	264.4	286.2	316.3	326.6	349.9	360.8	364.4	370.9	380.6	385.0	385.9

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE (1987): 18-FEB	25-FEB	4-MAR	11-MAR	18-MAR	25-MAR
	DAY OF STUDY: 91	98	105	112	119	126
86126M3 001	450.9	454.7	465.8	459.1	369.1	462.0
86126M3 002	368.7	371.3	382.2	381.0	387.7	413.5
86126M3 003	429.0	441.2	449.2	454.1	449.1	471.2
86126M3 004	477.9	483.0	510.5	519.7	527.6	544.3
86126M3 005	483.4	495.4	495.1	502.0	520.7	549.8
86126M3 006	444.7	447.5	461.7	461.6	473.7	503.3
86126M3 007	458.7	472.3	476.7	487.5	457.0	482.7
86126M3 008	614.2	626.4	640.5	651.3	665.2	696.4
86126M3 009	500.2	501.9	507.3	518.1	524.6	538.9
86126M3 010	500.8	500.6	503.2	502.1	516.3	538.4
86126M3 011	479.1	484.6	484.2	479.6	491.1	520.6
86126M3 012	413.1	420.4	428.6	423.8	437.9	453.0
86126M3 013	443.8	458.1	455.9	454.9	466.1	496.5
86126M3 014	524.0	532.4	535.2	529.3	535.8	569.1
86126M3 015	451.0	451.2	464.2	474.7	494.0	514.5
86126M3 016	483.2	491.9	501.0	503.0	515.4	540.0
86126M3 017	327.9	340.5	341.3	350.8	362.3	393.4
86126M3 018	534.2	546.9	557.3	562.4	532.7	559.9
86126M3 019	479.9	490.2	495.4	510.8	512.4	536.3
86126M3 020	432.3	441.4	445.0	452.5	460.9	490.1
86126M3 021	463.8	473.2	486.0	502.3	503.6	525.3
86126M3 022	468.1	490.0	484.2	487.8	491.0	512.9
86126M3 023	408.2	409.7	420.7	426.6	431.3	457.6
86126M3 024	449.6	458.9	472.0	482.5	494.8	513.3
86126M3 025	391.2	402.8	397.1	395.5	402.5	427.2

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: MALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	SPONTANEOUS - BODY INTACT	25-FEB-87	98	86126MN 014
	USE DISCONTINUED; DISPOSED	30-MAR-87	131	86126MN 001
				86126MN 002
				86126MN 003
				86126MN 004
				86126MN 005
				86126MN 006
				86126MN 007
				86126MN 008
				86126MN 009
				86126MN 010
				86126MN 011
				86126MN 012
				86126MN 013
				86126MN 015
				86126MN 016
				86126MN 017
				86126MN 018
				86126MN 019
				86126MN 020
				86126MN 021
				86126MN 022
				86126MN 023
				86126MN 024
				86126MN 025
MISCELLANEOUS	MISSING TAG	18-FEB-87	91	86126MN 006

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

SEX: MALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	USE DISCONTINUED; DISPOSED	30-MAR-87	131	86126M1 001
				86126M1 002
				86126M1 003
				86126M1 004
				86126M1 005
				86126M1 006
				86126M1 007
				86126M1 008
				86126M1 009
				86126M1 010
				86126M1 011
				86126M1 012
				86126M1 013
				86126M1 014
				86126M1 015
				86126M1 016
				86126M1 017
				86126M1 018
				86126M1 019
				86126M1 020
				86126M1 021
				86126M1 022
				86126M1 023
				86126M1 024
				86126M1 025
EYE(S)	PERIORBITAL ENCRUSTATION	11-FEB-87	84	86126M1 004
INTEGUMENT	PILOERECTION	10-DEC-86	21	86126M1 008

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

SEX: MALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	USE DISCONTINUED; DISPOSED	30-MAR-87	131	86126M2 001
				86126M2 002
				86126M2 003
				86126M2 004
				86126M2 005
				86126M2 006
				86126M2 007
				86126M2 008
				86126M2 009
				86126M2 010
				86126M2 011
				86126M2 012
				86126M2 013
				86126M2 014
				86126M2 015
				86126M2 016
				86126M2 017
				86126M2 018
				86126M2 019
				86126M2 020
				86126M2 021
				86126M2 022
				86126M2 023
				86126M2 024
				86126M2 025

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

SEX: MALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	USE DISCONTINUED; DISPOSED	30-MAR-87	131	86126M3 001
				86126M3 002
				86126M3 003
				86126M3 004
				86126M3 005
				86126M3 006
				86126M3 007
				86126M3 008
				86126M3 009
				86126M3 010
				86126M3 011
				86126M3 012
				86126M3 013
				86126M3 014
				86126M3 015
				86126M3 016
				86126M3 017
				86126M3 018
				86126M3 019
				86126M3 020
				86126M3 021
				86126M3 022
				86126M3 023
				86126M3 024
				86126M3 025

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: FEMALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL

** NO ABNORMAL CLINICAL SIGNS RECORDED **

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

SEX: FEMALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
INTEGUMENT	FOCAL LOSS OF HAIR	13-FEB-87	86	86126F1 012

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

SEX: FEMALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL

** NO ABNORMAL CLINICAL SIGNS RECORDED **

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

SEX: FEMALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL

** NO ABNORMAL CLINICAL SIGNS RECORDED **

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

SEX: FEMALE

GROUP	TARGET DOSE	DATE (1986): DAY OF STUDY:	PRE-TEST	13-FEB 86
FN		MEAN	147.4	290.2
NEGATIVE CONTROL		STD. DEV.	15.21	36.65
		SAMPLE SIZE	50	50
F1	2.500 MG/M3	MEAN	147.8	299.1
TEST GROUP		STD. DEV.	15.31	45.18
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	50	50
F2	15.00 MG/M3	MEAN	147.7	296.5
TEST GROUP		STD. DEV.	15.52	37.23
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	50	50
F3	50.00 MG/M3	MEAN	147.7	293.8
TEST GROUP		STD. DEV.	15.63	36.36
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	50	50

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .05$)
** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

INDIVIDUAL FERTILITY AND NIDATION DATA - 86126 - FØa

ANIMAL	CORPORA LUTEA L. OVARY	CORPORA LUTEA R. OVARY	TOTAL CORPORA LUTEA	VIABLE IMPLANTS	RESORPTIONS
FN ØØ2	1Ø	4	14	13	1
FN ØØ4	8	7	15	15	Ø
FN ØØ5	8	1Ø	18	1Ø	3
FN ØØ6	7	8	15	15	Ø
FN ØØ7	1Ø	5	15	14	1
FN ØØ9	5	1Ø	15	15	Ø
FN Ø1Ø	6	1Ø	16	16	Ø
FN Ø11	8	7	15	13	2
FN Ø12	8	6	14	8	Ø
FN Ø13	11	7	18	16	Ø
FN Ø15	9	5	14	13	Ø
FN Ø16	8	1Ø	18	17	Ø
FN Ø17	8	9	17	16	Ø
FN Ø19	9	1Ø	19	16	1
FN Ø2Ø	11	6	17	16	Ø
FN Ø21	5	12	17	14	2
FN Ø23	11	7	18	12	2
FN Ø24	1Ø	9	19	15	1
FN Ø25	8	7	15	15	Ø
F1 ØØ2	9	1Ø	19	19	Ø
F1 ØØ3	12	4	16	15	Ø
F1 ØØ4	5	12	17	17	Ø
F1 ØØ5	8	9	17	8	Ø
F1 ØØ6	7	1Ø	17	17	Ø
F1 ØØ7	1Ø	5	15	12	1
F1 ØØ8	8	9	17	1Ø	Ø
F1 ØØ9	8	11	19	17	1
F1 Ø11	8	13	21	18	Ø
F1 Ø12	1Ø	7	17	9	3
F1 Ø13	9	5	14	13	Ø
F1 Ø14	6	11	17	Ø	1
F1 Ø15	6	12	18	16	1
F1 Ø16	5	12	17	17	Ø
F1 Ø18	4	9	13	13	Ø
F1 Ø19	7	5	12	11	Ø
F1 Ø2Ø	7	9	16	12	3
F1 Ø22	13	3	16	16	Ø
F1 Ø23	8	8	16	13	3
F1 Ø24	11	6	17	1Ø	4
F1 Ø25	5	9	14	13	1
F2 ØØ1	9	4	13	11	2
F2 ØØ2	7	7	14	1	Ø
F2 ØØ3	9	9	18	8	Ø
F2 ØØ5	7	7	14	13	Ø
F2 ØØ6	6	11	17	15	1
F2 ØØ7	1Ø	4	14	13	1

INDIVIDUAL FERTILITY AND NIDATION DATA - 86126 - FØa

ANIMAL		CORPORA LUTEA L. OVARY	CORPORA LUTEA R. OVARY	TOTAL CORPORA LUTEA	VIABLE IMPLANTS	RESORPTIONS
F2	ØØ8	9	8	17	17	Ø
F2	ØØ9	7	9	16	16	Ø
F2	Ø11	6	5	11	11	Ø
F2	Ø12	6	9	15	13	1
F2	Ø14	1Ø	7	17	15	2
F2	Ø15	1Ø	4	14	13	Ø
F2	Ø16	7	8	15	8	1
F2	Ø17	8	9	17	16	Ø
F2	Ø18	1Ø	7	17	8	Ø
F2	Ø19	9	8	17	16	1
F2	Ø2Ø	8	9	17	7	1
F2	Ø21	1Ø	8	18	18	Ø
F2	Ø22	8	1Ø	18	18	Ø
F2	Ø25	11	5	16	14	2
F3	ØØ1	7	8	15	12	Ø
F3	ØØ2	9	7	16	15	Ø
F3	ØØ3	6	1Ø	16	16	Ø
F3	ØØ4	13	4	17	15	2
F3	ØØ5	1Ø	6	16	14	1
F3	ØØ6	6	8	14	14	Ø
F3	ØØ8	9	7	16	11	5
F3	ØØ9	5	8	13	12	1
F3	Ø1Ø	8	12	2Ø	18	1
F3	Ø11	11	9	2Ø	15	4
F3	Ø12	11	6	17	15	1
F3	Ø13	7	1Ø	17	16	1
F3	Ø14	7	7	14	13	1
F3	Ø15	8	11	19	14	4
F3	Ø16	4	1Ø	14	14	Ø
F3	Ø17	3	1Ø	13	9	3
F3	Ø18	1Ø	5	15	12	Ø
F3	Ø19	7	9	16	15	1
F3	Ø22	1Ø	5	15	12	2
F3	Ø23	9	8	17	16	1
F3	Ø25	1Ø	8	18	17	1

INDIVIDUAL FERTILITY AND NIDATION DATA - 86126 - FØb

ANIMAL	CORPORA LUTEA L. OVARY	CORPORA LUTEA R. OVARY	TOTAL CORPORA LUTEA	VIABLE IMPLANTS	RESORPTIONS
FN 027	14	10	24	12	2
FN 028	5	11	16	12	2
FN 029	9	6	15	12	1
FN 031	7	7	14	13	Ø
FN 032	8	7	15	14	1
FN 033	9	8	17	14	1
FN 034	10	4	14	13	1
FN 035	7	5	12	12	Ø
FN 036	8	8	16	16	Ø
FN 038	7	7	14	6	1
FN 040	4	11	15	9	2
FN 041	10	6	16	15	1
FN 042	7	9	16	14	1
FN 043	8	7	15	14	1
FN 044	6	10	16	16	Ø
FN 045	6	8	14	14	Ø
FN 046	7	6	13	13	Ø
FN 047	7	12	19	18	Ø
FN 048	6	11	17	13	4
FN 049	8	8	16	13	2
F1 026	10	7	17	15	2
F1 027	6	10	16	12	Ø
F1 028	5	10	15	15	Ø
F1 029	6	10	16	16	Ø
F1 030	5	4	9	8	Ø
F1 032	6	12	18	16	2
F1 033	9	7	16	15	1
F1 034	5	10	15	12	2
F1 035	4	10	14	12	Ø
F1 036	10	5	15	12	1
F1 037	6	8	14	14	Ø
F1 038	10	5	15	14	1
F1 039	7	11	18	18	Ø
F1 040	8	9	17	17	Ø
F1 043	5	11	16	15	1
F1 044	11	5	16	14	1
F1 046	5	7	12	12	Ø
F1 047	5	7	12	12	1
F1 048	9	10	19	13	2
F1 049	5	8	13	11	1
F1 050	10	6	16	16	Ø
F2 027	5	11	16	14	1
F2 028	9	8	17	14	1
F2 029	5	7	12	11	1
F2 030	6	10	16	11	3
F2 031	4	8	12	12	Ø

INDIVIDUAL FERTILITY AND NIDATION DATA - 86126 - FØb

ANIMAL	CORPORA LUTEA L. OVARY	CORPORA LUTEA R. OVARY	TOTAL CORPORA LUTEA	VIABLE IMPLANTS	RESORPTIONS
F2 033	10	5	15	13	Ø
F2 034	9	6	15	14	Ø
F2 035	8	8	16	12	1
F2 036	7	8	15	15	Ø
F2 037	10	8	18	12	Ø
F2 038	11	8	19	9	Ø
F2 039	12	12	24	13	1
F2 041	5	10	15	14	Ø
F2 042	6	9	15	14	1
F2 043	7	7	14	14	Ø
F2 044	6	10	16	16	Ø
F2 045	6	10	16	14	1
F2 046	7	8	15	14	1
F2 047	8	8	16	15	Ø
F2 048	9	9	18	15	Ø
F2 049	8	12	20	12	3
F2 050	7	8	15	12	1
F3 026	10	5	15	9	6
F3 027	7	8	15	14	1
F3 028	9	7	16	14	1
F3 029	6	9	15	13	1
F3 030	5	7	12	11	Ø
F3 031	6	7	13	13	Ø
F3 032	6	8	14	14	Ø
F3 033	9	6	15	15	1
F3 034	6	11	17	16	1
F3 035	5	11	16	15	1
F3 036	5	7	12	11	Ø
F3 038	8	8	16	14	Ø
F3 039	4	9	13	11	Ø
F3 040	6	9	15	13	2
F3 041	6	10	16	12	2
F3 042	9	8	17	10	1
F3 043	10	3	13	12	1
F3 045	10	6	16	14	1
F3 046	4	10	14	13	1
F3 047	7	8	15	13	2
F3 048	4	9	13	13	Ø
F3 049	6	10	16	15	Ø
F3 050	8	8	16	15	Ø

INDIVIDUAL MATING REPORT - 86126 - F0a

GENERATION : F0a

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	(B)
N										
NM001	NF001								X	N
NM002	NF002		X							P
NM003	NF003								X	N
NM004	NF004			X						P
NM005	NF005				X					P
NM006	NF006		X							P
NM007	NF007					X				P
NM008	NF008								X	N
NM009	NF009		X							P
NM010	NF010			X						P
NM011	NF011			X						P
NM012	NF012		X							P
NM013	NF013		X							P
NM014	NF014								X	N
NM015	NF015		X							P
NM016	NF016			X						P
NM017	NF017				X					P
NM018	NF018	X								N
NM019	NF019		X							P
NM020	NF020			X						P
NM021	NF021		X							P
NM022	NF022								X	N
NM023	NF023				X					P
NM024	NF024					X				P
NM025	NF025				X					P

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86126 - FØa

GENERATION : FØa

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	(B)
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	
1										
1MØØ1	1FØØ1								X	N
1MØØ2	1FØØ2		X							P
1MØØ3	1FØØ3		X							P
1MØØ4	1FØØ4		X							P
1MØØ5	1FØØ5	X								P
1MØØ6	1FØØ6	X								P
1MØØ7	1FØØ7		X							P
1MØØ8	1FØØ8		X							P
1MØØ9	1FØØ9		X							P
1MØ1Ø	1FØ1Ø		X							N
1MØ11	1FØ11			X						P
1MØ12	1FØ12	X								P
1MØ13	1FØ13		X							P
1MØ14	1FØ14	X								P
1MØ15	1FØ15		X							P
1MØ16	1FØ16				X					P
1MØ17	1FØ17								X	N
1MØ18	1FØ18			X						P
1MØ19	1FØ19			X						P
1MØ2Ø	1FØ2Ø	X								P
1MØ21	1FØ21	X								N
1MØ22	1FØ22		X							P
1MØ23	1FØ23		X							P
1MØ24	1FØ24				X					P
1MØ25	1FØ25			X						P

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86126 - F0a

GENERATION : F0a

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	(B)
2										
2M001	2F001	X								P
2M002	2F002		X							P
2M003	2F003	X								P
2M004	2F004	X								N
2M005	2F005					X				P
2M006	2F006				X					P
2M007	2F007	X								P
2M008	2F008			X						P
2M009	2F009	X								P
2M010	2F010	X								N
2M011	2F011			X						P
2M012	2F012		X							P
2M013	2F013								X	N
2M014	2F014	X								P
2M015	2F015	X								P
2M016	2F016	X								P
2M017	2F017				X					P
2M018	2F018			X						P
2M019	2F019		X							P
2M020	2F020	X								P
2M021	2F021			X						P
2M022	2F022		X							P
2M023	2F023								X	N
2M024	2F024	X								N
2M025	2F025		X							P

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86126 - FØa

GENERATION : FØa

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	(B)
3										
3MØØ1	3FØØ1	X								P
3MØØ2	3FØØ2				X					P
3MØØ3	3FØØ3		X							P
3MØØ4	3FØØ4		X							P
3MØØ5	3FØØ5			X						P
3MØØ6	3FØØ6	X								P
3MØØ7	3FØØ7								X	N
3MØØ8	3FØØ8			X						P
3MØØ9	3FØØ9	X								P
3MØ1Ø	3FØ1Ø				X					P
3MØ11	3FØ11		X							P
3MØ12	3FØ12			X						P
3MØ13	3FØ13		X							P
3MØ14	3FØ14				X					P
3MØ15	3FØ15				X					P
3MØ16	3FØ16			X						P
3MØ17	3FØ17		X							P
3MØ18	3FØ18		X							P
3MØ19	3FØ19	X								P
3MØ2Ø	3FØ2Ø								X	N
3MØ21	3FØ21	X								N
3MØ22	3FØ22		X							P
3MØ23	3FØ23		X							P
3MØ24	3FØ24								X	N
3MØ25	3FØ25			X						P

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86126 - F0b

GENERATION : F0b

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	(B)
N										
NM001	NF026								X	N
NM002	NF027			X						P
NM003	NF028	X								P
NM004	NF029		X							P
NM005	NF030								X	N
NM006	NF031				X					P
NM007	NF032					X				P
NM008	NF033			X						P
NM009	NF034				X					P
NM010	NF035	X								P
NM011	NF036		X							P
NM012	NF037								X	N
NM013	NF038			X						P
NM014	NF039								X	N
NM015	NF040				X					P
NM016	NF041	X								P
NM017	NF042				X					P
NM018	NF043				X					P
NM019	NF044				X					P
NM020	NF045			X						P
NM021	NF046				X					P
NM022	NF047		X							P
NM023	NF048				X					P
NM024	NF049							X		P
NM025	NF050								X	N

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86126 - FØb

GENERATION : FØb

CO-HOUSE PAIRS (A)		COPULATION							PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING						COPULATION NOT	
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7 CONFIRMED	(B)
1									
1MØØ1	1FØ26			X					P
1MØØ2	1FØ27					X			P
1MØØ3	1FØ28				X				P
1MØØ4	1FØ29		X						P
1MØØ5	1FØ30						X		P
1MØØ6	1FØ31				X				N
1MØØ7	1FØ32			X					P
1MØØ8	1FØ33			X					P
1MØØ9	1FØ34				X				P
1MØ10	1FØ35			X					P
1MØ11	1FØ36			X					P
1MØ12	1FØ37					X			P
1MØ13	1FØ38					X			P
1MØ14	1FØ39				X				P
1MØ15	1FØ40					X			P
1MØ16	1FØ41							X	N
1MØ17	1FØ42							X	N
1MØ18	1FØ43			X					P
1MØ19	1FØ44				X				P
1MØ20	1FØ45							X	N
1MØ21	1FØ46						X		P
1MØ22	1FØ47			X					P
1MØ23	1FØ48			X					P
1MØ24	1FØ49						X		P
1MØ25	1FØ50				X				P

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86126 - F0b

GENERATION : F0b

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	(B)
2										
2M001	2F026	X								N
2M002	2F027			X						P
2M003	2F028				X					P
2M004	2F029						X			P
2M005	2F030			X						P
2M006	2F031				X					P
2M007	2F032			X						N
2M008	2F033				X					P
2M009	2F034					X				P
2M010	2F035					X				P
2M011	2F036			X						P
2M012	2F037		X							P
2M013	2F038				X					P
2M014	2F039		X							P
2M015	2F040					X				N
2M016	2F041			X						P
2M017	2F042							X		P
2M018	2F043					X				P
2M019	2F044			X						P
2M020	2F045				X					P
2M021	2F046						X			P
2M022	2F047						X			P
2M023	2F048	X								P
2M024	2F049			X						P
2M025	2F050			X						P

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86126 - FØb

GENERATION : FØb

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	(B)
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	
3										
3MØØ1	3FØ26				X					P
3MØØ2	3FØ27					X				P
3MØØ3	3FØ28		X							P
3MØØ4	3FØ29				X					P
3MØØ5	3FØ30								X	P
3MØØ6	3FØ31				X					P
3MØØ7	3FØ32				X					P
3MØØ8	3FØ33			X						P
3MØØ9	3FØ34			X						P
3MØ1Ø	3FØ35			X						P
3MØ11	3FØ36							X		P
3MØ12	3FØ37	X								N
3MØ13	3FØ38			X						P
3MØ14	3FØ39								X	P
3MØ15	3FØ4Ø			X						P
3MØ16	3FØ41	X								P
3MØ17	3FØ42				X					P
3MØ18	3FØ43						X			P
3MØ19	3FØ44								X	N
3MØ2Ø	3FØ45			X						P
3MØ21	3FØ46	X								P
3MØ22	3FØ47						X			P
3MØ23	3FØ48					X				P
3MØ24	3FØ49		X							P
3MØ25	3FØ5Ø								X	P

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

APPENDIX 3

REPRODUCTION STUDY (86127) DATA

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: FEMALE

ANIMAL	DATE (1986): DAY OF STUDY:	PRE-TEST	26-NOV 7	3-DEC 14	10-DEC 21	17-DEC 28	23-DEC 34	30-DEC 41	7-JAN 49	14-JAN 56	21-JAN 63	28-JAN 70	4-FEB 77
86127FN	001	127.4	175.2	198.1	206.9	224.6	239.5	242.8	261.1	268.1	272.9	273.2	280.1
86127FN	002	135.9	179.5	207.6	228.5	245.2	250.8	269.3	279.6	283.3	302.3	309.3	327.8
86127FN	003	181.6	226.3	250.6	264.9	285.5	292.0	325.5	338.9	349.7	356.2	371.0	375.8
86127FN	004	150.6	190.1	207.1	228.1	241.0	244.9	257.6	266.4	271.8	281.1	287.0	292.0
86127FN	005	173.3	217.1	250.2	271.9	296.8	306.6	330.9	334.0	339.0	349.6	358.6	367.9
86127FN	006	158.2	198.6	215.3	234.6	257.2	269.4	285.1	298.9	303.7	310.4	319.9	318.2
86127FN	007	167.5	209.9	232.4	253.3	269.1	286.0	301.5	303.0	312.0	316.1	319.4	333.0
86127FN	008	154.4	193.1	214.6	233.1	251.9	275.0	284.8	292.7	302.3	303.3	312.7	321.5
86127FN	009	174.3	217.3	247.9	257.1	289.6	304.7	322.4	337.7	353.4	369.8	376.7	373.4
86127FN	010	164.2	212.5	228.9	249.8	269.0	282.6	294.8	306.2	313.4	302.7	309.1	310.3
86127FN	011	177.9	208.9	238.8	241.1	267.4	286.9	302.7	314.9	320.6	318.8	332.4	341.7
86127FN	012	169.3	207.1	227.1	240.3	256.9	256.2	279.4	280.1	283.2	286.6	289.8	298.1
86127FN	013	143.3	186.8	211.6	224.7	246.8	265.2	267.4	283.4	293.7	298.6	300.4	300.3
86127FN	014	155.4	200.2	227.1	244.4	263.4	275.6	294.0	299.3	308.6	311.8	318.6	325.0
86127FN	015	149.0	182.8	211.1	221.4	232.3	246.9	256.5	267.1	269.0	270.9	276.8	283.0
86127FN	016	159.5	216.8	244.2	272.5	296.7	308.2	336.0	351.2	349.5	379.7	381.0	390.5
86127FN	017	133.2	179.3	200.9	215.9	217.6	242.1	245.2	258.7	267.5	273.0	273.1	270.0
86127FN	018	180.2	232.2	263.8	287.7	290.8	315.9	338.3	355.5	359.5	368.5	365.1	368.7
86127FN	019	152.6	188.3	200.7	211.5	211.1	224.3	232.5	244.2	243.2	252.9	255.4	262.9
86127FN	020	130.8	166.7	183.4	203.2	218.6	221.2	239.0	244.9	251.1	246.8	251.2	255.9
86127FN	021	145.4	189.2	212.5	226.9	243.4	256.8	269.5	277.2	288.4	294.0	299.9	303.7
86127FN	022	125.0	167.6	188.3	203.9	217.3	232.9	244.8	251.5	256.4	254.8	266.3	268.7
86127FN	023	139.7	179.4	204.5	218.7	228.2	247.6	256.9	266.5	275.4	280.5	282.9	282.8
86127FN	024	163.7	208.5	232.1	244.3	259.0	275.0	286.9	295.8	302.0	306.2	317.5	316.6
86127FN	025	134.8	167.7	187.4	209.1	222.7	237.4	248.5	252.4	262.7	256.0	271.7	278.4
86127FN	026	137.1	178.2	198.1	213.5	228.3	239.6	258.4	262.0	270.4	275.8	272.7	282.2
86127FN	027	150.0	198.7	209.1	236.5	258.2	266.7	286.8	306.0	318.4	326.4	323.7	342.6
86127FN	028	139.3	176.7	197.3	204.3	215.8	227.3	240.4	249.1	253.4	249.2	258.2	272.1
86127FN	029	142.1	170.4	189.0	201.9	217.7	227.3	236.7	238.4	246.5	248.7	249.4	263.7
86127FN	030	143.9	189.3	213.2	228.7	235.8	249.6	264.1	275.6	278.1	275.8	284.6	288.0

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127 INDIVIDUAL BODY WEIGHT DATA (GM)
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: FEMALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE (1987): DAY OF STUDY:	11-FEB 84	18-FEB 91	25-FEB 98	4-MAR 105
86127FN	001	297.3			
86127FN	002	323.0	341.3		
86127FN	003	390.5	386.1		
86127FN	004	301.6	303.3		
86127FN	005	373.5			
86127FN	006	326.5	327.2		
86127FN	007	330.1			
86127FN	008	316.1			
86127FN	009	389.7			
86127FN	010	332.3			
86127FN	011	349.9			
86127FN	012	299.3			
86127FN	013	310.0			
86127FN	014	328.5			
86127FN	015	289.0	298.8	309.9	
86127FN	016	407.6			
86127FN	017	276.7			
86127FN	018	386.2	401.3	421.2	460.1
86127FN	019	269.9			
86127FN	020	263.6			
86127FN	021	310.5	318.8	335.5	359.1
86127FN	022	268.8			
86127FN	023	281.4			
86127FN	024	319.5			
86127FN	025	282.9	284.7		
86127FN	026	289.8			
86127FN	027	351.5	354.5	383.0	379.4
86127FN	028	282.5	278.2	280.6	288.7
86127FN	029	264.2			
86127FN	030	294.7	296.7		

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE (1986): DAY OF STUDY:	PRE-TEST	26-NOV 7	3-DEC 14	10-DEC 21	17-DEC 28	23-DEC 34	30-DEC 41	7-JAN 49	14-JAN 56	21-JAN 63	28-JAN 70	4-FEB 77
86127F1	001	138.6	184.0	209.5	228.3	239.8	253.7	256.5	280.6	287.5	285.5	291.3	292.4
86127F1	002	145.0	176.1	195.6	208.0	222.5	232.8	245.2	262.6	268.9	275.9	283.9	283.6
86127F1	003	169.1	215.5	235.8	251.3	267.7	279.4	281.5	303.5	303.8	318.4	316.3	301.5
86127F1	004	126.3	156.3	168.4	179.3	192.8	192.7	210.7	217.1	223.1	225.7	228.8	237.2
86127F1	005	160.0	206.7	224.8	247.0	266.9	277.1	294.5	303.5	313.0	320.8	325.1	329.6
86127F1	006	180.1	218.8	254.7	242.6	265.0	296.5	318.8	330.6	326.0	348.1	359.6	369.3
86127F1	007	157.0	194.4	214.1	234.6	250.6	259.1	277.3	293.8	299.2	293.9	306.2	315.2
86127F1	008	163.9	216.8	239.7	253.4	273.0	296.5	308.5	306.7	323.6	327.0	338.5	339.6
86127F1	009	177.3	218.7	233.8	261.3	280.7	296.4	314.1	326.3	334.2	337.4	337.7	350.5
86127F1	010	171.3	211.3	237.0	255.8	272.8	303.5	316.9	334.6	335.7	345.9	364.7	341.3
86127F1	011	155.5	196.4	219.8	229.6	246.1	261.8	269.4	279.4	292.6	301.7	300.1	300.4
86127F1	012	149.5	181.0	197.7	225.5	246.7	252.0	268.8	278.7	286.5	286.9	290.4	297.3
86127F1	013	142.2	180.1	198.8	213.4	222.1	240.9	249.8	261.2	264.3	269.3	270.4	273.4
86127F1	014	173.6	229.4	246.6	272.6	291.5	304.9	320.5	335.2	342.5	352.3	345.0	354.5
86127F1	015	130.0	164.7	188.7	206.7	225.6	241.5	257.0	268.8	284.2	286.6	296.9	301.5
86127F1	016	183.7	235.4	249.3	273.4	294.1	307.6	320.4	336.5	342.1	332.5	351.9	361.2
86127F1	017	152.2	194.2	215.0	233.9	250.4	263.7	265.1	287.5	287.0	293.9	296.2	307.4
86127F1	018	136.1	173.4	197.5	213.1	227.3	247.6	253.9	269.1	271.6	275.2	285.6	289.1
86127F1	019	151.7	194.0	207.8	233.8	257.5	262.0	283.4	291.9	296.3	302.1	306.3	310.9
86127F1	020	132.8	167.8	182.9	194.4	199.8	216.0	228.9	234.7	238.7	242.2	246.3	244.4
86127F1	021	141.2	179.8	200.0	216.4	226.2	239.8	245.8	257.9	262.9	258.5	270.0	275.6
86127F1	022	129.8	169.2	187.2	200.3	210.0	231.8	238.1	246.6	244.1	254.3	266.2	261.4
86127F1	023	137.1	166.5	185.9	199.1	211.4	225.0	234.5	237.2	240.3	245.1	251.6	252.2
86127F1	024	144.4	189.3	210.4	231.5	249.8	258.1	275.6	284.4	287.6	290.2	299.1	300.6
86127F1	025	165.1	199.8	226.5	241.2	267.0	287.9	293.1	306.5	321.4	326.1	332.4	333.9
86127F1	026	135.1	167.9	194.0	227.6	232.2	250.7	256.7	271.0	281.2	285.0	288.5	288.4
86127F1	027	141.0	190.4	215.6	234.7	254.9	272.1	278.9	296.2	303.6	302.8	303.5	314.4
86127F1	028	149.9	188.2	208.8	237.9	248.1	263.3	283.0	285.1	292.4	296.5	306.4	308.8
86127F1	029	154.2	191.7	217.7	223.6	248.4	271.9	283.5	290.9	289.7	304.1	295.4	309.8
86127F1	030	161.7	210.5	231.0	241.3	263.6	268.9	299.4	308.2	312.5	317.4	325.6	328.1

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE (1987): DAY OF STUDY:	11-FEB 84	18-FEB 91	25-FEB 98	4-MAR 105
86127F1	001	293.8			
86127F1	002	284.9	295.7		
86127F1	003	327.0	326.2		
86127F1	004	240.1			
86127F1	005	335.5			
86127F1	006	382.9	381.6		
86127F1	007	314.9			
86127F1	008	336.4			
86127F1	009	361.0			
86127F1	010	356.5	373.3		
86127F1	011	313.6			
86127F1	012	305.8			
86127F1	013	273.1	286.7		
86127F1	014	367.0			
86127F1	015	296.5			
86127F1	016	368.0			
86127F1	017	305.4			
86127F1	018	290.5	288.8		
86127F1	019	317.6			
86127F1	020	245.7			
86127F1	021	276.7	277.4	283.4	286.5
86127F1	022	257.6	271.5		
86127F1	023	253.0	255.9		
86127F1	024	300.4			
86127F1	025	343.8			
86127F1	026	299.9			
86127F1	027	317.2	310.1		
86127F1	028	314.7	300.6		
86127F1	029	313.5			
86127F1	030	336.1	339.1		

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE (1986): DAY OF STUDY:	PRE-TEST	26-NOV 7	3-DEC 14	10-DEC 21	17-DEC 28	23-DEC 34	30-DEC 41	7-JAN 49	14-JAN 56	21-JAN 63	28-JAN 70	4-FEB 77
86127F2	001	146.0	179.1	203.7	221.0	227.4	242.7	244.5	257.4	268.9	278.5	279.7	283.1
86127F2	002	154.9	191.6	227.3	245.0	264.9	281.0	293.3	296.0	314.2	322.3	327.0	332.1
86127F2	003	141.0	180.6	198.5	220.4	234.1	238.2	260.2	273.6	285.1	288.2	288.4	296.9
86127F2	004	149.2	190.2	214.6	232.9	242.4	243.8	265.9	272.6	283.7	273.7	290.8	293.2
86127F2	005	164.8	205.8	225.8	255.1	273.3	283.0	299.8	311.6	319.9	342.8	367.2	336.3
86127F2	006	173.0	202.5	239.7	262.1	277.6	290.7	307.3	313.9	318.5	321.4	337.1	342.5
86127F2	007	136.5	166.6	192.9	203.1	220.3	236.7	240.3	251.1	265.3	268.3	269.8	267.1
86127F2	008	126.0	159.3	179.7	196.1	209.5	221.8	229.6	231.4	239.9	245.1	249.0	253.2
86127F2	009	149.6	183.7	200.5	223.0	239.2	243.8	257.1	269.4	270.7	272.5	271.3	281.8
86127F2	010	155.4	191.4	213.3	229.2	250.5	266.0	281.2	286.7	294.5	297.7	302.1	307.0
86127F2	011	179.0	233.8	248.7	278.3	298.6	294.1	325.9	263.5	326.2	342.0	355.5	365.3
86127F2	012	159.0	197.5	222.8	233.1	253.5	271.9	287.5	297.0	307.7	306.4	319.9	327.7
86127F2	013	143.9	183.5	199.1	210.2	229.2	236.1	252.5	258.4	267.2	257.1	272.2	262.9
86127F2	014	126.5	161.3	180.2	198.2	211.1	221.8	231.2	244.2	252.9	248.7	251.6	253.6
86127F2	015	162.5	203.8	225.0	247.5	246.5	259.3	278.8	280.2	296.0	290.7	297.7	302.9
86127F2	016	175.2	205.6	226.1	242.8	263.4	271.8	275.8	286.0	303.3	310.9	310.7	318.4
86127F2	017	167.9	211.3	251.2	274.5	299.3	317.1	339.8	356.8	370.1	371.1	390.9	402.3
86127F2	018	176.9	229.2	254.7	265.8	282.9	299.1	303.5	318.0	331.7	334.0	345.3	337.8
86127F2	019	144.1	177.6	209.9	220.0	231.4	255.4	271.2	279.9	298.2	291.4	299.4	315.0
86127F2	020	160.8	191.1	213.9	231.6	247.2	261.6	272.1	282.9	285.1	294.4	299.8	308.3
86127F2	021	135.4	170.7	193.2	204.2	225.4	236.9	245.9	258.6	268.1	275.2	281.0	285.0
86127F2	022	136.0	162.5	183.2	186.1	202.6	211.4	207.4	218.6	232.5	235.3	239.1	231.6
86127F2	023	150.8	189.0	217.7	228.4	250.2	262.6	282.6	295.8	302.5	311.9	337.3	327.4
86127F2	024	133.4	167.4	196.1	209.6	221.5	241.2	258.6	268.3	278.5	286.0	287.4	290.8
86127F2	025	139.3	175.3	204.4	232.0	253.8	268.8	284.0	290.8	292.8	290.7	295.5	304.9
86127F2	026	130.2	161.2	180.6	197.7	208.4	227.6	234.1	237.6	244.4	250.0	255.4	257.6
86127F2	027	141.9	165.2	193.7	216.5	226.3	237.8	254.0	258.7	275.1	287.2	290.2	292.4
86127F2	028	182.4	221.6	251.6	265.0	280.1	295.8	305.4	319.2	321.6	311.6	320.7	326.7
86127F2	029	152.8	197.1	215.8	233.2	248.6	259.7	280.7	289.0	296.6	304.8	303.0	306.9
86127F2	030	168.1	209.9	241.2	244.7	272.0	291.7	301.6	319.1	331.4	343.3	352.8	346.5

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127 INDIVIDUAL BODY WEIGHT DATA (GM)
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE (1987): 11-FEB	18-FEB	25-FEB
	DAY OF STUDY: 84	91	98
86127F2 001	296.0		
86127F2 002	341.7		
86127F2 003	306.6		
86127F2 004	290.2	309.4	334.7
86127F2 005	347.4		
86127F2 006	347.2		
86127F2 007	281.1		
86127F2 008	254.0	262.9	
86127F2 009	283.7		
86127F2 010	312.5		
86127F2 011	379.8		
86127F2 012	336.1	348.3	
86127F2 013	278.4	281.9	
86127F2 014	256.6		
86127F2 015	314.8		
86127F2 016	318.6		
86127F2 017	400.9	405.9	
86127F2 018	356.6	360.3	
86127F2 019	311.6		
86127F2 020	304.8	307.2	
86127F2 021	294.3		
86127F2 022	242.0		
86127F2 023	326.5		
86127F2 024	302.6		
86127F2 025	308.3		
86127F2 026	258.0	266.4	
86127F2 027	303.0		
86127F2 028	339.0	340.1	
86127F2 029	321.5		
86127F2 030	363.9	355.1	

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

SEX: FEMALE

ANIMAL	DATE (1986): DAY OF STUDY:	PRE-TEST	26-NOV 7	3-DEC 14	10-DEC 21	17-DEC 28	23-DEC 34	30-DEC 41	7-JAN 49	14-JAN 56	21-JAN 63	28-JAN 70	4-FEB 77
86127F3	001	135.6	150.7	170.9	191.8	204.2	207.1	225.9	234.6	240.1	239.1	242.3	246.1
86127F3	002	144.4	168.8	189.8	201.2	206.7	215.6	226.4	227.6	237.5	237.1	244.0	235.1
86127F3	003	165.8	200.0	215.3	233.2	247.0	256.2	277.0	267.8	277.5	275.3	275.2	272.2
86127F3	004	158.2	187.7	202.2	216.4	229.6	236.2	251.5	255.1	258.4	264.8	272.0	274.8
86127F3	005	173.8	203.9	231.6	241.8	257.6	261.2	273.9	279.9	283.3	287.7	294.0	292.5
86127F3	006	179.4	208.5	231.8	242.9	257.2	261.3	283.0	281.2	289.7	283.9	287.9	288.6
86127F3	007	151.3	186.5	211.1	219.6	236.0	245.3	254.1	256.2	259.6	255.9	262.0	265.4
86127F3	008	163.9	189.2	216.2	225.8	248.9	258.4	266.0	276.7	284.9	288.3	296.0	305.6
86127F3	009	150.2	175.5	195.4	210.4	228.0	234.0	243.5	245.7	250.5	252.6	256.0	261.2
86127F3	010	141.5	171.7	188.7	212.5	225.7	234.0	243.0	262.3	261.9	259.3	268.5	259.8
86127F3	011	159.8	192.5	219.0	235.9	246.9	251.7	267.6	275.7	279.0	280.7	284.0	291.6
86127F3	012	140.9	167.1	183.7	198.5	211.1	211.2	223.5	224.3	234.6	234.8	244.9	247.5
86127F3	013	153.8	185.8	209.5	141.7	216.5	233.2	249.5	260.3	264.7	264.8	270.9	281.1
86127F3	014	148.9	172.3	190.6	204.1	220.1	230.0	239.1	241.7	249.8	244.9	239.8	246.2
86127F3	015	143.7	165.9	179.7	192.9	207.6	213.8	224.9	228.7	232.0	230.0	233.7	235.3
86127F3	016	177.6	211.2	242.4	248.1	261.7	276.4	291.8	290.1	292.8	293.5	297.3	302.5
86127F3	017	132.3	159.3	169.4	190.8	206.7	204.2	213.8	221.4	227.5	231.0	233.8	228.3
86127F3	018	155.0	186.9	212.4	222.4	237.4	236.7	260.0	270.5	271.6	270.9	268.1	284.7
86127F3	019	169.2	202.5	224.9	243.1	258.7	271.4	292.0	296.2	306.1	302.5	302.4	313.2
86127F3	020	154.6	183.1	196.8	208.7	218.0	223.2	232.1	241.5	242.8	241.4	245.2	248.7
86127F3	021	126.5	154.2	176.3	185.9	205.9	213.5	222.1	227.4	239.1	236.9	231.4	242.5
86127F3	022	137.7	167.9	186.5	207.4	219.5	226.4	232.5	241.0	247.9	246.3	250.4	256.8
86127F3	023	180.7	228.1	248.9	275.3	288.9	290.7	304.3	313.7	320.2	317.1	327.0	327.4
86127F3	024	133.8	162.5	182.5	201.5	208.6	222.9	242.1	248.7	254.4	247.4	258.5	255.8
86127F3	025	126.1	154.1	167.1	183.5	200.2	199.4	214.4	219.1	227.6	226.0	232.4	237.6
86127F3	026	149.3	175.2	198.0	216.1	225.6	237.7	243.5	248.6	255.9	261.9	267.7	271.5
86127F3	027	139.0	166.0	185.1	199.3	214.0	225.4	240.9	245.6	251.3	248.5	257.6	258.3
86127F3	028	132.7	159.8	183.4	194.3	208.2	215.1	224.9	232.8	233.4	239.2	241.3	244.6
86127F3	029	162.3	198.8	224.7	245.6	254.8	263.5	281.7	287.2	295.6	294.9	291.7	293.9
86127F3	030	170.1	208.3	230.2	247.1	264.3	274.6	290.1	297.6	301.4	300.0	307.7	313.1

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE (1987): 11-FEB	18-FEB	25-FEB	4-MAR
	DAY OF STUDY: 84	91	98	105
86127F3 001	254.1	259.6		
86127F3 002	248.1	248.5		
86127F3 003	290.4			
86127F3 004	278.4			
86127F3 005	297.9			
86127F3 006	295.8	294.9		
86127F3 007	272.5	285.7	307.3	295.0
86127F3 008	311.8			
86127F3 009	264.4			
86127F3 010	290.4			
86127F3 011	298.5	288.0	303.9	302.0
86127F3 012	249.5			
86127F3 013	284.4	283.0		
86127F3 014	246.6			
86127F3 015	242.1			
86127F3 016	309.7	304.0		
86127F3 017	245.8			
86127F3 018	289.9			
86127F3 019	321.4			
86127F3 020	251.4			
86127F3 021	251.2			
86127F3 022	261.2			
86127F3 023	338.0			
86127F3 024	263.5			
86127F3 025	243.0			
86127F3 026	274.2			
86127F3 027	266.3			
86127F3 028	249.6			
86127F3 029	304.6	308.4		
86127F3 030	324.7			

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127
DMEH NUMBER: ML8636Ø
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 2Ø-NOV-86

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: MALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	USE DISCONTINUED; DISPOSED	26-MAR-87	127	86127MN ØØ1
				86127MN ØØ2
				86127MN ØØ3
				86127MN ØØ4
				86127MN ØØ5
				86127MN ØØ6
				86127MN ØØ7
				86127MN ØØ8
				86127MN ØØ9
				86127MN Ø1Ø
				86127MN Ø11
				86127MN Ø12
				86127MN Ø13
				86127MN Ø14
				86127MN Ø15
				86127MN Ø16
				86127MN Ø17
				86127MN Ø18
				86127MN Ø19
				86127MN Ø2Ø
				86127MN Ø21
				86127MN Ø22
				86127MN Ø23
				86127MN Ø24
				86127MN Ø25
				86127MN Ø26
				86127MN Ø27
				86127MN Ø28
				86127MN Ø29
				86127MN Ø3Ø
INTEGUMENT	FOCAL LOSS OF HAIR	13-FEB-87	86	86127MN ØØ1

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127 INDIVIDUAL CLINICAL SIGNS
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	USE DISCONTINUED; DISPOSED	26-MAR-87	127	86127M1 001
				86127M1 002
				86127M1 003
				86127M1 004
				86127M1 005
				86127M1 006
				86127M1 007
				86127M1 008
				86127M1 009
				86127M1 010
				86127M1 011
				86127M1 012
				86127M1 013
				86127M1 014
				86127M1 015
				86127M1 016
				86127M1 017
				86127M1 018
				86127M1 019
				86127M1 020
				86127M1 021
				86127M1 022
				86127M1 023
				86127M1 024
				86127M1 025
				86127M1 026
				86127M1 027
				86127M1 028
				86127M1 029
				86127M1 030

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

SEX: MALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	SACRIFICED IN EXTREMIS	6-FEB-87	79	86127M2 018
	USE DISCONTINUED; DISPOSED	26-MAR-87	127	86127M2 001
				86127M2 002
				86127M2 003
				86127M2 004
				86127M2 005
				86127M2 006
				86127M2 007
				86127M2 008
				86127M2 009
				86127M2 010
				86127M2 011
				86127M2 012
				86127M2 013
				86127M2 014
				86127M2 015
				86127M2 016
				86127M2 017
				86127M2 019
				86127M2 020
				86127M2 021
				86127M2 022
				86127M2 023
				86127M2 024
				86127M2 025
				86127M2 026
				86127M2 027
				86127M2 028
				86127M2 029
				86127M2 030

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
DEATH	SPONTANEOUS - BODY INTACT	26-NOV-86	7	86127M3 013
	USE DISCONTINUED; DISPOSED	26-MAR-87	127	86127M3 001
				86127M3 002
				86127M3 003
				86127M3 004
				86127M3 005
				86127M3 006
				86127M3 007
				86127M3 008
				86127M3 009
				86127M3 010
				86127M3 011
				86127M3 012
				86127M3 014
				86127M3 015
				86127M3 016
				86127M3 017
				86127M3 018
				86127M3 019
				86127M3 020
				86127M3 021
				86127M3 022
				86127M3 023
				86127M3 024
				86127M3 025
				86127M3 026
				86127M3 027
				86127M3 028
				86127M3 029
				86127M3 030

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: FEMALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL	
MOUTH	SALIVATING	28-JAN-87	70	86127FN	010
INTEGUMENT	FOCAL LOSS OF HAIR	23-DEC-86	34	86127FN	009
		30-DEC-86	41	86127FN	009
		28-JAN-87	70	86127FN	008
		4-FEB-87	77	86127FN	008
		11-FEB-87	84	86127FN	008

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127
DMEH NUMBER: ML8636Ø
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
MOUTH	SALIVATING	28-JAN-87	7Ø	86127F1 Ø13

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL
INTEGUMENT	FOCAL LOSS OF HAIR	4-FEB-87	77	86127F2 016
		11-FEB-87	84	86127F2 016
				86127F2 020
MISCELLANEOUS	MISSING TAG	3-DEC-86	14	86127F2 019

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

INDIVIDUAL CLINICAL SIGNS

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

SEX: FEMALE

CATEGORY	OBSERVATION	DATE OF OBSERVATION	DAY OF STUDY	ANIMAL	
MOUTH	SALIVATING	23-DEC-86	34	86127F3	010
	PERIORAL WETNESS	23-DEC-86	34	86127F3	010
INTEGUMENT	FOCAL LOSS OF HAIR	23-DEC-86	34	86127F3	016
		30-DEC-86	41	86127F3	016
		7-JAN-87	49	86127F3	016
	PILOERECTION	10-DEC-86	21	86127F3	013
GENERAL APPEARANCE	DEHYDRATED	10-DEC-86	21	86127F3	013

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 13-APR-87

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

SEX: MALE

GROUP	TARGET DOSE	DATE (1986): DAY OF STUDY:	PRE-TEST	13-FEB 86
MN		MEAN	191.6	535.9
NEGATIVE CONTROL		STD. DEV.	9.67	45.36
		SAMPLE SIZE	30	30
M1	2.500 MG/M3	MEAN	191.5	537.9
TEST GROUP		STD. DEV.	9.71	40.49
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	30	30
M2	15.00 MG/M3	MEAN	191.5	535.1
TEST GROUP		STD. DEV.	9.91	44.84
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	30	29
M3	50.00 MG/M3	MEAN	191.4	533.0
TEST GROUP		STD. DEV.	9.74	42.72
2,6-DIETHYLPHENYL AZOMETHINE		SAMPLE SIZE	30	29

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P<.05$)
** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P<.01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P\leq.01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

INDIVIDUAL MATING REPORT - 86127 - FØa

GENERATION : FØa

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	(B)
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	
N										
NMØØ1	NFØØ1	X								P
NMØØ2	NFØØ2				X					P
NMØØ3	NFØØ3				X					P
NMØØ4	NFØØ4						X			P
NMØØ5	NFØØ5			X						P
NMØØ6	NFØØ6				X					P
NMØØ7	NFØØ7		X							P
NMØØ8	NFØØ8			X						P
NMØØ9	NFØØ9	X								P
NMØ1Ø	NFØ1Ø			X						N
NMØ11	NFØ11			X						N
NMØ12	NFØ12		X							N
NMØ13	NFØ13	X								P
NMØ14	NFØ14			X						P
NMØØ1	NFØ15							X		N
NMØ15	NFØ15								X	N
NMØ16	NFØ16	X								P
NMØ17	NFØ17	X								P
NMØ18	NFØ18								X	P
NMØ19	NFØ19		X							P
NMØ2Ø	NFØ2Ø		X							P
NMØ21	NFØ21								X	P
NMØ22	NFØ22			X						N
NMØ23	NFØ23	X								P
NMØ24	NFØ24	X								P
NMØ25	NFØ25					X				P
NMØ26	NFØ26	X								N
NMØ16	NFØ27								X	N
NMØ27	NFØ27								X	N
NMØ17	NFØ28								X	N
NMØ28	NFØ28								X	N
NMØ29	NFØ29		X							P
NMØ23	NFØ3Ø	X								N
NMØ3Ø	NFØ3Ø								X	N

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86127 - FØa

GENERATION : FØa

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	(B)
1										
1MØØ1	1FØØ1	X								N
1MØØ2	1FØØ2				X					P
1MØØ1	1FØØ3	X								P
1MØØ3	1FØØ3								X	N
1MØØ4	1FØØ4		X							P
1MØØ5	1FØØ5		X							P
1MØØ6	1FØØ6				X					P
1MØØ7	1FØØ7			X						P
1MØØ8	1FØØ8	X								P
1MØØ9	1FØØ9		X							P
1MØ1Ø	1FØ1Ø				X					N
1MØ11	1FØ11	X								P
1MØ12	1FØ12		X							P
1MØ13	1FØ13					X				P
1MØ14	1FØ14		X							P
1MØ15	1FØ15	X								P
1MØ16	1FØ16			X						N
1MØ17	1FØ17		X							N
1MØ18	1FØ18				X					P
1MØ19	1FØ19		X							P
1MØ2Ø	1FØ2Ø		X							N
1MØØ8	1FØ21								X	N
1MØ21	1FØ21								X	N
1MØ22	1FØ22				X					P
1MØ11	1FØ23	X								P
1MØ23	1FØ23								X	N
1MØ24	1FØ24		X							P
1MØ25	1FØ25	X								P
1MØ26	1FØ26	X								P
1MØ15	1FØ27	X								P
1MØ27	1FØ27								X	N
1MØ25	1FØ28	X								P
1MØ28	1FØ28								X	N
1MØ29	1FØ29			X						P
1MØ3Ø	1FØ3Ø				X					P

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86127 - FØa

GENERATION : FØa

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	(B)
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	
2										
2MØØ1	2FØØ1			X						P
2MØØ2	2FØØ2	X								P
2MØØ3	2FØØ3		X							P
2MØØ2	2FØØ4						X			N
2MØØ4	2FØØ4								X	N
2MØØ5	2FØØ5	X								P
2MØØ6	2FØØ6			X						P
2MØØ7	2FØØ7	X								P
2MØØ8	2FØØ8				X					P
2MØØ9	2FØØ9		X							P
2MØ1Ø	2FØ1Ø			X						P
2MØ11	2FØ11	X								P
2MØ12	2FØ12				X					P
2MØ13	2FØ13				X					P
2MØ14	2FØ14			X						P
2MØ15	2FØ15			X						P
2MØ16	2FØ16		X							P
2MØØ5	2FØ17	X								P
2MØ17	2FØ17								X	N
2MØØ2	2FØ18				X					P
2MØ19	2FØ19	X								N
2MØ2Ø	2FØ2Ø				X					P
2MØ21	2FØ21	X								P
2MØ22	2FØ22	X								P
2MØ23	2FØ23	X								N
2MØ24	2FØ24	X								P
2MØ25	2FØ25			X						P
2MØ26	2FØ26				X					P
2MØ27	2FØ27	X								P
2MØØ7	2FØ28	X								N
2MØ28	2FØ28								X	N
2MØ29	2FØ29		X							P
2MØ11	2FØ3Ø		X							P
2MØ3Ø	2FØ3Ø								X	N

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

INDIVIDUAL MATING REPORT - 86127 - F0a

GENERATION : F0a

CO-HOUSE PAIRS (A)		COPULATION								PREGNANCY STATUS
		CONFIRMED COPULATION DAYS AFTER PAIRING							COPULATION NOT	
MALE NO.	FEMALE NO.	1	2	3	4	5	6	7	CONFIRMED	(B)
3										
3M001	3F001				X					P
3M002	3F002								X	N
3M003	3F002	X								P
3M003	3F003	X								P
3M004	3F004			X						P
3M005	3F005		X							P
3M006	3F006				X					P
3M007	3F007								X	N
3M008	3F007								X	N
3M008	3F008	X								P
3M009	3F009	X								P
3M010	3F010			X						N
3M009	3F011								X	N
3M011	3F011								X	N
3M012	3F012		X							P
3M003	3F013			X						P
3M014	3F014		X							P
3M015	3F015		X							P
3M016	3F016				X					N
3M017	3F017	X								P
3M018	3F018	X								N
3M019	3F019		X							P
3M020	3F020			X						P
3M021	3F021			X						P
3M022	3F022		X							P
3M023	3F023			X						P
3M024	3F024		X							P
3M025	3F025		X							P
3M026	3F026		X							N
3M027	3F027			X						P
3M028	3F028	X								P
3M029	3F029						X			N
3M030	3F030		X							P

- - - LEGEND - - -

A -- STUDY NUMBER PREFIX OMITTED

B -- P:PREGNANT; N:NOT PREGNANT; ?:PREGNANCY STATUS NOT DETERMINED

LITTER MORTALITY REPORT - 86127

GENERATION : F1a MALES

GROUP	MEAN SURVIVING FRACTION (A) S.D. IN ( ) LACTATION DAY Ø - 4	LACTATION DAY 4 - 21
N	Ø.871(Ø.324)	1.ØØØ(Ø.ØØØ)
1	Ø.974(Ø.Ø73)	Ø.99Ø(Ø.Ø51)
2	Ø.972(Ø.1Ø6)	1.ØØØ(Ø.ØØØ)
3	Ø.91Ø(Ø.225)	1.ØØØ(Ø.ØØØ)

- - - LEGEND - - -

A -- ANALYZED WITH MANN-WHITNEY TEST AND BONFERRONI TEST IF SAMPLE SIZE > 2Ø

LITTER MORTALITY REPORT - 86127

GENERATION : F1a FEMALES

GROUP	MEAN SURVIVING FRACTION (A) S.D. IN ( ) LACTATION DAY Ø - 4	LACTATION DAY 4 - 21
N	Ø.931(Ø.236)	Ø.971(Ø.121)
1	Ø.971(Ø.067)	1.000(Ø.000)
2	Ø.990(Ø.035)	1.000(Ø.000)
3	Ø.948(Ø.211)	1.000(Ø.000)

- - - LEGEND - - -

A -- ANALYZED WITH MANN-WHITNEY TEST AND BONFERRONI TEST IF SAMPLE SIZE > 20

LITTER MORTALITY REPORT - 86127

GENERATION : F1a MALES AND FEMALES COMBINED

GROUP	MEAN SURVIVING FRACTION (A) S.D. IN ( ) LACTATION DAY 0 - 4	LACTATION DAY 4 - 21
N	0.871(0.316)	0.993(0.030)
1	0.976(0.041)	0.995(0.026)
2	0.979(0.068)	1.000(0.000)
3	0.928(0.215)	1.000(0.000)

- - - LEGEND - - -

A -- ANALYZED WITH MANN-WHITNEY TEST AND BONFERRONI TEST IF SAMPLE SIZE > 20

GESTATIONAL LENGTH REPORT - 86127

GENERATION : F0a

GROUP	TOTAL DAMS	GESTATIONAL LENGTH (DAYS) ≤20	21	22	23	24	≥25	MEAN DURATION (DAYS) (C)	STANDARD DEVIATION (DAYS)
N	19 (A)	0	0	10	7	2	0	22.6	0.7
1	24 (A)	0	0	17	7	0	0	22.3	0.5
2	26 (A)	0	0	17	9	0	0	22.3	0.5
3	23 (A)	0	0	19	4	0	0	22.2 *	0.4

- - - LEGEND - - -

A -- FEMALES WITHOUT COPULATION OBSERVED OR WITH UNCERTAIN DATE OF COPULATION NOT INCLUDED

C -- ANALYZED WITH MANN-WHITNEY TEST AND BONFERRONI TEST IF SAMPLE SIZE > 20

* -- TEST INDICATING STATISTICALLY SIGNIFICANT DIFFERENCE (P < .05)

INDIVIDUAL GESTATION BODY WEIGHTS - 86127

STUDY 86127 ANIMAL NUMBER		GROUP	STATUS (*)	GESTATION DAY	BODY WEIGHT (GMS) 0	6	13	20
86127FN	001	N	P		298.2	304.7	331.1	414.9
86127FN	002	N	P		333.1	352.5	374.3	448.4
86127FN	003	N	P		386.4	411.0	439.1	474.6
86127FN	004	N	P		305.8	326.7	355.9	427.4
86127FN	005	N	P		375.1	394.6	424.2	467.1
86127FN	006	N	P		328.5	363.5	390.8	449.8
86127FN	007	N	P		335.9	354.2	384.1	439.0
86127FN	008	N	P		321.7	354.0	383.6	427.0
86127FN	009	N	P		390.2	431.5	466.6	553.6
86127FN	010	N	N		335.3	358.3	378.8	361.2
86127FN	011	N	N		351.3	345.8	360.3	349.5
86127FN	012	N	N		292.2	322.1	336.3	327.9
86127FN	013	N	P		308.7	329.6	350.8	434.3
86127FN	014	N	P		333.0	355.7	382.0	458.8
86127FN	015	N	N		314.6	325.8	335.6	326.3
86127FN	016	N	P		400.1	436.4	470.8	539.2
86127FN	017	N	P		275.6	309.2	341.9	390.8
86127FN	019	N	P		266.3	288.5	305.8	341.6
86127FN	020	N	P		252.6	279.5	303.0	363.8
86127FN	022	N	N		273.2	284.6	296.1	287.6
86127FN	023	N	P		283.1	303.3	327.3	384.3
86127FN	024	N	P		324.4	343.7	374.3	424.3
86127FN	025	N	P		281.6	303.9	331.6	400.2
86127FN	026	N	N		274.6	295.6	300.3	320.0
86127FN	029	N	P		264.1	288.3	301.6	376.0
86127FN	030	N	N		289.5	316.8	319.0	320.3

(*) N, NON-PREGNANT; PN, PREGNANT WITH NO LIVE FETUSES/PUPS; P, PREGNANT WITH LIVE FETUSES/PUPS.

INDIVIDUAL GESTATION BODY WEIGHTS - 86127 (CONT)

STUDY 86127 ANIMAL NUMBER		GROUP	STATUS (*)	GESTATION DAY	BODY WEIGHT (GMS) 0	6	13	20
86127F1	001	1	N		296.2	322.3	339.7	326.9
86127F1	002	1	P		297.4	324.2	349.7	414.9
86127F1	003	1	P		325.1	359.4	389.8	467.2
86127F1	004	1	P		236.3	266.4	291.7	344.6
86127F1	005	1	P		337.9	363.4	395.0	474.7
86127F1	006	1	P		377.1	404.6	439.7	519.4
86127F1	007	1	P		318.1	354.3	391.7	490.4
86127F1	008	1	P		343.3	376.1	359.9	462.6
86127F1	009	1	P		351.7	393.8	422.3	487.2
86127F1	010	1	N		363.3	403.3	425.4	406.0
86127F1	011	1	P		303.2	337.8	374.0	470.1
86127F1	012	1	P		309.2	334.6	359.1	443.2
86127F1	013	1	P		285.4	305.1	306.5	378.6
86127F1	014	1	P		364.7	394.3	418.7	501.2
86127F1	015	1	P		302.1	330.9	362.8	402.4
86127F1	016	1	N		359.1	386.2	407.6	396.1
86127F1	017	1	N		310.5	347.5	372.0	343.9
86127F1	018	1	P		282.9	300.2	341.0	416.1
86127F1	019	1	P		321.7	352.5	388.5	479.8
86127F1	020	1	N		251.1	264.1	279.4	268.5
86127F1	022	1	P		274.7	292.9	324.8	392.1
86127F1	023	1	P		260.6	274.9	293.8	354.2
86127F1	024	1	P		298.4	312.7	339.5	402.5
86127F1	025	1	P		332.8	373.6	404.4	510.5
86127F1	026	1	P		297.5	321.4	344.8	394.0
86127F1	027	1	P		307.8	329.0	356.2	419.1
86127F1	028	1	P		308.2	338.2	356.4	404.9
86127F1	029	1	P		318.7	337.7	355.6	423.0
86127F1	030	1	P		337.5	366.0	406.6	475.2

(*) N, NON-PREGNANT; PN, PREGNANT WITH NO LIVE FETUSES/PUPS; P, PREGNANT WITH LIVE FETUSES/PUPS.

INDIVIDUAL GESTATION BODY WEIGHTS - 86127 (CONT)

STUDY 86127 ANIMAL NUMBER		GROUP	STATUS (*)	BODY WEIGHT (GMS)			
			GESTATION DAY	0	6	13	20
86127F2	001	2	P	290.9	322.8	338.9	379.2
86127F2	002	2	P	341.2	367.4	398.8	470.3
86127F2	003	2	P	296.9	322.5	357.9	454.9
86127F2	004	2	N	330.3	333.4	343.6	327.3
86127F2	005	2	P	344.3	375.8	416.7	515.1
86127F2	006	2	P	346.0	379.0	418.8	501.4
86127F2	007	2	P	281.4	307.3	339.8	413.7
86127F2	008	2	P	264.5	284.3	308.0	372.1
86127F2	009	2	P	281.2	303.4	328.8	403.4
86127F2	010	2	P	320.1	329.1	361.3	427.7
86127F2	011	2	P	375.0	402.7	447.3	531.0
86127F2	012	2	P	343.2	363.7	391.1	471.3
86127F2	013	2	P	282.5	311.6	337.5	405.5
86127F2	014	2	P	257.8	273.2	303.8	381.6
86127F2	015	2	P	312.6	337.2	365.3	447.3
86127F2	016	2	P	308.0	338.9	369.2	451.5
86127F2	017	2	P	402.4	451.6	495.4	605.2
86127F2	018	2	P	356.6	376.4	409.6	486.9
86127F2	019	2	N	309.7	324.0	332.7	328.2
86127F2	020	2	P	309.1	325.9	352.3	416.3
86127F2	021	2	P	295.1	316.7	339.1	390.3
86127F2	022	2	P	249.2	276.9	300.7	368.1
86127F2	023	2	N	327.9	351.1	353.8	357.9
86127F2	024	2	P	305.3	322.1	353.7	394.1
86127F2	025	2	P	311.8	324.9	349.2	427.2
86127F2	026	2	P	272.5	293.4	319.9	381.3
86127F2	027	2	P	309.8	324.5	348.5	418.2
86127F2	028	2	N	339.3	351.5	356.9	361.1
86127F2	029	2	P	310.5	336.6	355.9	389.2
86127F2	030	2	P	342.1	383.5	413.8	507.9

(*) N, NON-PREGNANT; PN, PREGNANT WITH NO LIVE FETUSES/PUPS; P, PREGNANT WITH LIVE FETUSES/PUPS.

INDIVIDUAL GESTATION BODY WEIGHTS - 86127 (CONT)

STUDY 86127 ANIMAL NUMBER		GROUP	STATUS (*)	GESTATION DAY	BODY WEIGHT (GMS) 0	6	13	20
86127F3	001	3	P		255.2	274.1	294.2	351.1
86127F3	002	3	P		257.2	276.3	302.8	372.4
86127F3	003	3	P		270.7	295.8	322.8	365.5
86127F3	004	3	P		281.0	300.3	331.5	412.5
86127F3	005	3	P		293.9	325.8	362.8	438.4
86127F3	006	3	P		294.0	313.1	349.3	424.8
86127F3	008	3	P		310.2	328.1	359.5	430.7
86127F3	009	3	P		262.7	283.7	317.7	377.9
86127F3	010	3	N		285.0	296.9	309.8	315.6
86127F3	012	3	P		247.0	266.5	290.2	348.3
86127F3	013	3	P		279.4	309.2	333.5	405.2
86127F3	014	3	P		243.8	259.8	291.8	350.0
86127F3	015	3	P		239.2	251.0	267.1	319.5
86127F3	016	3	N		303.2	323.4	321.5	316.0
86127F3	017	3	P		242.3	273.2	303.9	380.4
86127F3	018	3	N		289.4	304.4	318.4	335.8
86127F3	019	3	P		232.8	346.6	372.7	440.7
86127F3	020	3	P		249.3	271.7	296.7	363.0
86127F3	021	3	P		254.7	268.2	298.7	373.1
86127F3	022	3	P		262.9	281.2	304.3	372.4
86127F3	023	3	P		339.1	359.1	395.1	462.5
86127F3	024	3	P		269.8	280.4	298.4	354.0
86127F3	025	3	P		244.7	264.6	290.2	351.5
86127F3	026	3	N		278.6	279.5	286.2	282.8
86127F3	027	3	P		268.2	282.1	310.1	359.6
86127F3	028	3	P		244.7	259.9	287.8	341.8
86127F3	029	3	N		311.0	313.1	312.5	318.2
86127F3	030	3	P		318.5	332.7	364.4	436.3

(*) N, NON-PREGNANT; PN, PREGNANT WITH NO LIVE FETUSES/PUPS; P, PREGNANT WITH LIVE FETUSES/PUPS.

INDIVIDUAL LACTATION BODY WEIGHTS - 86127

STUDY 86127

ANIMAL NUMBER		GROUP	LACTATION DAY	BODY WEIGHT (GMS) 0	4	7	14	21
86127FN	001	N		302.0	312.9	322.3	345.2	338.4
86127FN	002	N		356.2	-1.0	-1.0	-1.0	-1.0
86127FN	003	N		458.1	434.2	430.7	444.4	431.7
86127FN	004	N		329.9	347.6	343.0	350.9	317.8
86127FN	005	N		430.2	-1.0	-1.0	-1.0	-1.0
86127FN	006	N		367.2	356.7	357.8	378.5	365.6
86127FN	007	N		363.4	380.0	376.3	387.7	367.8
86127FN	008	N		364.6	366.0	374.8	380.8	346.5
86127FN	009	N		431.5	404.9	419.4	448.0	431.7
86127FN	013	N		320.6	346.9	340.4	353.2	328.3
86127FN	014	N		353.7	366.0	372.7	367.1	379.1
86127FN	016	N		441.4	438.3	437.0	448.3	410.5
86127FN	017	N		336.2	347.5	362.0	403.8	381.9
86127FN	019	N		297.5	303.4	306.5	302.2	294.6
86127FN	020	N		280.1	302.4	318.1	319.1	299.2
86127FN	023	N		309.3	308.6	318.7	332.3	321.7
86127FN	024	N		370.2	364.5	377.7	387.8	379.5
86127FN	025	N		290.8	302.5	311.6	335.3	331.1
86127FN	029	N		283.8	297.1	290.5	315.6	284.6

-1.0 INDICATES BODY WEIGHT NOT RECORDED. DAM HAD NO SURVIVING PUPS.

INDIVIDUAL LACTATION BODY WEIGHTS - 86127 (CONT)

STUDY 86127 ANIMAL NUMBER		GROUP	LACTATION DAY	BODY WEIGHT (GMS)				
				Ø	4	7	14	21
86127F1	Ø02	1		329.8	342.5	346.9	356.7	333.1
86127F1	Ø03	1		373.9	367.7	370.9	397.6	370.5
86127F1	Ø04	1		267.1	278.9	287.6	291.1	258.8
86127F1	Ø05	1		367.5	383.7	388.5	395.7	374.2
86127F1	Ø06	1		391.4	431.5	430.8	430.2	390.5
86127F1	Ø07	1		372.6	392.7	399.1	412.4	387.Ø
86127F1	Ø08	1		363.1	378.4	374.7	376.9	359.8
86127F1	Ø09	1		416.9	411.4	415.4	417.5	398.5
86127F1	Ø11	1		339.7	363.9	364.Ø	385.7	343.3
86127F1	Ø12	1		339.Ø	375.Ø	386.4	388.9	363.5
86127F1	Ø13	1		297.2	316.1	311.4	336.3	3Ø1.5
86127F1	Ø14	1		391.2	4Ø6.2	423.Ø	397.2	394.3
86127F1	Ø15	1		341.3	326.3	326.5	332.6	325.4
86127F1	Ø18	1		313.6	35Ø.Ø	355.5	357.9	316.4
86127F1	Ø19	1		363.7	395.5	4Ø2.1	4Ø4.7	394.1
86127F1	Ø22	1		295.7	3Ø8.6	312.9	313.7	284.1
86127F1	Ø23	1		277.1	291.6	292.5	3Ø8.6	295.4
86127F1	Ø24	1		316.1	335.5	33Ø.2	334.2	333.Ø
86127F1	Ø25	1		386.5	372.6	379.8	383.4	367.7
86127F1	Ø26	1		331.4	319.3	331.5	335.9	318.7
86127F1	Ø27	1		337.9	359.2	357.8	364.7	35Ø.Ø
86127F1	Ø28	1		33Ø.6	347.2	354.3	366.4	352.6
86127F1	Ø29	1		325.2	334.8	33Ø.1	336.Ø	334.1
86127F1	Ø3Ø	1		382.3	39Ø.5	384.3	385.8	375.Ø

INDIVIDUAL LACTATION BODY WEIGHTS - 86127 (CONT)

STUDY 86127

ANIMAL NUMBER		GROUP	LACTATION DAY	BODY WEIGHT (GMS)				
				Ø	4	7	14	21
86127F2	Ø01	2		32Ø.1	328.2	329.5	329.9	322.4
86127F2	Ø02	2		363.1	388.3	384.2	4Ø4.7	388.3
86127F2	Ø03	2		325.3	349.8	358.1	363.9	346.9
86127F2	Ø05	2		41Ø.3	399.6	4Ø6.9	4Ø3.4	38Ø.Ø
86127F2	Ø06	2		396.7	395.5	4Ø3.9	4Ø2.2	392.5
86127F2	Ø07	2		314.9	317.Ø	335.1	336.8	325.1
86127F2	Ø08	2		277.2	3Ø2.6	311.8	325.7	281.8
86127F2	Ø09	2		332.3	336.7	331.Ø	345.6	326.8
86127F2	Ø1Ø	2		352.7	358.Ø	364.8	351.2	331.5
86127F2	Ø11	2		442.6	436.Ø	442.3	451.8	42Ø.5
86127F2	Ø12	2		35Ø.3	368.1	37Ø.4	365.2	332.1
86127F2	Ø13	2		311.1	339.3	342.1	352.4	336.3
86127F2	Ø14	2		278.2	295.2	294.7	31Ø.4	294.6
86127F2	Ø15	2		35Ø.4	362.9	366.4	359.3	354.1
86127F2	Ø16	2		344.6	349.8	358.7	368.6	371.1
86127F2	Ø17	2		473.4	466.3	463.8	463.9	422.5
86127F2	Ø18	2		383.3	4Ø2.Ø	412.2	433.4	4Ø3.1
86127F2	Ø2Ø	2		33Ø.1	345.Ø	344.6	354.2	332.2
86127F2	Ø21	2		325.2	313.Ø	323.5	333.5	33Ø.3
86127F2	Ø22	2		278.Ø	283.6	289.8	295.6	292.Ø
86127F2	Ø24	2		324.6	327.7	336.2	333.1	325.Ø
86127F2	Ø25	2		321.6	324.6	33Ø.1	347.3	318.9
86127F2	Ø26	2		288.3	3Ø1.9	315.2	319.4	311.2
86127F2	Ø27	2		317.6	326.5	319.8	331.1	3Ø8.9
86127F2	Ø29	2		367.5	335.8	341.2	349.1	354.9
86127F2	Ø3Ø	2		384.5	385.1	397.7	422.Ø	389.8

INDIVIDUAL LACTATION BODY WEIGHTS - 86127 (CONT)

STUDY 86127

ANIMAL NUMBER		GROUP	LACTATION DAY	BODY WEIGHT (GMS)				
				0	4	7	14	21
86127F3	001	3		270.0	-1.0	-1.0	-1.0	-1.0
86127F3	002	3		273.3	291.6	301.0	318.5	316.5
86127F3	003	3		316.3	308.3	289.2	325.4	334.9
86127F3	004	3		294.3	321.6	321.2	331.8	320.9
86127F3	005	3		343.7	362.3	386.0	390.2	367.0
86127F3	006	3		323.8	357.0	367.6	370.6	342.8
86127F3	008	3		344.3	337.9	350.8	338.9	325.0
86127F3	009	3		301.4	309.7	320.1	331.4	301.7
86127F3	012	3		267.8	293.0	300.0	314.2	300.1
86127F3	013	3		302.1	328.0	335.1	357.9	333.7
86127F3	014	3		285.2	282.6	301.3	314.2	293.2
86127F3	015	3		259.0	274.2	288.9	310.6	303.6
86127F3	017	3		283.1	293.5	305.5	317.5	294.7
86127F3	019	3		344.4	368.7	365.6	385.8	357.5
86127F3	020	3		289.6	295.0	305.8	310.0	298.5
86127F3	021	3		275.9	313.6	319.6	322.2	307.2
86127F3	022	3		298.2	316.8	320.8	342.0	317.1
86127F3	023	3		373.1	402.3	397.3	420.1	413.4
86127F3	024	3		273.7	306.9	314.1	331.0	316.5
86127F3	025	3		263.8	284.1	298.3	319.3	294.8
86127F3	027	3		269.4	291.0	309.1	328.0	306.2
86127F3	028	3		269.5	276.3	287.9	292.5	279.1
86127F3	030	3		353.3	363.3	366.5	380.7	341.4

-1.0 INDICATES BODY WEIGHT NOT RECORDED. DAM HAD NO SURVIVING PUPS.

APPENDIX 4

ANIMAL TERMINATION HISTORIES

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 20-MAY-87

STUDY NUMBER: 86126 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: MALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126MN 001	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 002	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 003	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 004	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 005	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 006	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 007	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 008	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 009	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 010	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 011	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 012	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 013	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 014	25-FEB-87	98	SPONTANEOUS - BODY INTACT
86126MN 015	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 016	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 017	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 018	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 019	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 020	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 021	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 022	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 023	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 024	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126MN 025	30-MAR-87	131	USE DISCONTINUED; DISPOSED

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126M1 001	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 002	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 003	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 004	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 005	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 006	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 007	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 008	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 009	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 010	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 011	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 012	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 013	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 014	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 015	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 016	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 017	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 018	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 019	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 020	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 021	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 022	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 023	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 024	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M1 025	30-MAR-87	131	USE DISCONTINUED; DISPOSED

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 20-MAY-87

STUDY NUMBER: 86126 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126M2 001	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 002	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 003	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 004	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 005	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 006	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 007	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 008	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 009	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 010	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 011	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 012	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 013	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 014	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 015	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 016	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 017	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 018	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 019	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 020	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 021	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 022	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 023	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 024	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M2 025	30-MAR-87	131	USE DISCONTINUED; DISPOSED

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 20-MAY-87

STUDY NUMBER: 86126 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126M3 001	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 002	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 003	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 004	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 005	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 006	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 007	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 008	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 009	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 010	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 011	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 012	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 013	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 014	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 015	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 016	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 017	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 018	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 019	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 020	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 021	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 022	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 023	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 024	30-MAR-87	131	USE DISCONTINUED; DISPOSED
86126M3 025	30-MAR-87	131	USE DISCONTINUED; DISPOSED

STUDY NUMBER: 86126 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: FEMALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126FN 001	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 002	2-MAR-87	103	SCHEDULED SACRIFICE
86126FN 003	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 004	3-MAR-87	104	SCHEDULED SACRIFICE
86126FN 005	4-MAR-87	105	SCHEDULED SACRIFICE
86126FN 006	2-MAR-87	103	SCHEDULED SACRIFICE
86126FN 007	5-MAR-87	106	SCHEDULED SACRIFICE
86126FN 008	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 009	2-MAR-87	103	SCHEDULED SACRIFICE
86126FN 010	3-MAR-87	104	SCHEDULED SACRIFICE
86126FN 011	3-MAR-87	104	SCHEDULED SACRIFICE
86126FN 012	2-MAR-87	103	SCHEDULED SACRIFICE
86126FN 013	2-MAR-87	103	SCHEDULED SACRIFICE
86126FN 014	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 015	2-MAR-87	103	SCHEDULED SACRIFICE
86126FN 016	3-MAR-87	104	SCHEDULED SACRIFICE
86126FN 017	4-MAR-87	105	SCHEDULED SACRIFICE
86126FN 018	2-MAR-87	103	SCHEDULED SACRIFICE
86126FN 019	2-MAR-87	103	SCHEDULED SACRIFICE
86126FN 020	3-MAR-87	104	SCHEDULED SACRIFICE
86126FN 021	2-MAR-87	103	SCHEDULED SACRIFICE
86126FN 022	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 023	4-MAR-87	105	SCHEDULED SACRIFICE
86126FN 024	5-MAR-87	106	SCHEDULED SACRIFICE
86126FN 025	4-MAR-87	105	SCHEDULED SACRIFICE
86126FN 026	13-MAR-87	114	SCHEDULED SACRIFICE
86126FN 027	5-MAR-87	106	SCHEDULED SACRIFICE
86126FN 028	9-MAR-87	110	SCHEDULED SACRIFICE
86126FN 029	5-MAR-87	106	SCHEDULED SACRIFICE
86126FN 030	12-MAR-87	113	SCHEDULED SACRIFICE
86126FN 031	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 032	10-MAR-87	111	SCHEDULED SACRIFICE
86126FN 033	10-MAR-87	111	SCHEDULED SACRIFICE

STUDY NUMBER: 86126 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: FEMALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126FN 034	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 035	4-MAR-87	105	SCHEDULED SACRIFICE
86126FN 036	5-MAR-87	106	SCHEDULED SACRIFICE
86126FN 037	11-MAR-87	112	SCHEDULED SACRIFICE
86126FN 038	5-MAR-87	106	SCHEDULED SACRIFICE
86126FN 039	11-MAR-87	112	SCHEDULED SACRIFICE
86126FN 040	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 041	4-MAR-87	105	SCHEDULED SACRIFICE
86126FN 042	9-MAR-87	110	SCHEDULED SACRIFICE
86126FN 043	5-MAR-87	106	SCHEDULED SACRIFICE
86126FN 044	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 045	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 046	6-MAR-87	107	SCHEDULED SACRIFICE
86126FN 047	9-MAR-87	110	SCHEDULED SACRIFICE
86126FN 048	9-MAR-87	110	SCHEDULED SACRIFICE
86126FN 049	12-MAR-87	113	SCHEDULED SACRIFICE
86126FN 050	12-MAR-87	113	SCHEDULED SACRIFICE

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126F1 001	6-MAR-87	107	SCHEDULED SACRIFICE
86126F1 002	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 003	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 004	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 005	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 006	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 007	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 008	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 009	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 010	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 011	3-MAR-87	104	SCHEDULED SACRIFICE
86126F1 012	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 013	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 014	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 015	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 016	4-MAR-87	105	SCHEDULED SACRIFICE
86126F1 017	6-MAR-87	107	SCHEDULED SACRIFICE
86126F1 018	3-MAR-87	104	SCHEDULED SACRIFICE
86126F1 019	3-MAR-87	104	SCHEDULED SACRIFICE
86126F1 020	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 021	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 022	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 023	2-MAR-87	103	SCHEDULED SACRIFICE
86126F1 024	4-MAR-87	105	SCHEDULED SACRIFICE
86126F1 025	3-MAR-87	104	SCHEDULED SACRIFICE
86126F1 026	10-MAR-87	111	SCHEDULED SACRIFICE
86126F1 027	9-MAR-87	110	SCHEDULED SACRIFICE
86126F1 028	6-MAR-87	107	SCHEDULED SACRIFICE
86126F1 029	4-MAR-87	105	SCHEDULED SACRIFICE
86126F1 030	9-MAR-87	110	SCHEDULED SACRIFICE
86126F1 031	5-MAR-87	106	SCHEDULED SACRIFICE
86126F1 032	5-MAR-87	106	SCHEDULED SACRIFICE
86126F1 033	5-MAR-87	106	SCHEDULED SACRIFICE

STUDY NUMBER: 86126 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126F1 034	6-MAR-87	107	SCHEDULED SACRIFICE
86126F1 035	5-MAR-87	106	SCHEDULED SACRIFICE
86126F1 036	6-MAR-87	107	SCHEDULED SACRIFICE
86126F1 037	6-MAR-87	107	SCHEDULED SACRIFICE
86126F1 038	9-MAR-87	110	SCHEDULED SACRIFICE
86126F1 039	5-MAR-87	106	SCHEDULED SACRIFICE
86126F1 040	9-MAR-87	110	SCHEDULED SACRIFICE
86126F1 041	12-MAR-87	113	SCHEDULED SACRIFICE
86126F1 042	13-MAR-87	114	SCHEDULED SACRIFICE
86126F1 043	6-MAR-87	107	SCHEDULED SACRIFICE
86126F1 044	9-MAR-87	110	SCHEDULED SACRIFICE
86126F1 045	11-MAR-87	112	SCHEDULED SACRIFICE
86126F1 046	9-MAR-87	110	SCHEDULED SACRIFICE
86126F1 047	5-MAR-87	106	SCHEDULED SACRIFICE
86126F1 048	5-MAR-87	106	SCHEDULED SACRIFICE
86126F1 049	10-MAR-87	111	SCHEDULED SACRIFICE
86126F1 050	9-MAR-87	110	SCHEDULED SACRIFICE

STUDY NUMBER: 86126 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126F2 001	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 002	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 003	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 004	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 005	5-MAR-87	106	SCHEDULED SACRIFICE
86126F2 006	4-MAR-87	105	SCHEDULED SACRIFICE
86126F2 007	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 008	3-MAR-87	104	SCHEDULED SACRIFICE
86126F2 009	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 010	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 011	3-MAR-87	104	SCHEDULED SACRIFICE
86126F2 012	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 013	6-MAR-87	107	SCHEDULED SACRIFICE
86126F2 014	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 015	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 016	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 017	4-MAR-87	105	SCHEDULED SACRIFICE
86126F2 018	3-MAR-87	104	SCHEDULED SACRIFICE
86126F2 019	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 020	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 021	3-MAR-87	104	SCHEDULED SACRIFICE
86126F2 022	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 023	6-MAR-87	107	SCHEDULED SACRIFICE
86126F2 024	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 025	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 026	2-MAR-87	103	SCHEDULED SACRIFICE
86126F2 027	5-MAR-87	106	SCHEDULED SACRIFICE
86126F2 028	5-MAR-87	106	SCHEDULED SACRIFICE
86126F2 029	9-MAR-87	110	SCHEDULED SACRIFICE
86126F2 030	9-MAR-87	110	SCHEDULED SACRIFICE
86126F2 031	9-MAR-87	110	SCHEDULED SACRIFICE
86126F2 032	4-MAR-87	105	SCHEDULED SACRIFICE
86126F2 033	9-MAR-87	110	SCHEDULED SACRIFICE

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126F2 034	6-MAR-87	107	SCHEDULED SACRIFICE
86126F2 035	6-MAR-87	107	SCHEDULED SACRIFICE
86126F2 036	6-MAR-87	107	SCHEDULED SACRIFICE
86126F2 037	4-MAR-87	105	SCHEDULED SACRIFICE
86126F2 038	11-MAR-87	112	SCHEDULED SACRIFICE
86126F2 039	3-MAR-87	104	SCHEDULED SACRIFICE
86126F2 040	6-MAR-87	107	SCHEDULED SACRIFICE
86126F2 041	4-MAR-87	105	SCHEDULED SACRIFICE
86126F2 042	11-MAR-87	112	SCHEDULED SACRIFICE
86126F2 043	9-MAR-87	110	SCHEDULED SACRIFICE
86126F2 044	5-MAR-87	106	SCHEDULED SACRIFICE
86126F2 045	5-MAR-87	106	SCHEDULED SACRIFICE
86126F2 046	9-MAR-87	110	SCHEDULED SACRIFICE
86126F2 047	9-MAR-87	110	SCHEDULED SACRIFICE
86126F2 048	9-MAR-87	110	SCHEDULED SACRIFICE
86126F2 049	4-MAR-87	105	SCHEDULED SACRIFICE
86126F2 050	5-MAR-87	106	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 20-MAY-87

STUDY NUMBER: 86126 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126F3 001	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 002	4-MAR-87	105	SCHEDULED SACRIFICE
86126F3 003	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 004	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 005	3-MAR-87	104	SCHEDULED SACRIFICE
86126F3 006	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 007	6-MAR-87	107	SCHEDULED SACRIFICE
86126F3 008	3-MAR-87	104	SCHEDULED SACRIFICE
86126F3 009	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 010	4-MAR-87	105	SCHEDULED SACRIFICE
86126F3 011	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 012	3-MAR-87	104	SCHEDULED SACRIFICE
86126F3 013	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 014	4-MAR-87	105	SCHEDULED SACRIFICE
86126F3 015	4-MAR-87	105	SCHEDULED SACRIFICE
86126F3 016	3-MAR-87	104	SCHEDULED SACRIFICE
86126F3 017	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 018	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 019	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 020	6-MAR-87	107	SCHEDULED SACRIFICE
86126F3 021	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 022	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 023	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 024	6-MAR-87	107	SCHEDULED SACRIFICE
86126F3 025	3-MAR-87	104	SCHEDULED SACRIFICE
86126F3 026	5-MAR-87	106	SCHEDULED SACRIFICE
86126F3 027	9-MAR-87	110	SCHEDULED SACRIFICE
86126F3 028	4-MAR-87	105	SCHEDULED SACRIFICE
86126F3 029	6-MAR-87	107	SCHEDULED SACRIFICE
86126F3 030	11-MAR-87	112	SCHEDULED SACRIFICE
86126F3 031	5-MAR-87	106	SCHEDULED SACRIFICE
86126F3 032	11-MAR-87	112	SCHEDULED SACRIFICE
86126F3 033	6-MAR-87	107	SCHEDULED SACRIFICE

STUDY NUMBER: 86126
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86126F3 034	4-MAR-87	105	SCHEDULED SACRIFICE
86126F3 035	9-MAR-87	110	SCHEDULED SACRIFICE
86126F3 036	9-MAR-87	110	SCHEDULED SACRIFICE
86126F3 037	4-MAR-87	105	SCHEDULED SACRIFICE
86126F3 038	5-MAR-87	106	SCHEDULED SACRIFICE
86126F3 039	12-MAR-87	113	SCHEDULED SACRIFICE
86126F3 040	9-MAR-87	110	SCHEDULED SACRIFICE
86126F3 041	4-MAR-87	105	SCHEDULED SACRIFICE
86126F3 042	6-MAR-87	107	SCHEDULED SACRIFICE
86126F3 043	9-MAR-87	110	SCHEDULED SACRIFICE
86126F3 044	11-MAR-87	112	SCHEDULED SACRIFICE
86126F3 045	10-MAR-87	111	SCHEDULED SACRIFICE
86126F3 046	2-MAR-87	103	SCHEDULED SACRIFICE
86126F3 047	9-MAR-87	110	SCHEDULED SACRIFICE
86126F3 048	9-MAR-87	110	SCHEDULED SACRIFICE
86126F3 049	9-MAR-87	110	SCHEDULED SACRIFICE
86126F3 050	11-MAR-87	112	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: MALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127MN 001	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 002	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 003	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 004	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 005	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 006	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 007	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 008	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 009	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 010	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 011	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 012	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 013	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 014	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 015	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 016	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 017	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 018	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 019	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 020	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 021	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 022	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 023	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 024	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 025	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 026	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 027	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 028	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 029	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 030	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127MN 101	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 102	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 103	31-MAR-87	132	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: MALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127MN 104	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 105	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 106	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 107	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 108	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 109	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 110	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 111	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 112	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 113	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 114	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 115	31-MAR-87	132	SCHEDULED SACRIFICE
86127MN 116	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 117	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 118	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 119	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 120	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 121	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 122	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 123	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 124	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 125	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 126	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 127	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 128	1-APR-87	133	SCHEDULED SACRIFICE
86127MN 129	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 130	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 131	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 132	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 133	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 134	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 135	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 136	2-APR-87	134	SCHEDULED SACRIFICE

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: MALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127MN 137	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 138	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 139	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 140	2-APR-87	134	SCHEDULED SACRIFICE
86127MN 141	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 142	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 143	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 144	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 145	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 146	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 147	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 148	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 149	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 150	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 151	3-APR-87	135	SCHEDULED SACRIFICE
86127MN 152	6-APR-87	138	SCHEDULED SACRIFICE
86127MN 153	6-APR-87	138	SCHEDULED SACRIFICE
86127MN 154	6-APR-87	138	SCHEDULED SACRIFICE
86127MN 155	6-APR-87	138	SCHEDULED SACRIFICE
86127MN 156	6-APR-87	138	SCHEDULED SACRIFICE
86127MN 157	6-APR-87	138	SCHEDULED SACRIFICE
86127MN 158	6-APR-87	138	SCHEDULED SACRIFICE
86127MN 159	6-APR-87	138	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M1 001	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 002	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 003	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 004	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 005	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 006	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 007	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 008	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 009	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 010	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 011	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 012	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 013	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 014	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 015	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 016	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 017	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 018	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 019	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 020	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 021	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 022	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 023	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 024	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 025	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 026	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 027	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 028	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 029	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 030	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M1 101	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 102	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 103	31-MAR-87	132	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M1 104	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 105	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 106	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 107	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 108	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 109	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 110	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 111	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 112	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 113	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 114	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 115	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 116	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 117	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 118	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 119	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 120	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 121	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 122	31-MAR-87	132	SCHEDULED SACRIFICE
86127M1 123	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 124	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 125	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 126	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 127	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 128	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 129	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 130	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 131	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 132	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 133	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 134	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 135	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 136	1-APR-87	133	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M1 137	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 138	1-APR-87	133	SCHEDULED SACRIFICE
86127M1 139	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 140	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 141	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 142	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 143	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 144	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 145	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 146	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 147	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 148	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 149	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 150	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 151	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 152	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 153	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 154	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 155	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 156	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 157	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 158	2-APR-87	134	SCHEDULED SACRIFICE
86127M1 159	3-APR-87	135	SCHEDULED SACRIFICE
86127M1 160	3-APR-87	135	SCHEDULED SACRIFICE
86127M1 161	3-APR-87	135	SCHEDULED SACRIFICE
86127M1 162	3-APR-87	135	SCHEDULED SACRIFICE
86127M1 163	3-APR-87	135	SCHEDULED SACRIFICE
86127M1 164	3-APR-87	135	SCHEDULED SACRIFICE
86127M1 165	3-APR-87	135	SCHEDULED SACRIFICE
86127M1 166	3-APR-87	135	SCHEDULED SACRIFICE
86127M1 167	3-APR-87	135	SCHEDULED SACRIFICE
86127M1 168	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 169	6-APR-87	138	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M1 170	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 171	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 176	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 177	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 178	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 179	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 180	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 181	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 182	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 183	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 184	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 185	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 186	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 187	6-APR-87	138	SCHEDULED SACRIFICE
86127M1 188	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 189	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 190	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 191	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 192	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 193	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 194	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 195	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 196	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 197	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 198	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 199	7-APR-87	139	SCHEDULED SACRIFICE
86127M1 200	8-APR-87	140	SCHEDULED SACRIFICE
86127M1 201	8-APR-87	140	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M2 001	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 002	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 003	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 004	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 005	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 006	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 007	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 008	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 009	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 010	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 011	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 012	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 013	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 014	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 015	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 016	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 017	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 018	6-FEB-87	79	SACRIFICED IN EXTREMIS
86127M2 019	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 020	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 021	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 022	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 023	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 024	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 025	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 026	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 027	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 028	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 029	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 030	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M2 101	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 102	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 103	31-MAR-87	132	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M2 104	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 105	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 106	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 107	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 108	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 109	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 110	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 111	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 112	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 113	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 114	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 115	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 116	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 117	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 118	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 119	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 120	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 121	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 122	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 123	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 124	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 125	31-MAR-87	132	SCHEDULED SACRIFICE
86127M2 126	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 127	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 128	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 129	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 130	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 131	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 132	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 133	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 134	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 135	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 136	1-APR-87	133	SCHEDULED SACRIFICE

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M2 137	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 138	1-APR-87	133	SCHEDULED SACRIFICE
86127M2 139	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 140	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 141	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 142	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 143	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 144	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 145	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 146	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 147	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 148	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 149	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 150	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 151	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 152	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 153	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 154	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 155	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 156	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 157	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 158	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 159	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 160	2-APR-87	134	SCHEDULED SACRIFICE
86127M2 161	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 162	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 163	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 164	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 165	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 166	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 167	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 168	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 169	3-APR-87	135	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M2 170	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 171	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 172	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 173	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 174	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 175	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 176	3-APR-87	135	SCHEDULED SACRIFICE
86127M2 177	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 178	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 179	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 180	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 181	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 182	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 183	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 184	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 193	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 194	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 195	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 196	6-APR-87	138	SCHEDULED SACRIFICE
86127M2 197	8-APR-87	140	SCHEDULED SACRIFICE
86127M2 198	8-APR-87	140	SCHEDULED SACRIFICE
86127M2 199	8-APR-87	140	SCHEDULED SACRIFICE
86127M2 200	8-APR-87	140	SCHEDULED SACRIFICE
86127M2 201	8-APR-87	140	SCHEDULED SACRIFICE
86127M2 202	8-APR-87	140	SCHEDULED SACRIFICE
86127M2 203	8-APR-87	140	SCHEDULED SACRIFICE
86127M2 204	8-APR-87	140	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

SEX: MALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M3 001	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 002	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 003	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 004	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 005	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 006	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 007	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 008	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 009	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 010	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 011	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 012	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 013	26-NOV-86	7	SPONTANEOUS - BODY INTACT
86127M3 014	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 015	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 016	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 017	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 018	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 019	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 020	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 021	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 022	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 023	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 024	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 025	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 026	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 027	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 028	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 029	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 030	26-MAR-87	127	USE DISCONTINUED; DISPOSED
86127M3 101	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 102	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 103	31-MAR-87	132	SCHEDULED SACRIFICE

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M3 104	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 105	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 106	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 107	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 108	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 109	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 110	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 111	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 112	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 113	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 114	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 115	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 116	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 117	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 118	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 119	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 120	31-MAR-87	132	SCHEDULED SACRIFICE
86127M3 121	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 122	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 123	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 124	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 125	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 126	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 127	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 128	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 129	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 130	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 131	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 132	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 133	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 134	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 135	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 136	1-APR-87	133	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: MALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M3 137	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 138	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 139	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 140	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 141	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 142	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 143	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 144	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 145	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 146	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 147	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 148	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 149	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 150	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 151	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 152	1-APR-87	133	SCHEDULED SACRIFICE
86127M3 153	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 154	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 155	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 156	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 157	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 158	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 159	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 160	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 161	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 162	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 163	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 164	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 165	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 166	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 167	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 168	2-APR-87	134	SCHEDULED SACRIFICE
86127M3 169	3-APR-87	135	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

SEX: MALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127M3 170	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 171	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 172	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 173	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 174	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 175	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 176	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 177	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 178	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 179	3-APR-87	135	SCHEDULED SACRIFICE
86127M3 180	6-APR-87	138	SCHEDULED SACRIFICE
86127M3 181	6-APR-87	138	SCHEDULED SACRIFICE
86127M3 182	6-APR-87	138	SCHEDULED SACRIFICE
86127M3 183	6-APR-87	138	SCHEDULED SACRIFICE
86127M3 184	7-APR-87	139	SCHEDULED SACRIFICE
86127M3 185	7-APR-87	139	SCHEDULED SACRIFICE
86127M3 186	7-APR-87	139	SCHEDULED SACRIFICE
86127M3 187	7-APR-87	139	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: FEMALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127FN 001	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 002	27-MAR-87	128	SCHEDULED SACRIFICE
86127FN 003	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 004	6-APR-87	138	SCHEDULED SACRIFICE
86127FN 005	27-MAR-87	128	SCHEDULED SACRIFICE
86127FN 006	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 007	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 008	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 009	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 010	18-MAR-87	119	SCHEDULED SACRIFICE
86127FN 011	18-MAR-87	119	SCHEDULED SACRIFICE
86127FN 012	17-MAR-87	118	SCHEDULED SACRIFICE
86127FN 013	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 014	2-APR-87	134	SCHEDULED SACRIFICE
86127FN 015	27-MAR-87	128	SCHEDULED SACRIFICE
86127FN 016	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 017	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 018	6-MAR-87	107	SCHEDULED SACRIFICE
86127FN 019	2-APR-87	134	SCHEDULED SACRIFICE
86127FN 020	2-APR-87	134	SCHEDULED SACRIFICE
86127FN 021	6-MAR-87	107	SCHEDULED SACRIFICE
86127FN 022	18-MAR-87	119	SCHEDULED SACRIFICE
86127FN 023	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 024	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 025	6-APR-87	138	SCHEDULED SACRIFICE
86127FN 026	16-MAR-87	117	SCHEDULED SACRIFICE
86127FN 027	6-MAR-87	107	SCHEDULED SACRIFICE
86127FN 028	6-MAR-87	107	SCHEDULED SACRIFICE
86127FN 029	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 030	23-MAR-87	124	SCHEDULED SACRIFICE
86127FN 101	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 102	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 103	31-MAR-87	132	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL SEX: FEMALE
SUBSTANCE :
TARGET DOSE :

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127FN 104	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 105	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 106	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 107	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 108	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 109	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 110	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 111	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 112	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 113	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 114	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 115	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 116	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 117	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 118	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 119	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 120	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 121	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 122	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 123	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 124	31-MAR-87	132	SCHEDULED SACRIFICE
86127FN 125	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 126	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 127	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 128	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 129	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 130	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 131	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 132	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 133	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 134	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 135	1-APR-87	133	SCHEDULED SACRIFICE
86127FN 136	2-APR-87	134	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : NEGATIVE CONTROL
SUBSTANCE :
TARGET DOSE :

SEX: FEMALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127FN 137	2-APR-87	134	SCHEDULED SACRIFICE
86127FN 138	2-APR-87	134	SCHEDULED SACRIFICE
86127FN 139	2-APR-87	134	SCHEDULED SACRIFICE
86127FN 140	2-APR-87	134	SCHEDULED SACRIFICE
86127FN 141	2-APR-87	134	SCHEDULED SACRIFICE
86127FN 142	2-APR-87	134	SCHEDULED SACRIFICE
86127FN 143	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 144	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 145	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 146	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 147	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 148	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 149	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 150	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 151	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 152	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 153	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 154	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 155	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 156	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 157	3-APR-87	135	SCHEDULED SACRIFICE
86127FN 158	6-APR-87	138	SCHEDULED SACRIFICE
86127FN 159	6-APR-87	138	SCHEDULED SACRIFICE
86127FN 160	6-APR-87	138	SCHEDULED SACRIFICE
86127FN 161	6-APR-87	138	SCHEDULED SACRIFICE
86127FN 162	6-APR-87	138	SCHEDULED SACRIFICE
86127FN 163	6-APR-87	138	SCHEDULED SACRIFICE
86127FN 164	6-APR-87	138	SCHEDULED SACRIFICE
86127FN 165	6-APR-87	138	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

SEX: FEMALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F1 001	16-MAR-87	117	SCHEDULED SACRIFICE
86127F1 002	3-APR-87	135	SCHEDULED SACRIFICE
86127F1 003	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 004	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 005	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 006	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 007	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 008	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 009	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 010	19-MAR-87	120	SCHEDULED SACRIFICE
86127F1 011	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 012	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 013	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 014	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 015	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 016	18-MAR-87	119	SCHEDULED SACRIFICE
86127F1 017	17-MAR-87	118	SCHEDULED SACRIFICE
86127F1 018	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 019	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 020	17-MAR-87	118	SCHEDULED SACRIFICE
86127F1 021	6-MAR-87	107	SCHEDULED SACRIFICE
86127F1 022	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 023	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 024	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 025	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 026	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 027	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 028	8-APR-87	140	SCHEDULED SACRIFICE
86127F1 029	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 030	3-APR-87	135	SCHEDULED SACRIFICE
86127F1 101	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 102	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 103	31-MAR-87	132	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

SEX: FEMALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F1 104	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 105	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 106	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 107	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 108	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 109	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 110	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 111	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 112	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 113	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 114	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 115	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 116	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 117	31-MAR-87	132	SCHEDULED SACRIFICE
86127F1 118	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 119	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 120	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 121	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 122	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 123	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 124	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 125	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 126	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 127	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 128	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 129	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 130	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 131	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 132	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 133	1-APR-87	133	SCHEDULED SACRIFICE
86127F1 134	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 135	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 136	2-APR-87	134	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

SEX: FEMALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F1 137	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 138	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 139	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 140	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 141	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 142	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 143	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 144	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 145	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 146	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 147	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 148	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 149	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 150	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 151	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 152	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 153	2-APR-87	134	SCHEDULED SACRIFICE
86127F1 154	3-APR-87	135	SCHEDULED SACRIFICE
86127F1 155	3-APR-87	135	SCHEDULED SACRIFICE
86127F1 156	3-APR-87	135	SCHEDULED SACRIFICE
86127F1 157	3-APR-87	135	SCHEDULED SACRIFICE
86127F1 158	3-APR-87	135	SCHEDULED SACRIFICE
86127F1 159	3-APR-87	135	SCHEDULED SACRIFICE
86127F1 160	3-APR-87	135	SCHEDULED SACRIFICE
86127F1 161	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 162	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 163	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 164	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 169	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 170	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 171	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 172	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 173	6-APR-87	138	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 2.500 MG/M3

SEX: FEMALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F1 174	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 175	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 176	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 177	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 178	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 179	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 180	6-APR-87	138	SCHEDULED SACRIFICE
86127F1 181	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 182	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 183	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 184	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 185	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 186	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 187	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 188	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 189	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 190	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 191	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 192	7-APR-87	139	SCHEDULED SACRIFICE
86127F1 193	8-APR-87	140	SCHEDULED SACRIFICE
86127F1 194	8-APR-87	140	SCHEDULED SACRIFICE
86127F1 195	8-APR-87	140	SCHEDULED SACRIFICE
86127F1 196	8-APR-87	140	SCHEDULED SACRIFICE
86127F1 197	8-APR-87	140	SCHEDULED SACRIFICE

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F2 001	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 002	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 003	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 004	27-MAR-87	128	SCHEDULED SACRIFICE
86127F2 005	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 006	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 007	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 008	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 009	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 010	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 011	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 012	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 013	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 014	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 015	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 016	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 017	8-APR-87	140	SCHEDULED SACRIFICE
86127F2 018	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 019	16-MAR-87	117	SCHEDULED SACRIFICE
86127F2 020	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 021	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 022	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 023	16-MAR-87	117	SCHEDULED SACRIFICE
86127F2 024	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 025	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 026	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 027	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 028	23-MAR-87	124	SCHEDULED SACRIFICE
86127F2 029	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 030	8-APR-87	140	SCHEDULED SACRIFICE
86127F2 101	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 102	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 103	31-MAR-87	132	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F2 104	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 105	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 106	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 107	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 108	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 109	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 110	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 111	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 112	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 113	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 114	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 115	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 116	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 117	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 118	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 119	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 120	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 121	31-MAR-87	132	SCHEDULED SACRIFICE
86127F2 122	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 123	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 124	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 125	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 126	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 127	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 128	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 129	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 130	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 131	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 132	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 133	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 134	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 135	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 136	1-APR-87	133	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

SEX: FEMALE

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F2 137	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 138	1-APR-87	133	SCHEDULED SACRIFICE
86127F2 139	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 140	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 141	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 142	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 143	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 144	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 145	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 146	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 147	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 148	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 149	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 150	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 151	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 152	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 153	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 154	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 155	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 156	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 157	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 158	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 159	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 160	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 161	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 162	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 163	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 164	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 165	2-APR-87	134	SCHEDULED SACRIFICE
86127F2 166	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 167	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 168	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 169	3-APR-87	135	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 15.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F2 170	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 171	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 172	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 173	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 174	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 175	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 176	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 177	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 178	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 179	3-APR-87	135	SCHEDULED SACRIFICE
86127F2 180	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 181	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 182	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 183	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 184	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 185	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 186	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 187	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 196	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 197	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 198	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 199	6-APR-87	138	SCHEDULED SACRIFICE
86127F2 200	8-APR-87	140	SCHEDULED SACRIFICE
86127F2 201	8-APR-87	140	SCHEDULED SACRIFICE
86127F2 202	8-APR-87	140	SCHEDULED SACRIFICE
86127F2 203	8-APR-87	140	SCHEDULED SACRIFICE
86127F2 204	8-APR-87	140	SCHEDULED SACRIFICE
86127F2 205	8-APR-87	140	SCHEDULED SACRIFICE
86127F2 206	8-APR-87	140	SCHEDULED SACRIFICE
86127F2 207	8-APR-87	140	SCHEDULED SACRIFICE

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F3 001	27-MAR-87	128	SCHEDULED SACRIFICE
86127F3 002	7-APR-87	139	SCHEDULED SACRIFICE
86127F3 003	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 004	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 005	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 006	6-APR-87	138	SCHEDULED SACRIFICE
86127F3 007	6-MAR-87	107	SCHEDULED SACRIFICE
86127F3 008	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 009	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 010	18-MAR-87	119	SCHEDULED SACRIFICE
86127F3 011	6-MAR-87	107	SCHEDULED SACRIFICE
86127F3 012	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 013	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 014	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 015	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 016	19-MAR-87	120	SCHEDULED SACRIFICE
86127F3 017	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 018	16-MAR-87	117	SCHEDULED SACRIFICE
86127F3 019	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 020	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 021	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 022	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 023	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 024	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 025	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 026	17-MAR-87	118	SCHEDULED SACRIFICE
86127F3 027	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 028	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 029	20-MAR-87	121	SCHEDULED SACRIFICE
86127F3 030	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 101	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 102	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 103	31-MAR-87	132	SCHEDULED SACRIFICE

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F3 104	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 105	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 106	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 107	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 108	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 109	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 110	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 111	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 112	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 113	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 114	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 115	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 116	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 117	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 118	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 119	31-MAR-87	132	SCHEDULED SACRIFICE
86127F3 120	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 121	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 122	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 123	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 124	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 125	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 126	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 127	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 128	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 129	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 130	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 131	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 132	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 133	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 134	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 135	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 136	1-APR-87	133	SCHEDULED SACRIFICE

STUDY NUMBER: 86127 ANIMAL TERMINATION HISTORY
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F3 137	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 138	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 139	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 140	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 141	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 142	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 143	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 144	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 145	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 146	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 147	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 148	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 149	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 150	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 151	1-APR-87	133	SCHEDULED SACRIFICE
86127F3 152	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 153	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 154	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 155	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 156	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 157	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 158	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 159	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 160	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 161	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 162	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 163	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 164	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 165	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 166	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 167	2-APR-87	134	SCHEDULED SACRIFICE
86127F3 168	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 169	3-APR-87	135	SCHEDULED SACRIFICE

STUDY NUMBER: 86127
DMEH NUMBER: ML86360
RTE OF ADMIN: INHALATION

ANIMAL TERMINATION HISTORY

SPECIES: RAT STRAIN/BREED: SPRAGUE-DAWLEY STUDY START DATE: 20-NOV-86

GROUP : TEST GROUP SEX: FEMALE
SUBSTANCE : 2,6-DIETHYLPHENYL AZOMETHINE
TARGET DOSE : 50.00 MG/M3

ANIMAL	DATE OF DEATH	DAY OF STUDY	TYPE OF DEATH
86127F3 170	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 171	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 172	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 173	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 174	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 175	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 176	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 177	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 178	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 179	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 180	3-APR-87	135	SCHEDULED SACRIFICE
86127F3 181	6-APR-87	138	SCHEDULED SACRIFICE
86127F3 182	6-APR-87	138	SCHEDULED SACRIFICE
86127F3 183	6-APR-87	138	SCHEDULED SACRIFICE
86127F3 184	6-APR-87	138	SCHEDULED SACRIFICE
86127F3 185	7-APR-87	139	SCHEDULED SACRIFICE
86127F3 186	7-APR-87	139	SCHEDULED SACRIFICE
86127F3 187	7-APR-87	139	SCHEDULED SACRIFICE
86127F3 188	7-APR-87	139	SCHEDULED SACRIFICE

MAR 12 1987

JMK

MONSANTO COMPANY
ENVIRONMENTAL HEALTH LABORATORY
ST. LOUIS, MISSOURI 63110

PROTOCOL
ISSUE DATE: 11/19/86

Title: Fertility and Reproduction Inhalation Studies with 2,6-Diethylphenyl Azomethine

Project Number: ML-86-360

EHL Study Numbers: 86126 and 86127

Amendment Number: I

Operating Company: Monsanto Agricultural Company

Study Director:

Signed: B.R. Dunlap Dated 3/2/87

Note: Please discard previous version(s) of the protocol and replace it with this version.

PROTOCOL AMENDMENT

1. INTRODUCTION:

1.1 Starting Date: November, 1986 (First Exposure)

1.2 Completion Date: April, 1987 (Final Necropsy)

1.3 Exposure: The purpose of this study is to determine if 2,6-diethylphenyl azomethine, administered by inhalation, will exert toxic effects on Sprague-Dawley rats, including effects on fertility, reproductive capability and effects in offspring of treated animals.

1.4 Route of Administration: Animals will be exposed by inhalation in an effort to simulate a potential route of human exposure.

1.5 Test System Justification: Rodents are frequently used in inhalation studies. Rats were selected because a large database exists on the relative toxicity of chemicals to this species.

2. MATERIALS AND METHODS:

2.1 Duration of Study: Approximately 4 months.

2.2 Test Material: The material for this study has been supplied by the operating company. The lot number and the unique identification number assigned to the sample will become part of the study record. The test material will be characterized prior to the start of the study; stability will be determined throughout the study.

2.3 Test System (Animals):

2.3.1 Species: Outbred albino rats.

2.3.2 Sex: Male and female.

2.3.3 Source, Strain: Charles River, Crl:CD® (SD)BR (Trademark of Charles River Laboratory, Wilmington, MA). Animals will be shipped from the Portage, MI, facility. Specifications to the vendor include different animal room origin for males and females to prevent male/female littermate pairs from being included in the study.

2.3.4 Age and Weight on Start Day: The animals will be 6 to 8 weeks old at the start of inhalation expoure. The variation (one standard deviation) in body weight within groups will be less than 10%, and the mean body weights among groups of the same sex will be within 5% at the start of the study (pre-test weighing).

2.3.5 Groups and Numbers of Animals: The groups and numbers of animals used in the study are:

Study	No. Levels	No./Level	Total
(Males)			
86126	4	25	100
86127	4	30	120
			220
(Females)			
86126	4	50	200
86127	4	30	120
			320
		Total Animals	540

2.4 Animal Husbandry:

2.4.1 Identification: Individual eartags and bar-coded cage cards.

2.4.2 Housing:

2.4.2.1 Animals to be exposed will be housed individually (except during mating) in all wire, inhalation-type rat cages.

2.4.2.2 Untreated animals will be housed individually (except during mating) in stainless steel rat cages.

2.4.2.3 Females with confirmed copulation which are expected to deliver litters will be housed individually in double-wide stainless steel cages equipped with solid bottoms and nesting material.

2.4.3 Animal Room: The animal study room is designed to be maintained at 72 ± 4 degrees F, 35-60% humidity and with a 12-hour light/12-hour dark cycle.

2.4.4 Food and Water: Ad libitum except during the exposure periods, when food and water will be withheld. Purina Certified (5002) Laboratory Rodent Chow® (Registered Trademark of Ralston Purina Co., St. Louis, Missouri) will be used. This diet is purchased against manufacturer's guaranteed analysis and is nutritionally acceptable. Toxic contaminants which would interfere with this test have not been reported by the vendor. All laboratory water is supplied by the City of St. Louis and is conditioned upon entering the laboratory by an ion exchange water softener using sodium zeolite.

2.4.5 Pretest Examination and Acclimatization: There will be a fourteen-day quarantine period (minimum) in which the health of the animals is assessed.

2.4.6 Bias Control: The animals will be randomly assigned to test groups by the computer on the basis of weight. The culling of litters and selection of F1 weanlings for histopathology will also be done on a random basis.

2.5 Absorption of Test Material: Determination of the degree of absorption of the test material is not necessary to achieve the objectives of the study and will not be performed.

2.6 Test Atmosphere Generation and Analysis:

2.6.1 Exposure System: The exposure system will consist of 10 m3 glass and stainless steel New York University-style inhalation chambers and an atmospheric generation system. Air from the central ventilation supply will flow through the chamber at 12-15 chamber volumes per hour.

Atmospheres of the test material will be generated by delivering a metered rate of test material through a sonic jet or some other appropriate method.

2.6.2 Analysis of Test Atmospheres: The chamber environment will be monitored for test material concentrations at least three times per day in all chambers except control. In addition, formaldehyde levels will also be monitored periodically. The control chamber will be checked for the presence of test material once in the first week and once every 2 weeks thereafter. Chamber air samples will be obtained by drawing test atmosphere through and collecting it in impingers. Impinger samples will be uniquely identified following collection, and the amount of

test material will be analytically determined. A specific method for this analysis will be available prior to the first exposure. Initially, two impingers in series will be used for sampling. If the amount of test material collected by the second impinger during four days (pretest or study) is either below the detectable limit of the analytical procedure or contains an average of less than 10% of the amount collected by the first impinger, the use of the second impinger will be terminated.

Uniformity of distribution of the test material will be determined for each exposure level once during the pre-test period, once during the first two weeks and once during the final two weeks of the study.

The nominal concentration of each exposure level will be determined at least once per test chamber per day.

If aerosol is determined, during pretest, to be present gravimetrically at a significant level (50 mg/cu. meter or greater), particle-size analysis will be determined (using a cascade impactor) for the high exposure level. These analyses will be performed daily during the first week and weekly thereafter. The mass median aerodynamic diameter and geometric standard deviation will be calculated for each analysis.

Chamber airflow, temperature and humidity will be monitored continuously with the specific values recorded every 30 minutes per chamber per exposure. Additional recordings of all measurements will be made at the discretion of the study director.

2.7 Experimental Design: This study consists of two projects: 1) a male fertility study and 2) a female reproduction study. To permit data handling and analysis by the computer, these projects have been given separate EHL study numbers. These numbers are 86126 and 86127, respectively. Flow charts of projects 86126 and 86127 are presented in Appendices I and II.

2.7.1 Exposure Levels: The following exposure levels will be used in all studies:

Group	Exposure Concentration (mg/m3)
Control	0
Low	2.5
Mid	15
High	50

2.7.2 Frequency and Duration of Exposure:

2.7.2.1 Male Fertility Study (86126): Prior to co-housing, males will be exposed 6 hours/day, 5 days/week (weekends and scheduled holidays excluded) for approximately 11 weeks. Exposures will continue 5 days/week through a 2-week mating phase. Following the mating phase, males will continue to be exposed 5 days/week for an additional 2 weeks. There will be approximately 72 total exposures (15 weeks). Females designated to mate with these males will not receive inhalation exposures.

2.7.2.2 Female Reproduction Study (86127): Prior to co-housing, females will be exposed 6 hours/day, 5 days/week (weekends and scheduled holidays excluded) for approximately 11 weeks. Females will continue to be exposed 5 days/week through the mating phase until copulation is confirmed. After individual copulation is confirmed, females will be exposed on a 7 days/week basis through gestation Day 20. Males designated to mate with these females will not receive inhalation exposures.

2.7.3 Mating of Animals:

2.7.3.1 Mating Procedure: One male and one female are co-housed per cage overnight. Each morning, the area under the cages of co-housed animals will be examined for the presence of copulatory plugs. The observation of these plugs constitutes confirmed copulation. If the location of a copulatory plug is ambiguous, a vaginal smear will be taken and examined for sperm to confirm copulation. All remaining animals with unconfirmed copulation will be examined for the presence of a vaginal plug. The day of confirmed copulation is designated as gestation Day 0.

2.7.3.1.1 Male Fertility Study (86126): Co-housing of animals begins approximately 11 weeks into

the study. Each male will be co-housed with one female until copulation is confirmed or 7 continuous nights have occurred without confirmed copulation. Each male will then be co-housed with a second female until copulation is confirmed or 7 nights have occurred without confirmed copulation.

2.7.3.1.2 Female Reproduction Study (86127): Co-housing of animals begins approximately 11 weeks into the study. Each female will be co-housed with one male until copulation is confirmed or 7 continuous nights have occurred without confirmed copulation. Females without copulation in the initial co-housing will be co-housed with a second male until copulation is confirmed or 7 nights have occurred without confirmed copulation. Where possible, the second male will be selected from males which have confirmed copulation with another female.

2.7.4 Nidation and Litter Examinations:

2.7.4.1 Male Fertility Study (86126): Females with confirmed copulation will be sacrificed on gestation Day 13 (or the next working day) to assess pregnancy status and pre- and postimplantation loss rates.

2.7.4.2 Female Reproduction Study (86127): The number of potentially pregnant females (based on confirmed copulation) may be reduced to at least 23 (from a potential of 30), following the 2-week mating period. Selection will be done randomly. Females not selected will be sacrificed and discarded. Selected females will be allowed to deliver their pups. On lacatation Day 4, litters will be culled to 8 pups, 4 of each sex when

possible. These culls will be discarded. For litters of less than 8 pups, all pups will be retained. Retained pups will be sacrificed on lactation Day 21 or the next working day, when practicable, and subjected to a gross necropsy. If it is necessary to hold animals over for longer than one day, equal numbers of animals from each group will be sacrificed on each day whenever possible.

3. OBSERVATIONS:

3.1 In-Life Observations:

3.1.1 General: All animals assigned to the study will be checked for mortality twice per day. Animals visible through the chamber doors will be observed for treatment-related signs of toxicity during exposures. All exposed animals will also be observed for any overt signs of toxicity following expoure. Additional observations will be made on some animals as discussed below.

3.1.2 Male Fertility Study (86126): Males will be weighed and given a thorough physical examination once every week until sacrifice. All females will be weighed and given a thorough physical examination prior to co-housing. Signs of abortion observed during the mortality checks will be recorded for these animals.

3.1.3 Female Reproduction Study (86127): Males will be weighed and given a thorough physical examination prior to co-housing. Females will be weighed and given a thorough physical examination once every week until copulation is confirmed. Females with confirmed copulation will be weighed on gestation Days 0, 6, 13, and 20. Signs of abortion observed during the mortality checks will be recorded. Females which do not exhibit confirmed copulation will be weighed and given a thorough physical examination once per week until sacrifice.

3.1.4 Litter and Dam Observation: Dams will be weighed on lactation Days 0, 4, 7, 14 and 21 (lactation Day 0 is defined as day on which delivery of litter is completed). The numbers and sexes of pups and the presence of abnormalities in these animals will be determined on lactation Days 0, 4 (pre- and postcull), 7, 14 and 21. Total weights of male pups and female pups in each litter will be measured on lactation Days 0, 4 (pre- and postcull), 7 and 14. Individual pup weights will be measured on lactation Day 21.

3.2 Necropsy:

(3.2.1) Male Fertility Study (86126): Any animal found dead or sacrificed in extremis will receive a gross necropsy (3.3.1). Tissues will be saved at the discretion of the pathologist.

Males: If treatment-related effects on male fertility are not observed, surviving male animals will be sacrificed without necropsy no sooner than 2 weeks after exposures are terminated. If treatment-related effects on male fertility are observed, these males may be used in further experiments. These experiments will be defined in an amendment to the study protocol.

Females: Females with confirmed copulation will be sacrificed on gestation Day 13 or the next normal work day. If there are no treatment-related reproductive effects, females without confirmed copulation will be sacrificed in the second week after the last night of co-housing. If treatment-related effects are observed, these females may be used in further experiments. These experiments will be defined in an amendment to the study protocol. Uteruses will be examined to determine pregnancy status and the number and state of nidations. The number of corpora lutea on the ovaries of pregnant animals will be determined. A complete gross necropsy will be performed on non-pregnant females and on females with increased resorptions and/or decreased viable implants. The presence of corpora lutea spurium in non-pregnant females will be noted. No organ weights will be measured, and no tissues will be saved.

3.2.2 Female Reproduction Study (86127): Any animal found dead or sacrificed in extremis will receive a gross necropsy (3.3.1). Tissues will be saved at the discretion of the pathologist.

Males: All surviving males will be sacrificed within four weeks after co-housing ends. No necropsy will be performed and no tissues will be saved.

Females: Females with litters will be sacrificed on lactation Day 21 or in the week after their expected delivery date (non-delivering animals). Females without confirmed copulation will be sacrificed within 2 weeks after the last night of co-housing, and pregnancy status will be noted. Any females found dead or sacrificed in extremis will also receive a pregnancy status determination. Complete gross necropsies will be performed on all females as described in 3.3.1; no organ weights will be measured. No histopathology is scheduled.

Pups: All pups found dead will receive gross necropsies only; no tissues will be saved or examined. Additional procedures will be performed on pups found dead on lactation Day 0 as follows: lungs will be examined to determine if the pup was live or stillborn; stomachs will be examined for the presence of milk. Tissues listed in 3.3.2 will be preserved from animals sacrificed in extremis.

Surviving pups will be sacrificed on lactation Day 21, or on the next working day when practicable, and subjected to a gross necropsy. If it is necessary to hold animals over for longer than one day, equal numbers of animals from each group will be sacrificed on each day whenever possible. Tissues from 10 randomly-selected pups/sex/level will be removed, fixed and examined as described in 3.3.2 and 3.4

3.3 Necropsy Procedures:

3.3.1 Gross necropsy will consist of examination of the external surfaces, tissues and organs of the abdominal, thoracic, cranial and scrotal (male) cavities.

3.3.2 F1 Offspring (86127): The following tissues, when present, will be taken and preserved:

abdominal aorta
adrenals
bone and bone marrow (femur)
brain (longitudinal section)
diaphram
esophagus
eyes with optic nerve
gonads
  ovaries
  testes with epididymides
heart
intestine
  duodenum
  colon
  ileum
kidneys (2)
liver (2 sections)
lung* (2 sections, at least
  2 lobes and mainstem
  bronchi)
lymph nodes
  mesenteric
  thymic
mammary gland
nasal passages (3 sections)
pancreas
pituitary
prostate
salivary gland (submaxillary)
sciatic nerve
seminal vesicle
skeletal muscle
skin
spinal cord
spleen
stomach (longitudinal section)
thymus
trachea
thyroid/parathyroid
urinary bladder
uterus (including the cervix)
vagina
gross lesions (if determined
  to be treatment-related by
  the pathologist)

*Lungs will be perfused via the trachea with an amount of formalin approximately equal to 75% of the lung capacity.

Fixative:
Eyes - glutaraldehyde in 10% neutral buffered formalin.
All other tissues - 10% neutral buffered formalin.

3.4 Histology and Microscopic Examination:

3.4.1 F1 Offspring (86127): All specimen containers will be identified with a bar-coded label. Slides of all tissues will be prepared and examined microscopically for all animals from control and high exposure groups. This includes all animals sacrificed in extremis as well as those sacrificed at scheduled necropsy. Tissues from low and mid exposure group animals will be held in fixative. Should the high exposure group have lesions which, in the opinion of the pathologist, might be treatment-related, slides of tissues from the suspect target organs of low and mid level groups will be prepared and examined microscopically.

4. STATISTICS: Comparisons between treatment and control groups will be made for the following measurements. The appropriate statistical procedures are indicated:

Body Weight -	Dunnett's Test (two-tailed) and Bartlett's Test (one-tailed)
Frequency of Histologic Abnormalities -	Fisher's Exact Test with Bonferroni's Inequality Procedure
Preimplantation losses, total implantations, viable and nonviable implantations expressed per pregnant female -	Kruskal-Wallis and Mann-Whitney U test, if indicated
Dead implantations/total implantations and corpora lutea/pregnant female -	Kruskal-Wallis and Mann-Whitney U test, if indicated

5. RECORDS AND REPORT:

5.1 Records: All records of data measured as described above as well as any other relevant study data and a copy of the final report will be maintained in the Environmental Health Laboratory Archives. Two copies of the final report will be available to the operating company.

5.2 Report: The following information will be contained in the report for this study. Other information or presentations of data may also be included in the report if necessary to properly interpret the study. Numerical data will be summarized for each appropriate group as a mean with an indication of variance (standard deviation or standard error of the mean). The results of statistical comparisons of treatment and control groups will also be presented.

5.2.1 Inhalation exposure data including exposure methods and procedures, analytical methods and procedures, analytical determinations, nominal concentration measurements, particle-size data (if applicable), and uniformity of distribution measurements.

5.2.2 In-life data including body weights, clinical signs, observations, and mortality.

5.2.3 Mating indices (number of copulations and mating opportunities).

5.2.4 Pregnancy rates.

5.2.5 Nidation data for females sacrificed during gestation (implants, resorptions, live implants, corpora lutea) and pre- and postimplantation loss.

5.2.6 Litter data including number, sex and weight measurements for litters, observations of clinical signs of toxicity and abnormalities observed in dams or pups, pups culled and survival.

5.2.7 Gross necropsy findings.

5.2.8 Microscopic examination findings.

5.2.9 Supplementary information required by EPA TSCA Good Laboratory Practices.

5.2.10 Statement of test material purity and stability.

5.2.11 Quality Assurance and GLP Compliance statements.

6. DISTRIBUTION:

C. L. Bechtel/EHL
M. P. Berry/EHL
M. W. Dietrich/EHL
B. R. Dudek/EHL
R. M. Folk/EHL
M. E. Holland/EHL
J. M. Kronenberg/C2SK
G. M. Mace/EHL
J. G. Napier/EHL
P. E. O'Donnell/EHL
M. V. Roloff/EHL
F. A. Ruecker/EHL
D. C. Thake/EHL
A. F. Uelner/ A3NF & EHL
T. V. Wilson/EHL

7. GENERAL INFORMATION:

7.1 All operations, unless specifically described herein, will be conducted in accordance with EHL SOP's in effect at that time and in accordance with Good Laboratory Practices.

7.2 The operating company will complete an EHL sample submission form and supply any additional physical or chemical property data for the test substance.

7.3 Reserved for amendments.

7.3.1 Amendment I (February 24, 1987)

Section	Reason
3.2.1	Because females sacrificed on the male fertility study (86126) were not exposed, it was decided a gross necropsy of females with no reproductive abnormalities was not necessary.
Appendix II	Correction - Adjustment to approximately 23 females per level should take place during gestation and not during lactation.

8. SIGNATURE PAGE:

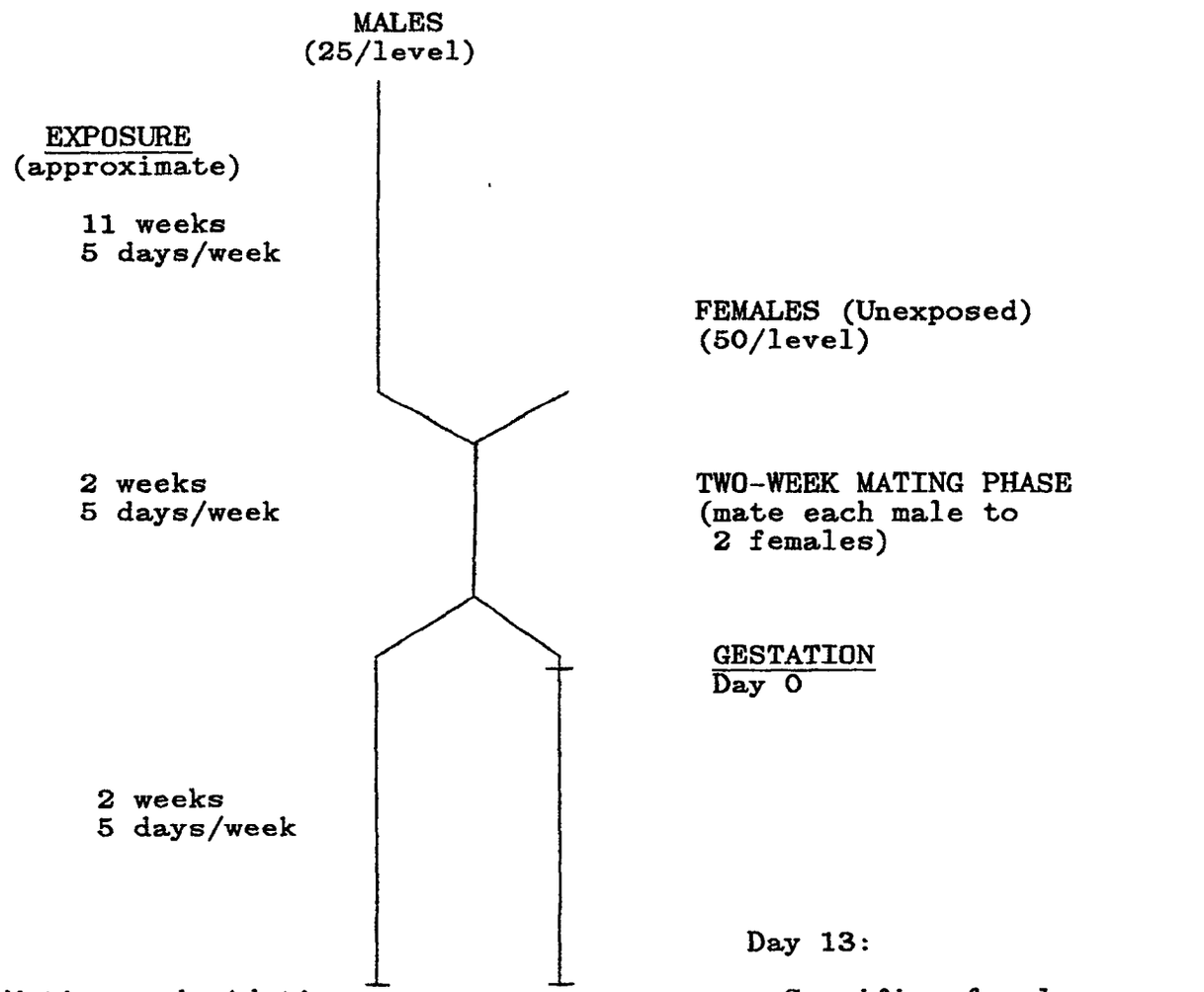
Pathology: _____ 3/6/87
Date

Analytical Chemistry: _____ 3/6/87
Date

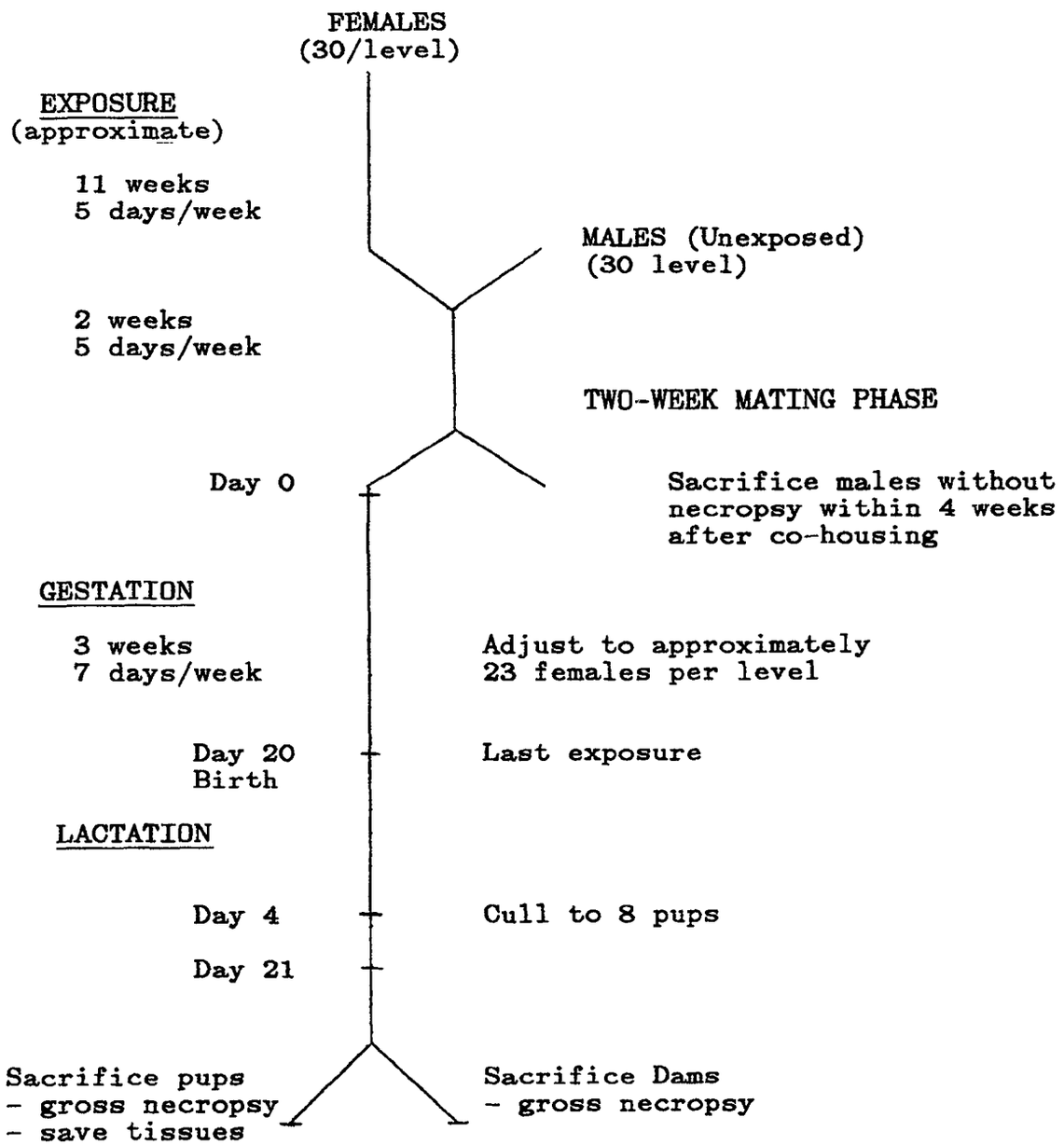
Inhalation Toxicology: _____ 3/6/87
Date

Product Toxicologist: _____ 3/11/87
Date

Appendix I
Male Fertility Study (86126)
Flow Chart



(Appendix II)
Female Reproduction Study (86127)
Flow Chart



Monsanto

MONSANTO COMPANY
ST. LOUIS, MISSOURI 63167

TOXICOLOGY SAMPLE SUBMISSION FORM

Monsanto Study No.	Testing Laboratory Study/Sample Code(s)
ML-86-360	

TEST MATERIAL IDENTIFICATION

Name (as on container label)	CP No.	CAS No.
Diethylphenyl azomethine	84781	35203-08-8

Synonyms	Batch/Lot No. or Notebook Ref.	Sample Size
Azo; 2,6-diethyl-N-methylene	W.STO-1-16-87	10 x 1 gal

Chemical Name, Formula, Structure, Composition of Mixture (as appropriate)

Benzonamine, 2,6-diethyl-N-methylene

The identity, purity, and composition or other characteristics needed to define this batch/lot of test material have been determined and documented: ☒ yes ☐ no

The methods of synthesis, fabrication or formulation of this material are documented: ☒ yes ☐ no

PHYSICAL/CHEMICAL CHARACTERISTICS

Purity	Color/Physical State	Molecular Weight
~~XXXXX~~ 97.0%	light yellow liquid	161.24

Melting Point	Boiling Point	Vapor Pressure	Specific Gravity
< -10°C	232°C; 67°C 1mm Hg	0.05 mm Hg 25°C	0.9571 25°C

Water Solubility	Octanol: Water Partition Coef.	Suitable Solvents
insoluble; reacts slowly		acetone, chloroform

Storage Conditions
☐ Room Temp., ☒ Refrigerate, ☐ Freeze, ☐ Avoid Light, ☐ Other _____

Expiration Date	Other Properties/Special Requirements
4/16/87	Tends to trimerize, reacts with alcohols and acids. Filter if precipitate appears.

Physical/Chemical Hazards
☐ None Known, ☐ Flammable, ☐ Explosive, ☐ Oxidizer, ☐ Other _____

TOXICOLOGY

Oral LD50 1470 mg/kg
Dermal LD50 1400 mg/kg
Eye Irritation severe
Skin Irritation severe - corrosive
Inhalation LC50 0.83 mg/L (nominal) 6 hr; no mortality
☐ Toxicity Unknown, ☐ See Attachment

Other _____
Handling Precautions YO-83-12, Y-69-5

MISCELLANEOUS

For instructions concerning disposition of unused test material contact:
Name Lydia A. Suba
Phone (314) 694-2124

Submitted By: (Name, Location, Phone, Date)
L.A. Suba /C2SK /4-2124 1/16/87

Toxicology Approval
T.W. Fuhremann
J.M. Kronenberg (T.W. Fuhremann)

White Copy-Testing Laboratory; Yellow Copy-Toxicology; Pink Copy-Submittor

G-3078 (REV. 12/85)

MAC/Administration/EHL
(CO./DIV./DEPT./LOCATION)

Final REPORT
(TYPE OF REPORT)

REPORT NO.: MSL-7297

JOB/PROJECT NO.: ML-87-104/EHL 87076

DATE: November 5, 1987

TITLE: Acute Inhalation Study of Ethylmethyl Azomethine (EMAZO)

AUTHORS: M. S. Reyna, B.S.

ABSTRACT: Four groups of five male and five female Sprague-Dawley rats were each exposed for 4 hours to an atmosphere of aerosolized ethylmethyl azomethine (EMAZO) at mean analytical concentrations of 0.48, 0.86, 1.1 and 1.5 mg per liter in air. Exposure was followed by a 14-day observation period and subsequent necropsy. All animals died at the 1.5 mg/l exposure level. At the 1.1 mg/l exposure level four males and all five females died. At the 0.86 mg/l exposure level four males and three females died. At the 0.48 mg/l exposure level two males and no females died. All deaths occurred prior to post-exposure Day 12, with the majority of deaths occurring prior to post-exposure Day 3. The LC50 data were calculated by the probit method for males and combined sexes, and by the binomial method for females.

(Continued on reverse side)

REPT. NO.: MSL-7297 AUTHORS: M. S. Reyna, B.S.
COPY NO.: 3 TITLE: Acute Inhalation Study of Ethylmethyl Azomethine (EMAZO)

There were no confidence limits for females, because a concentration-effect relationship was not achieved over a reasonable exposure range. The LC50 for males was calculated to be 0.56 mg/l, for females 0.80 mg/l, and for combined sexes 0.68 mg/l. Notable observations during exposure were labored breathing, gasping and hypoactivity. Immediately following exposure, notable observations included abnormal respiration, ocular opacity, hypoactivity, and discharges from eyes, nose and mouth. Notable observations during the 14-day post-exposure observation period included abnormal respiration, ocular opacity, hypoactivity, and discharges from the eyes and nose. An initial decrease in body weight occurred by post-exposure Day 2, however, most of the survivors at Day 14 were heavier than before exposure. Gross necropsy findings included corneal opacity, and abnormal discharge or encrustation of the eye and nose. Based on these results, EMAZO at mean exposure concentrations of 0.48 to 1.5 mg per liter in air caused respiratory distress, ocular discharge and opacity, an initial decrease in body weight and death. The LC50 value (combined sexes) for EMAZO, as administered in this study, was considered to be 0.68 mg/l in air.

ENVIRONMENTAL HEALTH LABORATORY
645 S. NEWSTEAD AVENUE
ST. LOUIS, MISSOURI 63110

Acute Inhalation Study of Ethylmethyl Azomethine (EMAZO)

Study Number: 87076
Project Number: ML-87-104

M. Reyna 11/5/87

M. S. Reyna, B.S. Date
Study Director

SUMMARY AND DISCUSSION

Four groups of five male and five female Sprague-Dawley rats were each exposed for 4 hours to an atmosphere of aerosolized ethylmethyl azomethine (EMAZO) at mean analytical concentrations of 0.48, 0.86, 1.1 and 1.5 mg per liter in air. Exposure was followed by a 14-day observation period and subsequent necropsy. All animals died at the 1.5 mg/l exposure level. At the 1.1 mg/l exposure level four males and all five females died. At the 0.86 mg/l exposure level four males and three females died. At the 0.48 mg/l exposure level two males and no females died. All deaths occurred prior to post-exposure Day 12, with the majority of deaths occurring prior to post-exposure Day 3. The LC50 data were calculated by the probit method for males and combined sexes, and by the binomial method for females. There were no confidence limits for females, because a concentration-effect relationship was not achieved over a reasonable exposure range. The LC50 for males was calculated to be 0.56 mg/l, for females 0.80 mg/l, and for combined sexes 0.68 mg/l. Notable observations during exposure were labored breathing, gasping and hypoactivity. Immediately following exposure, notable observations included abnormal respiration, ocular opacity, hypoactivity, and discharges from eyes, nose and mouth. Notable observations during the 14-day post-exposure observation period included abnormal respiration, ocular opacity, hypoactivity, and discharges from the eyes and nose. An initial decrease in body weight occurred by post-exposure Day 2, however, most of the survivors at Day 14 were heavier than before exposure. Gross necropsy findings included corneal opacity, and abnormal discharge or encrustation of the eye and nose. Based on these results, EMAZO at mean exposure concentrations of 0.48 to 1.5 mg per liter in air caused respiratory distress, ocular discharge and opacity, an initial decrease in body weight and death. The LC50 value (combined sexes) for EMAZO, as administered in this study, was considered to be 0.68 mg/l in air.

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TRADEMARKS

The following registered trademark was used in this report:

ITEM	REGISTERED TRADEMARK OF:
RODENT CHOW	Ralston Purina Company St. Louis, MO

INTRODUCTION

Purpose: To determine the toxicity of ethylmethyl azomethine (EMAZO) administered to Sprague-Dawley male and female rats for four hours by whole body inhalation
Exposure: Individual animals were treated once with the exposure involving five animals per sex; each of four different groups received a four hour exposure
Date of Study Start: May 12, 1987

MATERIALS AND METHODS

Test Material

Name: Ethylmethyl azomethine (EMAZO)
EHL Substance Identification No.: T870022
Lot Number: Batch 5-15
Stated Purity: 99.15% (Sample Submission Form)
Date Received: May 6, 1987
Description at Receipt: Clear liquid
Source: Monsanto Agricultural Company

Animals

Species: Albino rat
Strain: Sprague-Dawley
Source: Charles River Breeding Laboratory, Portage, MI
Date of Arrival at EHL: April 28, 1987
Number Used in Study: 40 (20 males, 20 females)
Method of Identification: Individual eartag, bar-coded cage card
Age at Study Start: Approximately seven weeks
Weight on Exposure Day: Males - approximately 231.0 g
Females - approximately 166.7 g
Type of Housing: Individual suspended stainless steel mesh cages, over paper bedding
Water Availability: ad libitum except during exposure (sodium zeolite-conditioned St. Louis public water supply)
Food Availability: ad libitum except during exposure (Ralston Purina RODENT CHOW No. 5002)
Light Cycle: 12 hours daily (On at 6:30 A.M.)
Animal Room Environmental Specifications: Temperature, 70 to 74 degrees F; humidity, 35 to 60% relative
There were no excursions in animal room environmental conditions which had any obvious impact on the results of the study.

Exposure System

Exposure Chamber: A 300 liter New York University-style stainless steel chamber with a pyramidal top and bottom (Figure 1)
Animal Housing during Exposure: Individual stainless steel wire mesh inhalation cages, positioned in two tiers in the chamber
Exposure Duration: 4 hours
Test Atmosphere Generation System: Test material was metered from a syringe using a syringe pump connected to a Laskin-style (1) nebulizer (sonic jet orifice) which generated the test atmosphere. The concentration of the test material in the inhalation chamber was controlled by the regulation of the speed of the syringe drive (pump) and consequently, the flowrate of the test material into the nebulizer, and airflow through the chamber
Chamber Airflow, Temperature and % Relative Humidity: Monitored continuously and recorded approximately every 30 minutes
Oxygen Level: Determined once per exposure

Procedures for Monitoring Amount of Test Material in the Chamber

Atmospheric Analytical Sampling: Four per exposure at approximately one-hour intervals
Sampling Method: Test atmosphere was drawn at a known rate through iso-octane contained in a 25 ml glass impinger
Volume of Test Atmosphere Sampled: Approximately 10 liters
Sampling Location: Port halfway down on chamber door
Analytical Method: Gas chromatography (Appendix 1, Exhibit 1)
Nominal Concentration: Calculated once for each exposure by determining the total amount of test material delivered to the chamber and dividing this amount by the air volume passing through the chamber
Particle-Size Analysis: Performed once during each exposure

In-life Observations

During Exposure Observations: Approximately hourly; however, the placement of cages allowed only limited observation of animals
Checks for Mortality and Moribundity: Twice daily
Observations for Signs of Toxicity: Immediately following exposure and daily (normal work days only) during the 14-day observation period following exposure
Body Weights: Exposure day (prior to exposure) and 2, 7 and 14 days following exposure

Gross Pathology

Animals Examined: All
Scheduled Sacrifice: Fourteen days after exposure
Extent of Examination: External and internal; internal cavities opened and organs examined in situ and then removed; hollow organs opened and examined

RESULTS

Mortality

Group 01 (1.5 mg/l)
5 males out of 5 exposed, 5 females out of 5 exposed
Group 02 (1.1 mg/l)
4 males out of 5 exposed, 5 females out of 5 exposed
Group 03 (0.86 mg/l)
4 males out of 5 exposed, 3 females out of 5 exposed
Group 04 (0.48 mg/l)
2 males out of 5 exposed, 0 females out of 5 exposed
(Table 1)

LC50 Data (Calculations (2) by Probit and Binomial Methods)

Males: 0.56 mg/l (95% confidence limits 0.0046, 0.82)
Females: 0.80 mg/l (no confidence limits for binomial method)
Combined: 0.68 mg/l (95% confidence limits 0.50, 0.82)
(Table 2)

Exposure Concentrations

Average analytical concentration for the exposures were 0.48, 0.86, 1.1, and 1.5 mg/l in air (Appendix 1, Exhibit 2, Table 1). The quality control results for EMAZO are presented in Appendix 1, Exhibit 2, Table 2.

Particle-Size Data

MMAD: Ranged from 2.3 to 3.0 microns with a geometric standard deviation of 1.9 to 2.1 microns (Table 3)
% Particles Less Than 10 Microns: Ranged from 96.1% to 98.7% (Table 3)

Exposure Atmosphere Conditions

Mean Temperature: Ranged from 23.1 to 23.6 degrees C
Mean Relative Humidity: Ranged from 46 to 63%
(Table 2)
Mean Airflow: Ranged from 58.9 to 64.7 l/min
Oxygen Level: 21%

In-life Observations

During Exposure: Labored breathing, gasping and hypoactivity
Immediately After Exposure (Day 0): Hypoactive, nonresponsive, prostrate, labored respiration, gasping, rapid respiration, slow respiration, shallow respiration, rattling sounds, clear nasal discharge, blood-like nasal discharge, red/brown perinasal encrustation, salivation, perioral wetness, red ocular discharge, lacrimation, ocular opacity, pale coloration
During Post-Exposure Period (Days 1-14): Hypoactive, labored respiration, gasping, slow respiration, rattling sounds, blood-like nasal discharge, red/brown perinasal encrustation, lacrimation, ocular opacity, emaciated, periocular encrustation, focal loss of hair (Table 5)

Body Weights

All animals had a decrease in body weight by post-exposure Day 2; most animals that survived to Day 14 were heavier than before exposure (Table 4).

Gross Necropsy Findings

Gross necropsy observations were corneal opacity of the eye, abnormal ocular discharge/encrustation, abnormal nasal turbinate discharge/encrustation (Table 6).

Termination History: Listed in Table 7.

REFERENCES

1. Drew, R.T., Bernstein, D.M., and Laskin, S. The Laskin Generator. J. Tox. Environ. Health 4, 661-670 (1978).

2. Stephan, C.E. Personal Communication to L. Bahner, Chairman of the ASTM Task Group on Calculating LC50.

SUPPLEMENTAL STUDY INFORMATION

Study Performed at: Environmental Health Laboratory (EHL), 645 S. Newstead, St. Louis, MO 63110
Date Protocol Signed by Study Director: May 8, 1987
Date of Last Necropsy: June 1, 1987
Location of Study Protocol, Original Data, and Final Report: Environmental Health Laboratory Archives

Supervisory Personnel:

M. W. Dietrich, Ph.D.
Group Leader, Analytical Chemistry

F. A. Ruecker, D.V.M., Dipl. A.C.V.P.
Manager, Pathology

M. V. Roloff, Ph.D.
Inhalation Toxicology Consultant

L. D. Stout, D.V.M., M.S.
Manager, Toxicology Studies

R. M. Folk, Ph.D.
Director, Environmental Health Laboratory

S&EH QUALITY ASSURANCE AUDIT STATEMENT

Study Number:	87076 ML-87-104
Protocol Amendments:	None
Study Title:	Acute Inhalation Study of Ethylmethyl Azomethine
Dates of Inspections and Communication of Findings:	May 14, 15, 27, 1987 June 26, 30, 1987 July 2, 13, 1987 August 7, 1987 September 24, 1987 October 2, 1987
Quality Assurance Review Conducted by:	S. M. Haag C. K. Russell B. M. Williamson
Results:	The Quality Assurance review indicates the final report accurately presents the raw data as developed during the study. There appears to be no significant deviation from applicable GLP regulations that adversely affected study quality or integrity.

Arthur J. Yelner
Manager, Quality Assurance

October 12, 1987
Date

STATEMENT OF COMPLIANCE

Environmental Health Laboratory Study Number: 87076

To the best of my knowledge, the study EHL 87076 (ML 87-104) was conducted in general conformance with the Environmental Protection Agency Good Laboratory Practice Standards, 40 CFR 160.

M. Reyna 11/4/87

Study Director Date

FIGURE 1

ROCHESTER-STYLE 300 LITER EXPOSURE CHAMBER
AND
SYRINGE PUMP ASSEMBLY FOR GENERATION OF TEST MATERIAL

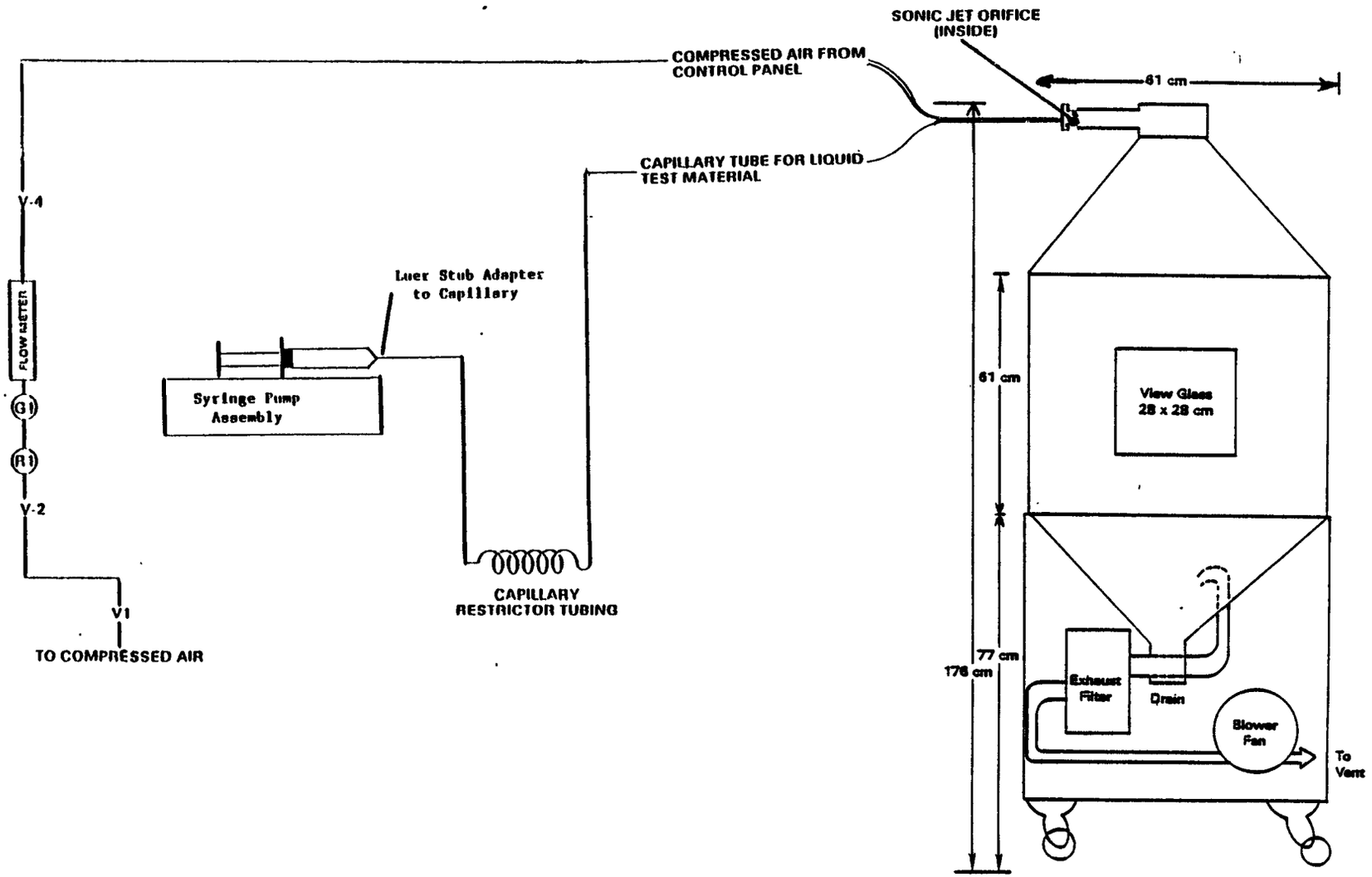

Table 1
EHL 87076
Mortality Data and Exposure Conditions

Grp	Mortality (Males)	Mortality (Females)	Mean Analytical (mg/l)	Nominal (mg/l)	Nominal to Analytical Ratio	Mean Chamber Temp. C.	% Mean Relative Humidity
Ø4	2/5	Ø/5	Ø.48	11	22.9	23.6	55
Ø3	4/5	3/5	Ø.86	21	24.4	23.1	63
Ø2	4/5	5/5	1.1	3Ø	27.3	23.6	55
Ø1	5/5	5/5	1.5	44	29.3	23.5	46

Table 2
EHL 87076
LC50 Data

Group	LC50 (mg/l)	95% Confidence Limits (LC50)	Slope	95% Confidence Limits (Slope)	Method of Calculation
Male	.56	.0046, .82	4.1	.27, 7.9	PROBIT
Female	.80				BINOMIAL
Combined	.68	.50, .82	6.2	3.0, 9.4	PROBIT

Table 3
EHL 87076
Particle-Size Analysis

Mean Analytical (mg/l)	Mass Median Aerodynamic Diameter in Micrometers	Geometric Standard Deviation in Micrometers	Percent of Particles Less than 10 Micrometers
0.48	2.4	2.1	97.1
0.86	2.6	2.1	96.4
1.1	2.3	1.9	98.7
1.5	3.0	2.0	96.1

Table 4

EHL 87076

Body Weights (grams)

Animal Number	Day 0	Day 2	Day 7	Day 14
M04 001	257	190	227	213
M04 002	282	213		
M04 003	276	221	215	
M04 004	259	211	232	288
M04 005	232	184	236	281
Mean	261	204	228	261
Std Dev	20	16	9	41
Mean Change from Day 0		-57	-33	0
F04 001	180	171	186	206
F04 002	168	147	183	196
F04 003	206	194	217	241
F04 004	187	171	201	215
F04 005	176	168	198	211
Mean	183	170	197	214
Std Dev	14	17	14	17
Mean Change from Day 0		-13	14	31

Table 4

EHL 87076

Body Weights (grams)

Animal Number	Day 0	Day 2	Day 7	Day 14
MØ3 ØØ1	220			
MØ3 ØØ2	280	216	260	262
MØ3 ØØ3	225			
MØ3 ØØ4	243			
MØ3 ØØ5	208			
Mean	235	216	260	262
Std Dev	28			
Mean Change from Day Ø		-19	25	27
FØ3 ØØ1	158			
FØ3 ØØ2	153			
FØ3 ØØ3	167	142	157	181
FØ3 ØØ4	162	137	156	163
FØ3 ØØ5	162	136		
Mean	160	138	157	172
Std Dev	5	3	1	13
Mean Change from Day Ø		-22	-3	12

Table 4

EHL 87076

Body Weights (grams)

Animal Number	Day 0	Day 2	Day 7	Day 14
MØ2 ØØ1	224			
MØ2 ØØ2	225			
MØ2 ØØ3	236			
MØ2 ØØ4	217			
MØ2 ØØ5	204	154	168	233
Mean	221	154	168	233
Std Dev	12			
Mean Change from Day Ø		-67	-53	12
FØ2 ØØ1	178			
FØ2 ØØ2	160			
FØ2 ØØ3	171			
FØ2 ØØ4	163	133		
FØ2 ØØ5	168			
Mean	168	133		
Std Dev	7			
Mean Change from Day Ø		-35		

Table 4

EHL 87076

Body Weights (grams)

Animal Number	Day 0	Day 2	Day 7	Day 14
MØ1 ØØ1	193			
MØ1 ØØ2	219			
MØ1 ØØ3	214	156		
MØ1 ØØ4	197			
MØ1 ØØ5	209			
Mean	206	156		
Std Dev	11			
Mean Change from Day Ø		-5Ø		
FØ1 ØØ1	154			
FØ1 ØØ2	143	114	122	
FØ1 ØØ3	158			
FØ1 ØØ4	161			
FØ1 ØØ5	160			
Mean	155	114	122	
Std Dev	7			
Mean Change from Day Ø		-41	-33	

Table 5

EHL 87076

Summary of Observations During Post-Exposure Period

Observation	Grp	No. Males Affected	No. Females Affected	First Day Observed	Last Day Observed
Emaciated	Ø1		1	9	1Ø
Hypoactive	Ø4	1	2	Ø	Ø
	Ø3	5	4	Ø	1
	Ø2	5	3	Ø	1
	Ø1	5	5	Ø	Ø
Nonresponsive	Ø3	2	2	Ø	Ø
	Ø2	4	2	Ø	Ø
	Ø1	5	5	Ø	Ø
Prostrate	Ø3	2	2	Ø	Ø
	Ø2	4	2	Ø	Ø
	Ø1	5	5	Ø	Ø
Labored Respiration	Ø4	3		1	3
	Ø3	5	3	Ø	2
	Ø2	5	4	Ø	5
	Ø1	5	5	Ø	1Ø
Gasping	Ø3	4	1	Ø	1
	Ø2	5	1	Ø	1
	Ø1	5	5	Ø	1
Rapid Respiration	Ø2		1	Ø	Ø
Slow Respiration	Ø3	3	2	Ø	Ø
	Ø2	2	1	Ø	1
	Ø1		2	Ø	1
Shallow Respiration	Ø1		2	Ø	Ø
Rattling Sounds	Ø4	5	3	Ø	14
	Ø3	5	2	Ø	8
	Ø2	4	3	Ø	9
	Ø1	5	1	1	1Ø
Clear Nasal Discharge	Ø4	2		Ø	Ø
	Ø3	4	3	Ø	Ø
	Ø2	5	4	Ø	Ø
	Ø1	5	5	Ø	Ø

Table 5

EHL 87076

Summary of Observations During Post-Exposure Period

Observation	Grp	No. Males Affected	No. Females Affected	First Day Observed	Last Day Observed
Bloodlike Nasal Discharge	Ø3	3	1	Ø	2
	Ø2	4	1	1	2
	Ø1	1	1	1	2
Red/Brown Perinasal Encrustation	Ø4	5	2	Ø	3
	Ø3	5	3	Ø	5
	Ø2	4	3	1	5
	Ø1	5	1	1	4
Salivating	Ø1		1	Ø	Ø
Perioral Wetness	Ø1		1	Ø	Ø
Red Ocular Discharge	Ø4		1	Ø	Ø
Lacrimation	Ø4		1	Ø	Ø
	Ø3	1	3	Ø	Ø
	Ø2	4	2	Ø	1
	Ø1	5	5	Ø	2
Ocular Opacity	Ø4	5	5	Ø	14
	Ø3	4	4	Ø	14
	Ø2	3	1	Ø	14
	Ø1	3	5	Ø	1Ø
Periocular Encrustation	Ø3	1		1	1
	Ø2	2		1	2
	Ø1	5	1	1	4
Focal Loss of Hair	Ø1		1	7	1Ø
Pale Coloration	Ø2	1	1	Ø	Ø
	Ø1		1	Ø	Ø

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

Table 6

STUDY NO: 87076 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: AC SPECIES: RAT SUBSTANCE: PRINTED: 3-SEP-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **
SELECTION CRITERIA: ALL DEATHS REPORTED

	MALE			
	MØ4	MØ3	MØ2	MØ1
NO. IN GROUP AT RISK:	5	5	5	5
EYE(S)				
-CORNEAL OPACITY	5	4	1	3
-ABNORMAL DISCHARGE/ENCRUSTATION	Ø	2	2	3
NOSE/TURBINATES				
-ABNORMAL DISCHARGE/ENCRUSTATION	1	4	3	4

THIS REPORT WAS GENERATED FROM DATA LOCKED THROUGH 7-AUG-87

Table 6

STUDY NO: 87076 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N

STUDY TYPE: AC SPECIES: RAT SUBSTANCE: PRINTED: 3-SEP-87

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **

SELECTION CRITERIA: ALL DEATHS REPORTED

	---- F E M A L E ----			
	F04	F03	F02	F01
NO. IN GROUP AT RISK:	5	5	5	5
EYE(S)				
-CORNEAL OPACITY	3	5	2	3
-ABNORMAL DISCHARGE/ENCRUSTATION	0	0	2	1
NOSE/TURBINATES				
-ABNORMAL DISCHARGE/ENCRUSTATION	0	2	5	5

Table 7

EHL 87076
Termination History

Animal Number	Fate	Day of Death After Exposure
F04 001	Sac'd	14
F04 002	Sac'd	14
F04 003	Sac'd	14
F04 004	Sac'd	14
F04 005	Sac'd	14
M04 002	Died	3
M04 003	Died	9
M04 001	Sac'd	14
M04 004	Sac'd	14
M04 005	Sac'd	14
F03 002	Died	1
F03 001	Died	2
F03 005	Died	3
F03 003	Sac'd	14
F03 004	Sac'd	14
M03 001	Died	2
M03 003	Died	2
M03 004	Died	2
M03 005	Died	2
M03 002	Sac'd	14
F02 005	Died	0
F02 002	Died	1
F02 001	Died	2
F02 003	Died	2
F02 004	Died	6
M02 002	Died	1
M02 001	Died	2
M02 003	Died	2
M02 004	Died	2
M02 005	Sac'd	14
F01 004	Died	0
F01 001	Died	1
F01 003	Died	1
F01 005	Died	1
F01 002	Died	11
M01 001	Died	2
M01 002	Died	2
M01 004	Died	2
M01 005	Died	2
M01 003	Died	3

Appendix 1

Analytical Procedure for Determination of 2-Ethyl-6-methylphenyl azomethine in Air

Description

This GC method is designed to measure 2-ethyl-6-methylphenyl azomethine (EMAZO) and its degradation product 2-ethyl-6-methylaniline (EMA) in air. It is based upon trapping EMAZO and EMA from about 10 l of air in an impinger containing iso-octane. Quantitation is achieved using a gas chromatograph with a nitrogen/phosphorus detector and integration of the summed chromatographic peaks due to EMAZO and EMA.

Instruments:

Typical GC Operating Parameters

Column: Fused Silica, 10 M x 0.53 mm ID., wide-bore capillary, 3 um film of OV-1701 from Quadrex Corp.

Gas Flows:
He - 10 mL/min
H2 - 30 mL/min
Air - 400 mL/min

Temperatures:
Detector: 350 deg. C
Injector: 150 deg. C
Column: 110 deg. C

Injection Volume: 2 uL

Chromatograph: Varian 3700 GC modified for wide-bore capillary column with autosampler, Integration by Spectra Physics 4720 integrator

Materials:

2-Ethyl-6-methylphenyl azomethine: EHL Test Substance Control Number T870022

Iso-octane: Burdick and Jackson, Inc., HPLC Grade

2-Ethyl-6-methylaniline: 99.3%, from Ethyl Corp. supplied by MAC, St. Louis, MO

Required Standard Solutions (EMAZO)

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Stock Standards (a)

Identification	Approximate Sample Weight (mg) (b)	Volume of Sample Standard (mL)	Approximate Stock Standard Concentration (mg/L)
A	100	100	1000
B	500	100	5000

Working Standards

Identification	Stock Standard	Volume of Stock Standard (mL)	Volume of Working Standard (mL)	Approximate Concentration of Working Standard (mg/L)
WS-1	A	1	100	10
WS-2	B	2	100	100
WS-3	B	10	100	500
WS-4	A	neat	-	1000
WS-5	B	25	50	2500
WS-6	B	neat	-	5000
QC-EMAZO	B	10	100	500

(a) Prepared using EHL Test Substance T870022.

(b) To the nearest 0.1 mg.

Comments: Fresh stock and working standards will be prepared in iso-octane every two weeks.

Additional standards, fewer standards and/or alternate concentrations of standards may be used for the calculation of regression coefficients at the discretion of the chemistry group.

EMAZO should not be refrigerated.

1. Working Standard Concentrations

$C_w = (C_s * V_s)/V_w$

where: C_w = concentration of working standard (mg/L)

C_s = concentration of stock standard (mg/L)

V_s = volume of stock standard (mL)

V_w = volume of working standard (mL)

Values are reported to three significant figures.

2. Regression Coefficients

Peak areas of EMAZO and EMA will be summed and treated as EMAZO. A linear regression will be calculated from the standard concentrations C_w (in mg/L) and the corresponding areas A. The A and C_w will be treated as X and Y, respectively. The expression $C_w = a+b*A$ will be used to calculate the concentrations of the impinger solutions.

Standards 1-3 will be used to calculate the regression coefficients for any solution having a peak area less than or equal to WS-3. Standards 1-6 will be used to calculate regression coefficients for samples with area counts greater than WS-3.

3. Net Peak Area

If the blank sample exhibits a peak interfering with either test material peak with an area sum exceeding 10% of the area of the lowest standard then a net peak area will be calculated.

$A_N = A_T - A_b$

where: A_N = net area of test material

A_b = area of blank peak at test material retention time

A_T = apparent area of test material peak

4. Solution Concentration

The solution concentration C_x will be calculated directly from the regression equation by the labnet computer.

Solution concentrations will be reported to three significant figures. Solution concentrations less than the lowest standard will be reported as NM (not measurable).

5. Air Concentration

$$C_{air} = C_x * V_{imp} * 10^{-3} \text{ liter/mL} * 1/V_{air}$$

where:
C_x = Solution concentration (mg/L)
C_{air} = Air concentration of AZO (mg/l air)
V_{imp} = Impinger sample volume (mL)
V_{air} = Volume of air sampled (l)

Air concentrations will be reported to two significant figures.

Comments

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A typical chromatogram of a working standard is attached.

Prestudy data has shown the NPD detector responses to EMAZO and EMA are within 10%. Area percent of EMAZO and EMA will be made using needle volume injections to assess stability of the test material.

It is necessary to re-analyze the QC if the mean value for that sample differs from expected by 10% or greater. The study director, upon comparison of nominal and analytical measurements, may recommend re-analysis of impinger samples.

Two sets of standards will be run for each set of analysis; one set will be run at the start of the samples and the second set will be run at the end of the samples. Unless otherwise directed by a professional of the chemistry group, mean peak areas will be used to calculate the correlation coefficient and the linear regression line and all sample concentrations.

QC samples will be run in duplicate both near the beginning and near the end of each analytical run (thus bracketing all samples for that day.) Unless a professional of the chemistry group determines that analytical, sampling or instrumental condition dictate otherwise, mean peak area for QC samples will be used for concentration calculations. QC sample concentrations may vary during the course of the study to approximately match impinger concentrations.

Different standard weights and volumes of stocks and volumetric flasks may be used as long as the approximate concentrations of the stocks and working standards still correspond to those given on page 2.

Computer generated "interim" data may contain more significant figures than is specified in this analytical method. The final analytical data (in the analytical report) will, however, be rounded to the number of significant figures indicated.

This method was developed by Sue Schermes and Roger D. Holm, Ph.D. The following technician is judged capable of performing this analysis.

Technician	Date Training Completed
Sue Schermes	5/8/87

Prepared By: Roger D. Holm Date: 6-1-87

Reviewed By: Mark E. Holland Date: 6/1/87

CHANNEL A INJECT 05/14/87 14:15:14

87076 EMAZO DAY 3 05/14/87 14:15:14 CH= "A" PS= 1.

FILE 1. METHOD 5. RUN 4 INDEX 4

ANALYST: SUSAN SCHERMES

SAMPLE 4 WS-4

SA	IS	XF
0.	0.	1.

NAME	RT	AREA	BC	RF
1	2.43	2475	01	
EMAZO	3.26	428230	01	1.
3	4.05	1889	01	
EMA	5.36	63526	03	1.
TOTALS		496120		

Results of the Analysis of 2-Ethyl-6-methylazomethine
in an Acute Inhalation Study

Authors:

Susan Schermes 9/3/87
S. Schermes Date

Roger D. Holm 9-3-87
R. D. Holm, Ph.D. Date

Approved by:

Martin W Dietrich 9/3/87
M. W. Dietrich, Ph.D. Date
Chemistry Group Leader

Impinger samples of 2-ethyl-6-methylazomethine (EMAZO) were collected during an acute exposure inhalation study, and the solutions were analyzed for the active ingredient using gas chromatography. The data represent the sum of EMAZO and its degradation product, 2-ethyl-6-methylaniline (EMA).

Chamber air concentrations of EMAZO were calculated from first impinger concentrations and air sampling data. Second impinger carryover amounted to only about 2% of the concentrations in the first impingers and thus were ignored. Table 1 presents test material concentrations together with daily means and standard deviations.

Quality control results are presented in Table 2. The close agreement indicates the method had no significant bias and provided analyses both accurate and precise.

Needle volume injections of neat EMAZO were made before, during and after the study and indicate no significant change or degradation in the test material. The observed percents of EMA relative to EMAZO, presented in Table 3, are essentially unchanged.

Table 1

EMAZO Acute Inhalation Study Results

Exposure Day	Chamber Air Concentration (mg/l EMAZO)	Mean Exposure Concentration ± Standard Deviation (mg/l EMAZO)
1	1.7 1.6 1.2 1.3	1.5 ± 0.2
2	1.3 1.2 1.0 1.0	1.1 ± 0.2
3	0.86 0.83 0.85 0.90	0.86 ± 0.03
4	0.49 0.47 0.49 0.48	0.48 ± 0.01

Table 2

Quality Control Results for EMAZO

Exposure Day	Concentrations (mg/L solution) Expected	Observed*	% Difference**
1	497	485	-2.4
2	497	493	-0.8
3	497	497	0
4	497	489	-1.6

* Mean of duplicate analyses.

** % Difference = (Observed - Expected) (100)/Expected

Table 3

EMA Peak Area Expressed as Percent of EMAZO

Date	EMA as Percent of EMAZO	Mean ± Standard Deviation
May 12, 1987	1.5 1.4 0.83	1.2 ± 0.4
May 15, 1987	1.5 0.90 0.94 1.2	1.1 ± 0.3
May 19, 1987	1.2 1.2 0.88	1.1 ± 0.2