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MONSANTO CO			
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INITIAL SUBMISSION: TOXICOLOGICAL INVESTIGATION OF: P-PHENETIDINE WITH COVER LETTER DATED 080592			
Chemical Category			
P-PHENETIDINE			

Contains NO CBI

Monsanto

ENVIRONMENT, SAFETY & HEALTH

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone: (314) 694-1000

August 5, 1992



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Environmental Protection Agency
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88920008337

Attention: Section 8(e) Coordinator (CAP Agreement)

This submission is pursuant to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement #8ECAP-0036.

The information included herein is characterized as follows:

Chemical Identity - P-PHENETIDINE (single distilled);CP 5685

Chemical CAS No. - 000156434

Information/Study Type - II,B,2,b/Acute Toxicity/Irritation Study

Information/Study Identification - Acute Toxicity of p-Phenetidine (Single-distilled) Administered to Male and Female Sprague-Dawley Rats by Inhalation
ML-78-316

Identification of Reportable Endpoint: SIGNS OF NEUROTOXICITY

Previous TSCA 8(e) or PMN submissions, if any, for the reference chemical can be found in Appendix A.

It should be noted that this summary is not all inclusive. Therefore, it may not highlight all adverse effects that EPA may judge to meet TSCA 8(e) reportability. This submission/report does not contain confidential business information.

Sincerely,

J. R. Condray
Director, Regulatory Management
(314) 694-8883

08/28/92

TEST SUBSTANCE : p-Phenetidine (single distilled) Tech. Grade
 LOT NUMBER : KK-07-45
 CP NUMBER : 5685
 DMEH PROJECT NUMBER : ML-78-316
 DATE : February 16, 1979

CAS 000156434

ACUTE ORAL TOXICITY Species: Sprague-Dawley Rat (Male)
 STUDY NUMBER: EHL 78-0052 SOP Number: L-58081-R021
 LD₅₀: 754 Mg/Kg 95% Confidence Limits: 656-868 Mg/Kg Slope: 12.3
 CONDITIONS: Single oral dose (diluted with vegetable oil)

Dosage (Mg/Kg)	Body Weight (Gm)			Mortalities/Dosed			Time of Mortality
	Day 0 Male/Female	Day 7 Male/Female	Day 14 Male/Female	Male	Female	Combined	
100	233	305	348	0/10			
300	233	299	341	0/10			
500	234	290	336	0/10			
700	227	275	316	4/10			Day 1:2; Day 3:2
900	231	280	355	8/10			Day 1:5; Day 3:1; Day 4:2

Physical Observations: All treated animals appeared to be sedated. Animals at the 900 Mg/Kg dose were ataxic, cyanotic and dyspneic. Chromodyscrorrhea and nasal discharge were observed in two rats. Otherwise, animals appeared normal.

Gross Necropsy: Moderate to severe hemorrhagic lungs were observed in decedents. At terminal sacrifice, the lungs of the survivors appeared mottled and the spleens were unusually dark looking. Otherwise, viscera appeared normal.

PRIMARY SKIN IRRITATION (Max. Score = 8. Erythema + Edema) Species: New Zealand Rabbit
 STUDY NUMBER: EHL 78-0069 SOP Number: L-58081-R013
 Irritation Score (24, 72 Hour Avg.): 0.9
 Dose and Conditions: 0.5 Ml Applied undiluted.

Hours	24				72			
	ERYTHEMA		EDEMA		ERYTHEMA		EDEMA	
ANIMAL NUMBER	Intact	Abraded	Intact	Abraded	Intact	Abraded	Intact	Abraded
1 Male	1	1	0	0	0	0	0	0
2 Male	2	2	0	0	0	0	0	0
3 Male	0	0	0	0	0	0	0	0
4 Female	2	2	0	0	0	1	0	0
5 Female	2	2	0	1	0	1	0	0
6 Female	1	1	0	1	0	1	0	0

Mean Score: 1.5 0.3
 Comments: p-Phenetidine (singled distilled) can be classified as a "non-irritant" to the skin.

ACUTE DERMAL TOXICITY

Species: New Zealand Rabbit

STUDY NUMBER: EHL 78-0054

SOP Number: L-58081-R019

LD₅₀: > 2000 Mg/Kg

95% Confidence Limits:

Slope:

CONDITIONS: Applied undiluted

Dosage (Mg/Kg)	Initial Weight (Kg)		Mortalities/Dosed			Time of Mortality
	Male	Female	Male	Female	Combined	
2000	2.32	2.77	0/2	0/2	0/4	Day 1:1; Day 2:1 Day 1:1
2500	2.33	2.29	2/2	0/2	2/4	
3000	2.19	1.98	1/2	0/2	1/4	

Physical Observations: Mydriasis and no pupillary response to light were observed in treated animals. Ataxia and peripheral vasoconstriction were noted in rabbits after topical application of 3 g/kg dose.

Gross Necropsy: Necrotic foci were noted in the livers of two animals. The spleen was unusually dark in two rabbits. Bloody urine was observed in the bladders of three animals. Viscera appeared normal in the rest of the rabbits.

ACUTE EYE IRRITATION (Max. Score = 110. Cornea + Iris + Conjunctivae)

Species: New Zealand Rabbit

STUDY NUMBER: EHL 78-0067

SOP Number: L-58081-R015

Irritation Score (24, 48, 72 Hour Avg.): 9.9

Dose and Conditions: 0.1 Ml Applied undiluted

Hours	24			48			72		
	Cornea	Iris	Conjunctivae	Cornea	Iris	Conjunctivae	Cornea	Iris	Conjunctivae
1 Male	0	0	4	0	0	6	0	0	0
2 Male	5	5	6	0	5	2	0	0	2
3 Male	10	10	10	5	10	12	5	0	4
4 Female	0	5	4	0	0	4	0	0	2
5 Female	15	5	4	0	5	4	0	0	2
6 Female	5	10	6	0	0	4	0	0	2

Mean Score: 17.3 9.5 2.8

Comments: p-Phenetidine (single distilled) can be classified as a "slight irritant" to the eye.

Submitted by: Paul Chew, Ph.D.

Date: _____

Environmental Health Laboratory
Department of Medicine & Environmental Health

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166

ACUTE DERMAL TOXICITY

Species: New Zealand Rabbit

STUDY NUMBER: EHL 78-0054

SOP Number: L-58081-R019

LD₅₀: > 2000 Mg/Kg

95% Confidence Limits:

Slope:

CONDITIONS: Applied undiluted

Dosage (Mg/Kg)	Initial Weight (Kg)		Mortalities/Dosed			Time of Mortality
	Male	Female	Male	Female	Combined	
2000	2.32	2.77	0/2	0/2	0/4	Day 1:1; Day 2:1 Day 1:1
2500	2.33	2.29	2/2	0/2	2/4	
3000	2.19	1.98	1/2	0/2	1/4	

Physical Observations: Mydriasia and no pupillary response to light were observed in treated animals. Ataxia and peripheral vasoconstriction were noted in rabbits after topical application of 3 g/kg dose.

Gross Necropsy: Necrotic foci were noted in the livers of two animals. The spleen was unusually dark in two rabbits. Bloody urine was observed in the bladders of three animals. Viscera appeared normal in the rest of the rabbits.

ACUTE EYE IRRITATION (Max. Score = 110. Cornea + Iris + Conjunctivae)

Species: New Zealand Rabbit

STUDY NUMBER: EHL 78-0067

SOP Number: L-58081-R015

Irritation Score (24, 48, 72 Hour Avg.): 9.9

Dose and Conditions: 0.1 Ml Applied undiluted

Hours	24			48			72		
	Cornea	Iris	Conjunctivae	Cornea	Iris	Conjunctivae	Cornea	Iris	Conjunctivae
1 Male	0	0	4	0	0	6	0	0	0
2 Male	5	5	6	0	5	2	0	0	2
3 Male	10	10	10	5	10	12	5	0	4
4 Female	0	5	4	0	0	4	0	0	2
5 Female	15	5	4	0	5	4	0	0	2
6 Female	5	10	6	0	0	4	0	0	2

Mean Score: 17.3 9.5 2.8

Comments: p-Phenetidine (single distilled) can be classified as a "slight irritant" to the eye

Submitted by:

Paul Chew, Ph.D.

Date:

**Environmental Health Laboratory
Department of Medicine & Environmental Health**

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St. Louis, Missouri 63166

Monsanto

ML-78-316 CORPORATE/EPD/DMEH/EHL
(CO./DIV./DEPT./LOCATION)

FINAL REPORT
(TYPE OF REPORT)

REPORT NO.: MSL-3383

JOB/PROJECT NO.: ML-78-316/790126

DATE: January 27, 1984

TITLE: Acute Toxicity of p-Phenetidine (Single-distilled) Administered to Male and Female Sprague-Dawley Rats by Inhalation

AUTHORS: M. Val Roloff

ABSTRACT: Five male and five female rats were exposed by inhalation to p-Phenetidine (Single-distilled) for four hours at a mean nominal concentration of 4.87 ± 0.14 mg test material/liter of air. Signs of toxicity observed during exposure and post-exposure included shallow, rapid or labored breathing, listlessness, a depressed-like condition, lacrimation, eye irritation, ptosis and ataxia. One male and one female died as a result of exposure. Gross lesions were observed only in the one female rat which died during the exposure. These included multiple hemorrhages of all lobes of the lung, a reddened intestine and petechial hemorrhages on the thymus.

M. Val Roloff
Acute Toxicity of p-Phenetidine (Single-distilled)
Administered to Male and Female Sprague-Dawley
Rats by Inhalation

AUTHORS:
TITLE:

MSL-3383

REPT. NO.:

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