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Contains No CBI



PHILLIPS PETROLEUM COMPANY
BARTLESVILLE, OKLAHOMA 74004 918 661-6600

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HEALTH, ENVIRONMENT AND SAFETY

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August 24, 1992

Compliance Audit Program
CAP ID#: 8ECAP-0075

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Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street, SW
Washington, D. C. 20460

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

Gentlemen:

Phillips Petroleum Company is submitting the enclosed sixty (60) reports (two boxes, numbered 1 and 2) of toxicological studies pursuant to category II.B.2.b of the CAP Agreement 8ECAP-0075 Reports. Reports being submitted contain no confidential business information.

We are sending an additional five boxes (box numbers 3-7) of reports of studies that have, previously, been submitted to the FYI coordinator of the Office of Pollution Prevention and Toxics by the American Petroleum Institute (API). These are being provided solely for the Agency's convenience.

For questions concerning this correspondence, please contact Fred Marashi at 918-661-8153.

Very truly yours,

Barbara J. Price
Vice President
Health, Environment & Safety

Enclosure (Seven Boxes)

FFM/dh:29

mm
3/21/95



Phillips Petroleum Company

52

2

CAP Identification Number: 8ECAP-0075
Pursuant to Category: II.B.2.b

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Title of Study: Acute Toxicity Tests of API 79-2 #6 Heavy Fuel Oil (API Gravity 5.2/1.2% S)

Name of Chemical: #6 Heavy Fuel Oil

CAS#: 68553-00-4

Summary: The acute dermal test resulted in moderate skin irritation and severe signs of systemic toxicity. Subacute dermal testing produced not only acute dermal irritation, but also obvious treatment-related signs at the 1 ml/kg, 2 ml/kg, and 2.5 ml/kg dosage levels; histopathologic examination of tissues confirmed dermal and hepatic toxicity at all dosage levels.

Fiche # 1627

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ELARS BIORESEARCH LABORATORIES

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Acute Toxicity Tests
API 79-2
#6 Heavy Fuel Oil
(API Gravity 5.2/1.2%S)

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BIORESEARCH LABORATORIES
September 2, 1980

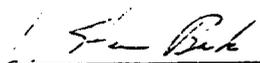
Project No. 1443

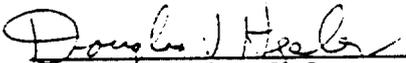
Acute Toxicity Tests
API 79-2
#6 Heavy Fuel Oil (API Gravity 5.2/1.2%)

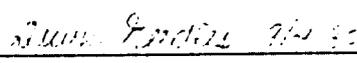
Conducted By:
Elars Bioresearch Laboratories, Inc.
225 Commerce Drive
Fort Collins, Colorado 80524

Dates of Studies:
May 21, 1979 - June 9, 1980

Report To:
American Petroleum Institute
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REVIEWED BY QUALITY ASSURANCE: 

Acute Toxicity Tests
API 79-2
#6 Heavy Fuel Oil (API Gravity 56/1.2%)

TABLE OF CONTENTS

Abstract	1
Primary Skin Irritation	1
Primary Eye Irritation	8
Skin Sensitization	18
Acute Dermal Toxicity	26
Rat Acute Oral Toxicity	32
Subacute Dermal Toxicity	39
Feed Analysis	52

ABSTRACT

The test material, API 79-2, #6 Heavy Fuel Oil (API Gravity 5.2/1.2XS), was tested for potential acute toxicity, using a battery of six tests: Primary Skin Irritation, Primary Eye Irritation, Skin Sensitization, Acute Dermal Toxicity, Acute Oral Toxicity, and Subacute Dermal Toxicity. Materials, methods, and results of individual tests are presented in this report.

The test material API 79-2 produced slightly irritating primary skin effects. The acute dermal test resulted in moderate skin irritation and severe signs of systemic toxicity. Subacute dermal testing produced not only acute dermal irritation, but also obvious treatment-related signs at the 1 ml/kg, 2 ml/kg, and 2.5 ml/kg dosage levels; histopathologic examination of tissues confirmed dermal and hepatic toxicity at all dosage levels. The oral median lethal dose, i.e., oral LD₅₀, of the test material is 5.13 ml/kg. The test material, on the other hand, was considered mildly irritating for primary eye irritation and did not cause skin sensitization.

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BIORESEARCH LABORATORIES
February 25, 1980

Project No. 1444-3

Primary Skin Irritation
API 79-1

#6 Heavy Fuel Oil (API Gravity 5.2 @ 15.2°C)

Conducted By:

Elars Bio Research Laboratories, Inc.
225 Commerce Drive
Fort Collins, Colorado 80524

Dates Of Study:

December 27, 1979 - January 10, 1980

Report To:

American Petroleum Institute
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POOR
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REVIEWED BY QUALITY ASSURANCE: _____

BIORESEARCH LABORATORIES
February 25, 1980

Project No. 1443-A

Primary Skin Irritation

API 79-2

#6 Heavy Fuel Oil (API Gravity 5.2/1.2%S)

OBJECTIVE:

The objective of this study was to determine the potential dermal irritation of the test material in albino rabbits.

MATERIALS AND METHODS:

1. Test Material:

The test material, a liquid in a metal container identified as API 79-2, #6 Heavy Fuel Oil (API Gravity 5.2/1.2%S), was received at Elars on October 8, 1979. The concentration, purity, and stability of the test material were not provided by the sponsor. The test material was stored in Elars' test material storage room and removed in 500 ml allotments as needed for testing.

2. Animals:

Three male and three female New Zealand White rabbits purchased from Dutchland Rabbitry, Denver, Pennsylvania, were used. Upon arrival at Elars on December 18, 1979, all animals were individually identified by ear tags and corresponding cage tags. Rabbits were housed individually in stainless steel cages with grated bottoms. All animals were provided Purina Rabbit Chow[®] and fresh water ad libitum.

BIORESEARCH LABORATORIES
Primary Skin Irritation
API 79-2

Project No. 1443-A
February 20, 1968

3. Procedures:

The animals were allowed to acclimate for at least one week at Elars. Before application of the test material, the rabbits were examined and clipped free of hair with a No. 40 Oster® clipper blade in an area extending from the shoulders to the hips and halfway down either side of the thorax.

There were four test sites per animal which were located lateral to the midline of the back (two sites on each side) and approximately 10 cm apart. The day of the study, the test sites on the right anterior and the left posterior of each rabbit were abraded with the tip of an eighteen gauge needle. Abrasions consisted of four incisions, two parallel to the long axis of the rabbit and two at right angles to the first. Incisions penetrated the stratum corneum but not the dermis. Test areas on the left anterior and the right posterior were left intact. A dose of test material equal to 0.5 ml was applied to each of four one-inch square gauze patches backed by plastic wrap. The patches were then applied to the four test sites on each rabbit and secured in place with bandage strips. The rabbits' trunks were wrapped with plastic wrap and then with elastic tape to help prevent movement of the patches. The test substance was kept in contact with the skin for 24 hours. At the end of the exposure period, the wrapping material and patches were removed. Excess test material was removed by wiping (but not washing) the skin with gauze sponges.

At 24 and 72 hours and 7 and 14 days postdose, animals were observed and signs of erythema and edema were scored according to the technique of Draize (1).

BIORESEARCH LABORATORIES
Primary Skin Irritation
API 79-2

Project No. 1443-A
February 25, 1980

RESULTS:

Individual rabbit erythema and edema scores for the 24 and 72 hour and 7 and 14 day readings are presented in Table 1A and 1B. Computation of the mean primary irritation score is presented in Table 2.

For the 24 hour reading, scores for edema and erythema were noted to be slightly irritating. At 72 hours, erythema was noted to be slight and edema was not present. At 7 days, slight irritation was noted for edema and erythema, and at 14 days edema and erythema were still present.

CONCLUSIONS:

Based on the conditions of this trial, the test substance is to be considered slightly irritating.

RAW DATA:

Raw data can be found in Elars' notebook #1037 in file #1443-A.

PERSONNEL:

Personnel responsible for the conduct and interpretation of this test include the following Elars personnel: Denice E. Morita, B.S., Toxicology Technician and Study Coordinator; Vicki J. Mills, B.S., and Irma Albinana, Toxicology Technicians; L. Steven Beck, D.V.M., M.S., Senior Toxicologist and Study Director; and Douglas I. Hepler, Ph.D., Director of Toxicology.

REFERENCES:

1. Draize, J. H., 1959, "Dermal Toxicity," The Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Assoc. of Food and Drug Officials of the U.S., Austin, Texas, p. 46.
2. Draize, J. H.; Woodward, Geoffrey; and Calvery, Herbert O., "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes.", J. Pharm. And Exp. Ther., 82, p. 377 (1944).

BIORESEARCH LABORATORIES
 Primary Skin Irritation
 API 79-2

Project No. 1449-A
 February 23, 1960

Table 1A
 Dermal Irritation Scores

Rabbit Number	Erythema				Edema			
	Abraded		Intact		Abraded		Intact	
	RF*	LR*	LF*	RR*	RF*	LR*	LF*	RR*
	<u>24 Hour</u>							
804F	1	1	1	1	2	1	0	0
806F	3	3	3	3	2	1	2	1
808F	1	0	1	0	1	1	1	0
815M	1	1	1	0	1	1	1	0
817M	1	2	2	1	2	1	2	2
819M	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>2</u>
Totals	8	8	9	6	9	6	7	5
Averages	1.33		1.25		1.25		1.00	
	<u>72 Hour</u>							
804F	0	0	0	0	0	0	0	0
806F	1	1	1	1	0	0	0	0
808F	0	0	0	0	0	0	0	0
815M	1	1	1	1	0	0	0	0
817M	0	0	0	0	0	0	0	0
819M	<u>2</u>	<u>2</u>	<u>2</u>	<u>2</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Totals	4	4	4	4	0	0	0	0
Averages	0.67		0.67		0.00		0.00	

* Patch Location: RF = Right Front
 LR = Left Rear
 LF = Left Front
 RR = Right Rear



BIORESEARCH LABORATORIES
 Primary Skin Irritation
 API 79-2

Project: 100-1-A
 February 11, 1960

Table 13
 Dermal Irritation Scores

Rabbit Number	Erythema				Edema			
	Abraded		Intact		Abraded		Intact	
	RF*	LR*	LF*	RR*	RF*	LR*	LF*	RR*
	<u>7 Days</u>							
804F	0	0	0	0	0	0	0	0
806F	0	0	0	0	0	0	0	0
808F	0	0	0	0	0	0	0	0
815M	0	0	0	0	0	0	0	0
817M	0	0	0	0	0	0	0	0
819M	<u>2</u>	<u>0</u>	<u>2</u>	<u>0</u>	<u>1</u>	<u>0</u>	<u>1</u>	<u>0</u>
Totals	2	0	2	0	1	0	1	0
Averages	0.17		0.17		0.08		0.08	
	<u>14 Days</u>							
804F	0	0	0	0	0	0	0	0
806F	0	0	0	0	0	0	0	0
808F	1	1	0	2	0	1	0	1
815M	0	0	0	0	0	0	0	0
817M	0	0	0	0	0	0	0	0
819M	<u>1</u>	<u>1</u>	<u>1</u>	<u>1</u>	<u>0</u>	<u>1</u>	<u>1</u>	<u>1</u>
Totals	2	2	1	3	0	2	1	2
Averages	0.33		0.33		0.17		0.25	

* Patch Location: RF = Right Front
 LR = Left Rear
 LF = Left Front
 RR = Right Rear



BIORESEARCH LABORATORIES
 Primary Skin Irritation
 API 7402

Project No. 1443-A
 February 15, 1980

Table 2
 Summary of Dermal Irritation Scores

Summary	Exposure Time Hours	Exposure Unit Values*
<u>Erythema</u>		
Intact Skin	24	1.25
	72	0.67
Abraded Skin	24	1.33
	72	<u>0.67</u>
Subtotal		3.92
<u>Edema</u>		
Intact Skin	24	1.00
	72	0.00
Abraded Skin	24	1.25
	72	<u>0.00</u>
Subtotal		<u>2.25</u>
TOTAL		6.17

Primary Irritation Score = Total + 4 = 1.54

Irritation Category - Slightly Irritating

* The "value" recorded for each reading is the average value of the animals used on the test.

Mean Primary Irritation Scores (Range Of Values)	Descriptive Rating
0	Non-irritating
0.1 - 0.5	Minimally Irritating
0.6 - 1.5	Slightly Irritating
1.6 - 3.0	Mildly Irritating
3.1 - 5.0	Moderately Irritating
5.1 - 6.5	Severely Irritating
6.6 - 8.0	Extremely Irritating



ELARS BIO RESEARCH LABORATORIES
January 7, 1980

8

Project No. 1443-B

Primary Eye Irritation
API 79-2
#6 Heavy Fuel Oil (API Gravity 5.2/1.2%S)

Conducted By:
Elars Bio Research Laboratories, Inc.
225 Commerce Drive
Fort Collins, Colorado 80524

Dates Of Study:
December 1, 1979 - December 17, 1979

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ORIGINAL

Report To:
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REVIEWED BY QUALITY ASSURANCE:

Valerie Beattie Nelson



BIORESEARCH LABORATORIES
January 7, 1980

Project No. 1443-B

Primary Eye Irritation
API 79-2
#6 Heavy Fuel Oil (API Gravity 5.2/1.2%)

OBJECTIVE:

The objective of this study was to determine the potential ocular irritation of the test material.

MATERIALS AND METHODS:

1. Test Material:

The test material, a liquid in a metal container identified as API 79-2, #6 Heavy Fuel Oil (API Gravity 5.2/1.2%), was received at Elars on October 8, 1979. The concentration, purity, and stability of the test material were not provided by the sponsor. The test material was stored in Elars' test material storage room and removed in 500 ml allotments as needed for testing.

2. Test System:

Nine young adult New Zealand White rabbits, four females and five males, were purchased from Dutchland Rabbitry, Denver, Pennsylvania. They were individually identified by ear tags and cage tags and were allowed to acclimate at Elars. Rabbits were housed in suspended cages and fed Purina Rabbit Chow[®] and fresh water ad libitum. Both eyes of all nine rabbits were examined at least 24 hours before beginning of testing with fluorescein dye to determine the absence of pre-existing corneal lesions.

DESCRIPTION OF STUDY DESIGN AND PROCEDURES:

A dose of 0.1 ml of undiluted test material was placed on the everted lower lid of the right eye of each rabbit within the group. The upper



BIORESEARCH LABORATORIES

Primary Eye Irritation
API 79-2Project No. 1443-1
January 7, 1960

and lower lids were then held together for one second to prevent loss of test material. The test eyes of three rabbits, two females and one male, were flushed for one minute with warm distilled water starting 30 seconds after application of the test material. The untreated left eye of each rabbit served as a control. All nine rabbits were dosed on December 3.

Scoring of ocular lesions was done at 24, 48, and 72 hours and 7 and 14 days after treatment. Fluorescein dye evaluation was used for each reading. Grading and scoring of irritation was done in accordance with the procedure described by Draize (1959).

RESULTS:

Individual scores for each rabbit are presented in Table 1. Table 2 gives the averages for each reading for rinsed and unrinsed groups.

Two rabbits showed corneal opacities at the 48 hour examination that were believed to be treatment related. Other rabbits showed opacities at 72 hours and 14 days that were not due to treatment. No iridial inflammation was seen in any of the rabbits.

Conjunctival irritation was present in all nine rabbits at the 24 hour observation. All rabbits were negative for treatment related irritation by 14 days.

The averages for the eyes that were rinsed appeared better than the unrinsed group at the 24 and 72 hour and 7 day readings but worse at the 48 hour reading.



BIORESEARCH LABORATORIES
Primary Eye Irritation
APE 79-2

Project No. 1443-B
January 7, 1969

CONCLUSIONS:

According to the attached classification scheme, the test substance can be considered mildly irritating, with a 24 hour average of 7.11, and all scores zero at the 7 day reading.

PERSONNEL:

Personnel responsible for the conduct and interpretation of this test include the following Elars personnel: Denice E. Morita, B.S., Toxicology Technician and Study Coordinator; Anne E. McDowell, B.S., Toxicology Technician; L. Steven Beck, D.V.M., M.S., Senior Toxicologist and Study Director; and Douglas I. Hepler, Ph.D., Director of Toxicology.

RAW DATA:

Raw data can be found in Elars' notebook #1028 in project file #1443-B.

Primary Eye Irritation
API 79-2

Table 1
Individual Rabbit Eye Irritation Scores*

Project No. 1443-4
January 7, 1960

Page 1 of 3

Rabbit No. & Sex	Item	Tissue	Reading				
			12/4 24 hr	12/5 48 hr	12/6 72 hr	12/10 7 days	12/17 14 days
775 Male Rinsed	A	Cornea Opacity	0	0	0	0	1 ^a
	B	Cornea Area	0	0	0	0	1
		(1) CORNEA TOTAL = (AxB) x 5	0	0	0	0	5 ^a
	C	Iris	0	0	0	0	0
		(2) IRIS TOTAL = (C) x 5	0	0	0	0	0
	D	Conjunctiva Redness	1	1	1	0	0
	E	Conjunctiva Chemosis	1	0	0	0	0
	F	Conjunctiva Discharge	0	0	0	0	0
		(3) CONJ. TOTAL = (D+E+F) x 2	4	2	2	0	0
	TOTALS ADDED = (1+2+3)	4	2	2	0	0 ^a	
776 Female Rinsed	A	Cornea Opacity	0	1	0	0	0
	B	Cornea Area	0	1	0	0	0
		(1) CORNEA TOTAL = (AxB) x 5	0	5	0	0	0
	C	Iris	0	0	0	0	0
		(2) IRIS TOTAL = (C) x 5	0	0	0	0	0
	D	Conjunctiva Redness	1	1	0	0	0
	E	Conjunctiva Chemosis	1	1	0	0	0
	F	Conjunctiva Discharge	0	0	0	0	0
		(3) CONJ. TOTAL = (D+E+F) x 2	4	4	0	0	0
	TOTALS ADDED = (1+2+3)	4	9	0	0	0	
778 Female Rinsed	A	Cornea Opacity	0	0	0	0	0
	B	Cornea Area	0	0	0	0	0
		(1) CORNEA TOTAL = (AxB) x 5	0	0	0	0	0
	C	Iris	0	0	0	0	0
		(2) IRIS TOTAL = (C) x 5	0	0	0	0	0
	D	Conjunctiva Redness	3	1	0	0	0
	E	Conjunctiva Chemosis	3	1	1	1	0
	F	Conjunctiva Discharge	0	0	0	0	0
		(3) CONJ. TOTAL = (D+E+F) x 2	12	4	2	2	0
	TOTALS ADDED = (1+2+3)	12	4	2	2	0	

* See attached sheet for "Scale for Scoring Ocular Lesions"

^a Observations believed to be non-treatment induced. Scores are not entered into the calculations.

Primary Eye Irritation
API 79-1

Table 1
Individual Rabbit Eye Irritation Scores*

Project No. 1443-B
January 7, 1980

13

Page 2 of 3

Rabbit No. & Sex	Item	Tissue	Reading							
			12/4 24 hr	12/5 48 hr	12/6 72 hr	12/10 7 day	12/17 14 day			
783 Male Unrinsed	A	Cornea Opacity	0	0	1 ^a	0	1 ^a			
	B	Cornea Area	0	0	1	0	1			
		(1) CORNEA TOTAL = (AxB) x 5	0	0	5 ^a	0	5 ^a			
	C	Iris	0	0	0	0	0			
		(2) IRIS TOTAL = (C) x 5	0	0	0	0	0			
	D	Conjunctiva Redness	3	2	2	1	0			
	E	Conjunctiva Chemosis	2	1	1	1	0			
	F	Conjunctiva Discharge	1	0	0	0	0			
		(3) CONJ. TOTAL = (D+E+F) x 2	12	6	6	4	0			
	TOTALS ADDED = (1+2+3)	12	6	6 ^a	4	0 ^a				
795 Male Unrinsed	A	Cornea Opacity	0	1	0	0	0			
	B	Cornea Area	0	1	0	0	0			
		(1) CORNEA TOTAL = (AxB) x 5	0	5	0	0	0			
	C	Iris	0	0	0	0	0			
		(2) IRIS TOTAL = (C) x 5	0	0	0	0	0			
	D	Conjunctiva Redness	2	1	0	0	1 ^a			
	E	Conjunctiva Chemosis	1	0	0	0	0			
	F	Conjunctiva Discharge	0	0	0	0	0			
		(3) CONJ. TOTAL = (D+E+F) x 2	6	2	0	0	2 ^a			
	TOTALS ADDED = (1+2+3)	6	7	0	0	0 ^a				
801 Male Unrinsed	A	Cornea Opacity	0	0	0	0	0			
	B	Cornea Area	0	0	0	0	0			
		(1) CORNEA TOTAL = (AxB) x 5	0	0	0	0	0			
	C	Iris	0	0	0	0	0			
		(2) IRIS TOTAL = (C) x 5	0	0	0	0	0			
	D	Conjunctiva Redness	1	1	0	0	0			
	E	Conjunctiva Chemosis	1	1	0	0	0			
	F	Conjunctiva Discharge	0	0	0	0	0			
		(3) CONJ. TOTAL = (D+E+F) x 2	4	4	0	0	0			
	TOTALS ADDED = (1+2+3)	4	4	0	0	0				

* See attached sheet for "Scale for Scoring Ocular Lesions"

^a Observations believed to be non-treatment induced. Scores are not entered into the calculation.

Primary Eye Irritation
API 79-2

Table 1
Individual Rabbit Eye Irritation Scores

Project No. 1443-B
January 7, 1980

Page 3 of 3

Rabbit No. & Sex	Item	Tissue	Reading				
			12/4 24 hr	12/5 48 hr	12/6 72 hr	12/10 7 day	12/17 14 day
780 Female Unrinsed	A	Cornea Opacity	0	0	0	0	1 ^a
	B	Cornea Area	0	0	0	0	2
		(1) CORNEA TOTAL = (AxB) x 5	0	0	0	0	10 ^a
	C	Iris	0	0	0	0	0
		(2) IRIS TOTAL = (C) x 5	0	0	0	0	0
	D	Conjunctiva Redness	1	0	0	0	1 ^a
	E	Conjunctiva Chemosis	0	0	0	0	1 ^a
	F	Conjunctiva Discharge	0	0	0	0	0
		(3) CONJ. TOTAL = (D+E+F) x 2	2	0	0	0	4 ^a
	TOTALS ADDED = (1+2+3)	2	0	0	0	0 ^a	
781 Male Unrinsed	A	Cornea Opacity	0	0	0	0	0
	B	Cornea Area	0	0	0	0	0
		(1) CORNEA TOTAL = (AxB) x 5	0	0	0	0	0
	C	Iris	0	0	0	0	0
		(2) IRIS TOTAL = (C) x 5	0	0	0	0	0
	D	Conjunctiva Redness	2	1	0	0	0
	E	Conjunctiva Chemosis	3	1	0	0	1 ^a
	F	Conjunctiva Discharge	0	0	0	0	0
		(3) CONJ. TOTAL = (D+E+F) x 2	10	4	0	0	2 ^a
	TOTALS ADDED = (1+2+3)	10	4	0	0	0 ^a	
782 Female Unrinsed	A	Cornea Opacity	0	0	0	0	1 ^a
	B	Cornea Area	0	0	0	0	1
		(1) CORNEA TOTAL = (AxB) x 5	0	0	0	0	5 ^a
	C	Iris	0	0	0	0	0
		(2) IRIS TOTAL = (C) x 5	0	0	0	0	0
	D	Conjunctiva Redness	2	1	0	0	0
	E	Conjunctiva Chemosis	2	0	1	1	0
	F	Conjunctiva Discharge	1	0	0	0	0
		(3) CONJ. TOTAL = (D+E+F) x 2	10	2	2	2	0
	TOTALS ADDED = (1+2+3)	10	2	2	2	0 ^a	

See attached sheet for "Scale for Scoring Ocular Lesions"

^a Observations believed to be non-treatment induced. Scores are not entered into the calculations.



BIORESEARCH LABORATORIES
Primary Eye Irritation
API 79-2

Project No. 1-43-B
January 7, 1980

Table 2
Averages of Rabbit Eye Irritation Scores

-----Rinsed-----				
24 Hour	48 Hour	72 Hour	7 Day	14 Day
6.67	5.00	1.33	0.67	0.00

-----Unrinsed-----				
24 Hour	48 Hour	72 Hour	7 Day	14 Day
7.33	3.83	1.33	1.00	0.00

LABS BIORESEARCH LABORATORIES
 Primary Eye Irritation
 API 79-2

Project No. 1443-R
 January 7, 1960

Classification Of Test Materials
 Based On Eye Irritation Properties

Rating	Average For 24 Hr. Reading	Definition
Non-Irritating	0.0 - 0.5	To maintain this rating, all scores at the 24 hour reading must be zero; otherwise, increase rating one level.
Practically Non-Irritating	Greater than 0.5 - 2.5	To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase rating one level.
Minimally Irritating	Greater than 2.5 - 15.0	To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase the rating one level.
Mildly Irritating	Greater than 15.0 - 25.0	To maintain this rating, all scores at the 7 day reading must be zero; otherwise, increase rating one level.
Moderately Irritating	Greater than 25.0 - 50.0	To maintain this rating, scores at 7 days must be less than or equal to 10 for 60% or more of the animals. Also, mean 7 day score must be less than or equal to 20 but less than 60% of animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if rating is to be maintained; otherwise, increase rating one level.
Severely Irritating	Greater than 50.0 - 80.0	To maintain this rating, scores at 7 days must be less than or equal to 30 for 60% or more of the animals. Also mean 7 day score must be less than or equal to 40. If 7 day mean score is less than or equal to 40 but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if rating is to be maintained; otherwise, increase rating one level.
Extremely Irritating	Greater than 80.0 - 110.0	

Kay, J.H., and Colandra, J.C., "Interpretation Of Eye Irritation Tests." Journal Of Society Of Cosmetic Chemists, 13, 281-289 (1962).

Primary Eye Irritation
API 70-2

Project No. 144-58
January 7, 1980

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Scale for Scoring Ocular Lesions*

(1) Cornea	
(A) Opacity-degree of density (area most dense taken for reading)	
No opacity.....	0
Scattered or diffuse area, details of iris clearly visible.....	1
Easily discernible translucent areas, details of iris slightly obscured...	2
Opalescent areas, no details of iris visible, size of pupil barely discernible.....	3
Opaque, iris invisible.....	4
(B) Area of cornea involved	
One quarter (or less) but not zero.....	1
Greater than one quarter, but less than half.....	2
Greater than half, but less than three quarters.....	3
Greater than three quarters, up to whole area.....	4
Score equals A x B x 5	Total maximum = 80
(2) Iris	
(A) Values	
Normal.....	0
Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof) iris still reacting to light (sluggish reaction is positive).....	1
No reaction to light, hemorrhage, gross destruction (any or all of these).	2
Score equals A x 5	Total maximum = 10
(3) Conjunctivae	
(A) Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris).....	0
Vessels normal.....	0
Vessels definitely injected above normal.....	1
More diffuse, deeper crimson red, individual vessels not easily discernible.....	2
Diffuse beefy red.....	3
(B) Chemosis	
No swelling.....	0
Any swelling above normal (include nictitating membrane).....	1
Obvious swelling with partial eversion of lids.....	2
Swelling with lids about half closed.....	3
Swelling with lids about half closed to completely closed.....	4
(C) Discharge	
No discharge.....	0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals).....	1
Discharge with moistening of the lids and hairs just adjacent to lids.....	2
Discharge with moistening of the lids and hairs, and considerable area around the eye.....	3
Score equals (A+B+C)x2	Total maximum = 20

The maximum total score is the sum of all scores obtained for the cornea, iris, and conjunctivae. Total maximum score possible = 110.

* Adapted from A. J. ...

BIORESEARCH LABORATORIES
February 26, 1980

Project No. 1443-C

Skin Sensitization

API 79-2

#6 Heavy Fuel Oil (API Gravity 5.2/1.2XS)

Conducted By:

Elars Bioresearch Laboratories, Inc.
225 Commerce Drive
Fort Collins, Colorado 80524

Dates of Study:

November 10, 1979 - December 15, 1979

Report To:

American Petroleum Institute
2101 L Street, Northwest
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REVIEWED BY QUALITY ASSURANCE:

Karla Routh 2/28/80

BIORESEARCH LABORATORIES
February 26, 1980

Project No. 1443-C

Skin Sensitization

API 79-2

#6 Heavy Fuel Oil (API Gravity 5.2/1.2%S)

OBJECTIVE:

The study described herein was conducted to evaluate the test material's potential for causing dermal sensitization in guinea pigs.

MATERIALS AND METHODS:

1. Test and Control Material:

The test material, a liquid in a metal container identified as API 79-2, #6 Heavy Fuel Oil (API Gravity 5.2/1.2%S), was received at Elars on October 8, 1979. The concentration, purity, and stability of the test material were not provided by the sponsor. An allotment of 30 ml was removed from Elars' test material storage room, placed in an amber vial, and kept in the study room for the duration of testing. More test material was removed as needed.

The positive control was a 0.05 percent (w/v) dilution of chlorodinitrobenzene in absolute ethanol. The positive control was stored in an amber glass jar under refrigeration throughout the study.

2. Test System:

The test animals, young adult male albino guinea pigs, arrived at Elars on October 29, 1979, from CAMM Research Institute, Wayne, New Jersey, and were acclimated 11 days before dosing. The test and control groups each consisted of ten guinea pigs. The guinea pigs were housed in stainless steel cages with indirect bedding and were fed Purina Guinea Pig Chow[®] and fresh water ad libitum. The guinea pigs were identified by cage tag, but not ear tags because the animals easily tear the tags from their ears.

BIORESEARCH LABORATORIES
Skin Sensitization
API 79-2

2

Project No. 1443-C
February 26, 1980

3. Study Design:

A dose titration was not conducted since the primary skin irritation test in rabbits produced only slight irritation for the test material.

On November 9, 1979, the day prior to dosing, the guinea pigs were shaved in an area on their backs approximately 3" x 3" with a No. 40 Oster[®] clipper blade. The shaved area was depilicated with Neet[®]. On November 10, 1979, a dose of 0.5 ml of the test material was placed on a gauze patch, covered with plastic wrap and placed on the shaved area of each test animal. Elastic bandaging was wrapped over the test site area to prevent movement of the patch. The gauze patch was left in place for 6 hours before removal. This procedure was followed three times a week for three weeks (for a total of 10 treatments). After the last treatment, the animals were given a two week rest period with no dosing. At the end of the two week rest period, a final challenge dose was given in the same manner as before, but on the animals' left sides.

In addition to the test group, a positive control consisting of ten guinea pigs was also employed according to the described test procedure. A 0.05 percent (w/v) dilution of chlorodinitrobenzene in ethanol was used as the positive control material. The positive control was wrapped only five times during the study since it was felt that ten times would be oversensitizing.

Scoring of erythema and edema was made at 24 hours after each application according to the attached scale, except for scoring #1 which was done 48 hours after the first application.

BIORESEARCH LABORATORIES
Skin Sensitization
API 79-2

3

Project No. 1443-C
February 26, 1980

RESULTS:

Guinea pig #265 (positive control) had a broken leg and abscessed foot. He was euthanatized on November 16, 1979. From this date on, the positive control group consisted of nine animals.

Individual animal scores for erythema and edema are presented for test and control groups in Table 1. The mean scores for sensitizing and challenge treatments are statistically compared for both erythema and edema in the test and control groups in Table 2.

For compound 79-2, no statistically significant differences between sensitizing and challenge scores for erythema were noted; edema was not observed. For the positive control, a significant difference ($p < 0.05$) between sensitizing and challenge scores was observed for edema.

CONCLUSIONS:

Under the conditions of the test and on the basis of study results, API compound 79-2 is non-sensitizing.

PERSONNEL:

Personnel responsible for the conduct and interpretation of this test include the following Elars' personnel: Denice E. Morita, B.S., Toxicology Technician and Study Coordinator; Vicki J. Mills, B.S., Anne E. McDowell, B.S., Jeanette Walker, Susan Almasy, Irma Albinana, David Carlson, B.S., Toxicology Technicians; L. Steven Beck, D.V.M., M.S., Senior Toxicologist and Study Director; and Douglas I. Hepler, Ph.D., Director of Toxicology.

RAW DATA:

Raw data regarding this study are to be found in Elars' notebook #1019 and in file #1443-C.



BIORESEARCH LABORATORIES
Skin Sensitization

Project No. 1443-C

Table 1
Individual Animal Scores for Treatments and Challenge
Page 1 of 2

API 79-2

Animal Number	Treatment 1		Treatment 2		Treatment 3		Treatment 4		Treatment 5		Treatment 6	
	Erythema	Edema										
295	0	0	1	0	1	0	0	0	1	0	0	0
296	0	0	0	0	0	0	0	0	1	0	1	0
297	0	0	1	0	1	0	1	0	0	0	0	0
298	0	0	1	0	0	0	1	0	0	0	1	0
299	0	0	0	0	0	0	2	0	2	0	0	0
300	0	0	0	0	1	0	0	0	0	0	0	0
301	0	0	0	0	0	0	0	0	0	0	0	0
302	0	0	1	0	0	0	0	0	0	0	0	0
303	0	0	1	0	0	0	0	0	1	0	0	0
304	0	0	0	0	0	0	2	0	3	0	0	0

API 79-2

Animal Number	Treatment 7		Treatment 8		Treatment 9*		Treatment 10		X̄		Challenge	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
295	0	0	0	0	0	0	0	0	0.3	0.0	0	0
296	1	0	0	0	0	0	0	0	0.3	0.0	0	0
297	0	0	0	0	0	0	0	0	0.3	0.0	0	0
298	0	0	0	0	0	0	0	0	0.3	0.0	1	0
299	0	0	0	0	0	0	0	0	0.4	0.0	0	0
300	0	0	0	0	0	0	0	0	0.1	0.0	0	0
301	0	0	0	0	0	0	0	0	0.0	0.0	1	0
302	0	0	0	0	0	0	0	0	0.1	0.0	0	0
303	0	0	0	0	0	0	0	0	0.2	0.0	0	0
304	1	0	0	0	0	0	0	0	0.6	0.0	0	0

* Test results to place for 24 h before removal.

RESEARCH LABORATORIES
Skin Sensitization

5

Project No. 1443-C

Table 1
Individual Animal Scores for Treatments and Challenge
Page 2 of 2

Animal Number	Treatment 1		Treatment 3		Treatment 5		Treatment 7		Treatment 9		X		Challenge	
	Erythema	Edema	Erythema	Edema	Erythema	Edema								
265	0	0	1	0	---	---	---	---	---	---	---	---	---	---
266	0	0	1	0	2	0	1	0	0	0	0.8	0.0	1	0
267	0	0	0	0	2	0	2	0	3	0	1.4	0.0	2	1
268	0	0	0	0	2	0	2	0	3	1	1.4	0.2	3	0
269	0	0	0	0	2	0	1	0	2	0	1.0	0.0	2	1
270	0	0	1	0	1	0	1	0	1	0	0.8	0.0	1	0
271	0	0	0	0	2	0	2	0	2	0	1.2	0.0	3	1
272	0	0	1	0	2	0	1	0	0	0	0.8	0.0	0	0
273	2	1	1	1	2	0	1	0	1	0	1.4	0.4	2	1
274	1	0	1	0	2	0	1	0	0	0	1.0	0.0	1	1

** Animal #265 euthanized.

FLARS BIOMRESEARCH LABORATORIES
Skin Sensitization

5

Project No. 1443-C

Table 2
Mean Erythema and Edema Scores for Treatments and Challenge

	Mean	Difference Mean	T. Value	Degrees of Freedom	Two Tail Probability
Compound API 79-2					
Erythema Sensitizing	0.2600				
Challenge	0.2000	0.0600	0.37	9	0.716
Edema Sensitizing	0.0000				
Challenge	0.0000	0.0000	0.00	9	*
Positive Control					
Erythema Sensitizing	1.0889				
Challenge	1.6667	-0.5778	-2.14	8	0.065
Edema Sensitizing	0.0667				
Challenge	0.5556	-0.4889	-2.77	8	0.024 [†]

* No edema seen - statistical analysis not possible.

† Probability <0.05 - statistically significant difference.

Evaluation Of Skin Reactions

	<u>Value</u>
Erythema and eschar formation:	
No erythema.....	0
Very slight erythema (barely perceptible).....	1
Well-defined erythema.....	2
Moderate to severe erythema.....	3
Severe erythema (best redness) to slight eschar formation (injuries in depth).....	4
Edema formation:	
No edema.....	0
Very slight edema (barely perceptible).....	1
Slight edema (edges of area well defined by definite raising).....	2
Moderate edema (raised approximately 1 millimeter).....	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure).....	4

Draize, J.H.: Dermal Toxicity. In Appraisal Of The Safety Of Chemicals In Foods, Drugs and Cosmetics. Published by the Assoc. of Food and Drug Officials of the U.S. Texas State Dept. of Health, Austin, Texas, pp. 46, 1959.



BIORESEARCH LABORATORIES
January 7, 1980

Project No. 1443-D

Acute Dermal Toxicity

API 79-2

#6 Heavy Fuel Oil (API Gravity 5.2/1.2%S)

Conducted By:

Elars Bioresearch Laboratories, Inc.
225 Commerce Drive
Fort Collins, Colorado 80524

POOR
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Dates Of Study:

November 6, 1979 - November 21, 1979

Report To:

American Petroleum Institute
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REVIEWED BY QUALITY ASSURANCE

Karla Peeth 1/9/80

BIORESEARCH LABORATORIES
January 7, 1980

Project No. 1443-B

Acute Dermal Toxicity

API 79-2

#6 Heavy Fuel Oil (API Gravity 5.2/1.2%S)

OBJECTIVE:

The study described herein was conducted to evaluate the acute (single dose) dermal toxicity of the test material in New Zealand White rabbits.

MATERIALS AND METHODS:

A. Test Material:

The test material, a liquid in a metal container identified as API 79-2, #6 Heavy Fuel Oil (API Gravity 5.2/1.2%S), was received at Elars on October 8, 1979. The concentration, purity, and stability of the test material were not provided by the sponsor. The test material was stored in Elars' test material storage room and removed in 500 ml allotments as needed for testing.

B. Animals:

Eight adult New Zealand White rabbits, four males and four females, weighing between 2.5 and 3.5 kg, were purchased from L.I.T. Rabbitry, Aptos, California. They were identified individually by metal ear tags and corresponding cage tags. The rabbits were allowed to acclimate at Elars at least one week. Purina Rabbit Chow[®] and fresh water were provided ad libitum. Throughout acclimation and testing, the rabbits were housed individually in standard stainless steel laboratory rabbit cages.

BIORESEARCH LABORATORIES
Acute Dermal Toxicity
API 79-2

2

Project No. 1443-D
January 7, 1980

C. Method:

On November 6, 1979, twenty-four hours prior to application of test material, the rabbits were shaved free of hair with a number 40 Oster® clipper blade. The shaved area on each animal constituted about 30 percent of the total body surface area. The animals were then returned to their stock cages. The 24-hour waiting period allows recovery of the stratum corneum from the disturbance which accompanies the close-clipping procedure and also permits healing of any microscopic abrasions possibly produced during the process.

On the testing day, prior to application of test material, the exposure sites of four rabbits (2 males and 2 females) were abraded by making four epidermal incisions with an 18-gauge needle every two or three cm longitudinally over the area of exposure. The abrasions were minor incisions through the stratum corneum that were not sufficiently deep to disturb the derma or to produce bleeding.

A single dose of 5 ml of test material per kilogram body weight was calculated for each test rabbit, measured in a syringe, and applied to gauze sponges backed with plastic wrap to help prevent evaporation of the test material. The sponges and plastic wrap were then taped to the shaved area of the rabbits' backs with porous adhesive tape. The entire trunk was wrapped with elastic tape to prevent slippage of the patches. The rabbits were then returned to their cages.

The test material remained in contact with the skin for 24 hours. Behavioral reactions were observed and recorded during the contact period. At 24 hours the bandaging was removed and



BIORESEARCH LABORATORIES
Acute Dermal Toxicity
API 79-2

3

Project No. 1443-D
January 7, 1980

the skin wiped with gauze sponges to remove excess test material. The exposure sites were examined for local reactions and the animals returned to their stock cages. Observations for mortality, local reactions, and behavioral abnormalities were continued for a total of 14 days following the skin applications. Initial, 7 and 14 day body weights were recorded. All animals which succumbed during the study were subjected to gross necropsy. On the 14th day, all surviving rabbits were euthanized with T-61 and subjected to gross necropsy.

RESULTS:

Individual animal weights, doses and day of termination are given in Table 1. Erythema and edema were initially noted in the skin at the test site which later became thickened, dry, and cracked. During the fourteen day observation period, three rabbits were found dead with several others appearing lethargic, anorexic and ataxic. All rabbits lost weight during the testing period.

The gross necropsy that was performed on the rabbits revealed mottled, congested livers (acute toxic hepatitis) in seven of the eight rabbits. Other treatment related observations included gastric and intestinal irritation, congested lungs, and large amounts of hair and some test material contained in the stomach.

CONCLUSIONS:

The test material, API 79-2, produced three mortalities (37.5% mortality), moderate skin irritation, and severe signs of systemic toxicity at the gross necropsy.



BIORESEARCH LABORATORIES
Acute Dermal Toxicity
API 70-2

Project No. 14-3-D
January 7, 1980

PERSONNEL:

Personnel responsible for the collection and interpretation of data generated in the course of this study were Denice E. Morita, B.S., Toxicology Technician and Study Coordinator; Anne E. McDowell, B.S., Vicki J. Mills, B.S., Arthur M. Siegel, B.S., Jeanette Walker, Irma Albinana, and Susan Almasy, Toxicology Technicians; L. Steven Beck, D.V.M., M.S., Senior Toxicologist and Study Director; and Douglas I. Hepler, Ph.D., Director of Toxicology.

RAW DATA:

Raw data regarding this study are to be found in Elars' notebook #1031 in file #1443-D.

ELAB BIORESEARCH LABORATORIES
Acute Dermal Toxicity
API 79-2

5

Project No. 1447-D
January 7, 1980

Table 1

Dose Level 5 ml/kg, 37.5% Mortality

Animal No./Sex	Skin Intact/Abraded	Body Wt. Day 0 (g)	Dose (ml)	Body Wt. Day 7 (g)	Body Wt. Terminal	Weight Gain (g)	Termination Day
722F	A	3.4	17.0	3.1	3.0	-0.4	14
724F	A	3.4	17.0	-	3.0	-0.4	6
739M	A	3.1	15.5	-	2.5	-0.6	5
751M	A	2.9	14.5	2.8	2.5	-0.4	14*
746F	I	3.0	15.0	2.5	1.7	-1.3	14
748F	I	3.1	15.5	2.7	2.2	-0.9	14
763M	I	2.7	13.5	2.5	2.4	-0.3	14
767M	I	2.9	14.5	2.7	2.6	-0.3	14

*found dead in morning



BIORESEARCH LABORATORIES
June 9, 1980

Project No. 1443-E

Rat Acute Oral (LD₅₀) Toxicity Study
API 79-2
#6 Heavy Fuel Oil (API Gravity 5.2/1.2%S)

Conducted By:
Elars Bioresearch Laboratories, Inc.
225 Commerce Drive
Fort Collins, Colorado 80524

Dates of Study:
October 16, 1979 - February 5, 1980

Report To:
American Petroleum Institute
2101 L Street Northwest
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REVIEWED BY QUALITY ASSURANCE: _____

BIORESEARCH LABORATORIES
June 9, 1980

Project No. 1443-E

Rat Acute Oral (LD₅₀) Toxicity Study
API 79-2
#6 Heavy Fuel Oil (API Gravity 5.2/1.2%S)

OBJECTIVES:

The objectives of this study were to test the toxicity of the test substance when administered orally by gavage in a single dose to albino rats, and to establish the oral median lethal dose (LD₅₀) of the test material in rats.

MATERIALS AND METHODS:

1. Test Material:

The test material, a viscous liquid in a metal can identified as API 79-2, #6 Heavy Fuel Oil (API Gravity 5.2/1.2%S), arrived at Elars on October 8, 1979. The concentration, purity, and stability were not provided by the sponsor. The test material was stored in Elars' test material storage room and removed in 500 ml aliquots for storage in the Department of Toxicology.

2. Test System:

Healthy young adult male and female Sprague-Dawley rats with an average body weight of approximately 200-400 grams were used. Rats were obtained from Gibco Animal Resources, Madison, Wisconsin, and were allowed to acclimate for at least one week before administration of test material. Animals were housed individually in suspended wire mesh cages and provided Purina Formulab[®] and water ad libitum. Identification of the animals was by ear tag and corresponding cage tags. Rats were divided into six groups of ten rats each (five males, five females).

BIORESEARCH LABORATORIES
Rat Acute Oral (LD₅₀)
Toxicity Study
API 79-2

2

Project No. 1443-E
June 9, 1980

3. Study Design:

Feed was withheld for 16-24 hours prior to dosing. Each rat was weighed the day of dosing and then administered a single dose of the appropriate amount of test material (ml/kg body weight) by means of gavage. Six dosage levels were chosen to produce expected mortality rates between 10% and 90%.

All rats were anesthetized slightly with ether in order to gavage the test material through plastic catheters.

Observations for death or toxic signs were made twice on the first day of dosing and daily thereafter for the duration of the study (14 days). Initial (day 0), day 7, and terminal weights were taken and recorded. Gross necropsy was performed on each animal that died prior to day 14, and upon all killed survivors on day 14.

RESULTS:

Individual doses, body weights, and day of termination are presented for dosage levels 3.0 ml/kg, 5.0 ml/kg, 6.5 ml/kg, 7.5 ml/kg, 10.0 ml/kg, and 25.0 ml/kg in Tables 1 to 6, respectively. The mortality experienced by the dosage groups ranged from 10% at the 3.0 ml/kg group to 100% at dosage levels 10.0 ml/kg and 25.0 ml/kg.

Toxic signs were observed soon after dosing. In all dosage groups, lethargy was the most frequently observed toxic sign.

Gross necropsy of rats that succumbed during the study revealed congested livers and intestinal irritation. Rats surviving until day 14 had slightly congested livers and kidneys.



BIORESEARCH LABORATORIES
Rat Acute Oral (LD₅₀)
Toxicity Study
API 79-2

3

Project No. 1443-E
June 9, 1980

35

CONCLUSIONS:

Under the conditions of this study, the material, API 79-2, #6 Heavy Fuel Oil (API Gravity 5.2/1.2%S), administered orally by gavage to young adult rats, was determined to have an oral median lethal dose, i.e., oral LD₅₀, of 5.13 ml/kg. The 95% confidence interval is 4.05 ml/kg to 6.50 ml/kg.

PERSONNEL:

Personnel responsible for the conduct and interpretation of this test include the following Elars personnel: Kris L. Hansen, B.S., M.S., Toxicology Technician, Study Coordinator; L. Steven Beck, D.V.M., M.S., Assistant Director of Toxicology, Study Director; Anne E. McDowell, B.S., John A. Liddell, Toxicology Technician Supervisors; Denice E. Morita, B.S., Vicki J. Mills, B.S., Irma Albinana, Susan M. Almasy, Toxicology Technicians; Jeanette Walker, Laboratory Technician; Rexann Story, Laboratory Assistant; and Douglas I. Hepler, Ph.D., Vice President, Toxicity Evaluation Division.

RAW DATA:

The raw data generated in this study can be found in notebooks #1016 and #1041 located in Elars file #1443-E.



BIORESEARCH LABORATORIES
Rat Acute Oral (LD50)
Toxicity Study
API 79-2

4

Project No. 1443-E
June 9, 1980

36

Table 1
Individual Animal Weights and Dosages
Dosage Level 3.0 ml/kg, 10% Mortality
January 22, 1980

Animal Number	Sex	Body Wt. Day 0 (g)	Dose (ml)	Body Wt. Day 7 (g)	Body Wt. Terminal	Weight Gain (g)	Termination Day
231	M	292	0.88	316	327	35	14
232	M	280	0.84	285	306	26	14
233	M	292	0.88	301	328	36	14
234	M	291	0.87	284	312	21	14
235	M	282	0.85	276	308	26	14
236	F	217	0.65	233	248	31	14
237	F	211	0.63	225	236	25	14
238	F	202	0.61	219	247	45	14
239	F	223	0.67	---	178	-45	7
240	F	212	0.64	223	252	40	14

Table 2
Individual Animal Weights and Dosages
Dosage Level 5.0 ml/kg, 33% Mortality
January 9, 1980

Animal Number	Sex	Body Wt. Day 0 (g)	Dose (ml)	Body Wt. Day 7 (g)	Body Wt. Terminal	Weight Gain (g)	Termination Day
181	M	229	1.1	216	265	36	14
182	M	261	1.3	282	309	48	14
183	M	275	1.4	---	231	-44	4
184	M	268	1.3	---	219	-49	5
185*	M	256	1.3*				
186	F	179	0.9	187	218	39	14
187	F	200	1.0	187	237	37	14
188	F	213	1.1	224	240	27	14
189	F	193	1.0	---	166	-27	5
190	F	223	1.1	220	243	20	14

* did not receive full dose - not counted in LD50

BIORESEARCH LABORATORIES
Rat Acute Oral (LD50)
Toxicity Study
API 79-2

5

Project No. 1443-E
June 9, 1980

Table 3

Individual Animal Weights and Dosages
Dosage Level 6.5 ml/kg, 90% Mortality
January 22, 1980

Animal Number	Sex	Body Wt. Day 0 (g)	Dose (ml)	Body Wt. Day 7 (g)	Body Wt. Terminal	Weight Gain (g)	Termination Day
241	M	287	1.9	---	241	-46	4
242	M	285	1.9	---	260	-25	4
243	M	290	1.9	---	252	-38	5
244	M	277	1.8	---	257	-20	4
245	M	287	1.9	238	265	-22	14
246	F	201	1.3	---	166	-35	5
247	F	199	1.3	---	179	-20	3
248	F	202	1.3	---	180	-22	4
249	F	210	1.4	---	192	-18	4
250	F	243	1.6	---	201	-42	6

Table 4

Individual Animal Weights and Dosages
Dosage Level 7.5 ml/kg, 80% Mortality
January 16, 1980

Animal Number	Sex	Body Wt. Day 0 (g)	Dose (ml)	Body Wt. Day 7 (g)	Body Wt. Terminal	Weight Gain (g)	Termination Day
211	M	280	2.1	---	251	-29	4
212	M	272	2.0	---	244	-28	5
213	M	289	2.2	---	252	-37	3
214	M	310	2.3	---	271	-39	3
215	M	255	1.9	---	217	-38	4
216	F	230	1.7	207	230	0	14
217	F	199	1.5	---	183	-16	4
218	F	188	1.4	---	164	-24	4
219	F	213	1.6	167	193	-20	14
220	F	209	1.6	---	181	-28	4

BIORESEARCH LABORATORIES
Rat Acute Oral (LD50)
Toxicity Study
API 79-2

6

Project No. 1443-E
June 9, 1980

Table 5
Individual Animal Weights and Dosages
Dosage Level 10.0 ml/kg, 100% Mortality
January 4, 1980

Animal Number	Sex	Body Wt. Day 0 (g)	Dose (ml)	Body Wt. Day 7 (g)	Body Wt. Terminal	Weight Gain (g)	Termination Day
161	M	208	2.1	---	189	-19	3
162	M	258	2.6	---	230	-28	3
163	M	237	2.4	---	208	-29	3
164	M	228	2.3	---	207	-21	3
165	M	251	2.6	---	216	-45	3
166	F	170	1.7	---	155	-15	3
167	F	200	2.0	---	189	-11	3
168	F	194	1.9	---	174	-20	3
169	F	182	1.8	---	165	-17	3
170	F	183	1.8	---	159	-24	4

Table 6
Individual Animal Weights and Dosages
Dosage Level 25.0 ml/kg, 100% Mortality
October 17, 1979

Animal Number	Sex	Body Wt. Day 0 (g)	Dose (ml)	Body Wt. Day 7 (g)	Body Wt. Terminal	Weight Gain (g)	Termination Day
131	M	353	8.8	---	319	-34	3
132	M	355	8.9	---	326	-29	3
133	M	364	9.1	---	352	-32	3
134	M	365	9.1	---	341	-24	3
135	M	308	7.7	---	295	-13	3
136	F	355	8.9	---	338	-17	3
137	F	257	6.4	---	242	-15	4
138	F	234	5.9	---	212	-22	3
139	F	225	5.6	---	209	-16	3
140	F	193	4.8	---	183	-10	2



BIORESEARCH LABORATORIES
August 15, 1980

Project No. 1443-F

Subacute Dermal Toxicity

API 79-2

#6 Heavy Fuel Oil (API Gravity 5.2/1.2% S)

Conducted By:

Elars Bioresearch Laboratories, Inc.
225 Commerce Drive
Fort Collins, Colorado 80524

Dates of Study:

May 21, 1979 - June 9, 1980

Report To:

American Petroleum Institute
2101 L Street Northwest
Washington, D.C. 20037

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REVIEWED BY QUALITY ASSURANCE: *Bawn Gordon 8/28/80*

Westpach Laboratories, Inc.
Project Number 1014
August 11, 1980

Elars Bioreserch Laboratories
Project Number 1443-F
API 79-2

QUALITY ASSURANCE STATEMENT

A quality assurance inspection was made of 20% of the data in this report and included inspection of pathologist's dictation to individual animal histopathology forms and review of tabular summaries.

Cindy Teska
Cindy Teska, B.S.
Quality Assurance

8/11/80
Date



BIORESEARCH LABORATORIES
August 15, 1980

Project No. 1443-F

Subacute Dermal Toxicity

API 79-2

#6 Heavy Fuel Oil (API Gravity 5.2/1.0% S)

OBJECTIVE:

The study described herein was conducted to evaluate the dermal toxicity of the test material when applied in repeated doses over a period of two weeks.

MATERIALS AND METHODS:

1. Test Material:

The test material, a liquid in a metal container identified as API 79-2, #6 Heavy Fuel Oil (API Gravity 5.2/1.2% S), was received by Elars on October 8, 1979. The concentration, purity, and stability were not provided by the sponsor. The test material was stored in Elars test material storage room.

2. Animals:

Each dose group and a control group consisted of eight adult New Zealand White rabbits, four males and four females, weighing approximately 2-4 kg. The rabbits were purchased from Elkhorn Rabbitry, Watsonville, California, Dutchland Rabbitry, Denver, Pennsylvania, Stevinson Rabbitry, Stevinson, California, and Pel-Freez Farms, Rogers, Arkansas, and were identified individually by metal ear tags and corresponding cage tags. The rabbits were allowed to acclimate at Elars at least one week. Purina Rabbit Chow[®] and fresh water were provided ad libitum. Throughout acclimation and testing, the rabbits were housed individually in standard laboratory rabbit cages.

BIORESEARCH LABORATORIES
Subacute Dermal Toxicity
API 79-2

2

Project No. 1443-F
August 15, 1980

3. Method:

Prior to application of test material, the rabbits were shaved free of hair with a number 40 Oster[®] clipper blade. The shaved area on each animal constituted about 30 percent of the total body surface area.

The daily dosages used for this compound were 1 ml/kg, 2 ml/kg, and 2.5 ml/kg body weight, and an untreated control group. The rabbits were exposed to the test material for five consecutive days followed by a two day rest period and then again for five consecutive days. The test material was applied to four-inch square gauze sponges backed by plastic wrap. The sponges and plastic wrap were taped to the shaved area of the animals' back with porous adhesive tape. The entire trunk of each rabbit was wrapped with elastic tape to prevent slippage of the patches. The rabbits remained bandaged for 24 hours, at which time the patches were removed and a new dose of test material was applied. This procedure was followed each day of the five day dosing period. During the two day rest period the animals were not dosed.

Observations for mortality, local reactions, and behavioral abnormalities were made daily during the 14 day period. Initial and final body weights were recorded.

Any animals which succumbed during the study as well as those killed with T-61[®] at the termination of the study were subjected to necropsy, and all significant gross pathological alterations were recorded. In addition, the following tissues were submitted for histopathologic examination: skin from the test site, liver, kidney, spleen and urinary bladder.

BIORESEARCH LABORATORIES
Subacute Dermal Toxicity
API 79-2

3

Project No. 1443-F
August 15, 1980

The collected tissues were fixed in 10% neutral buffered formalin. Afterwards, the tissues were trimmed, embedded in paraffin, sectioned at 4 to 5 microns, affixed to glass slides, and stained with hematoxylin and eosin. Histopathologic examination of the submitted tissues was conducted at Westpath Laboratories by William H. Halliwell, D.V.M., Ph.D., Diplomate: ACVP.

RESULTS:

Individual animal weights and doses are given in Tables 1-4 for dosage levels 1 ml/kg, 2 ml/kg, 2.5 ml/kg, and the control, respectively. Daily observations on all dose groups revealed progressive loss of activity and anorexia. Observation of the skin revealed irritation of the test site and alopecia on the surrounding areas. An average weight loss of 0.5 kg was observed for the 1 ml/kg dosage group with no mortality. The 2 ml/kg group showed an average weight loss of 0.5 kg and 62.5% mortality. Animals in the 2.5 ml/kg group showed an average weight loss of 0.6 kg and 75% mortality. The control group had an average weight gain of 0.2 kg with no mortality.

Gross post mortem examination of the 1 ml/kg group revealed six animals with abnormal livers, including areas of light discoloration, paleness and congestion. Four animals also had enlarged spleens and one animal had pale kidneys. Necropsy of animals treated at 2 ml/kg showed all eight rabbits with abnormal livers, ranging in severity from congested and mottled to necrotic and friable. Kidneys were observed to be pale in two rabbits and congested in three rabbits. One animal had hemorrhagic intestines. Gross postmortem examinations of the 2.5 ml/kg group revealed all eight rabbits with abnormal livers. The livers were observed to be congested, friable, swollen, mottled or to have areas of yellow discoloration. Three animals had pale kidneys, and three animals had congested kidneys. Two animals had darkened and enlarged spleens and two rabbits had hemorrhagic stomachs.

BIORESEARCH LABORATORIES
Subacute Dermal Toxicity
API 79-2

Project No. 1443-F
August 15, 1980

The histopathologic diagnoses of selected tissues from rabbits exposed to 1.0 ml/kg, 2.0 ml/kg and 2.5 ml/kg of test material API 79-2 and from untreated control rabbits are presented in Tables 5-8. The test material at all three dose levels produced some or all of the following changes at the test site (skin): acanthosis, acute inflammation, chronic inflammation, crusting, deep pyoderma, dermal congestion, dermal edema, hyperkeratosis, and epidermal necrolysis. These changes varied in severity from very slight to severe.

Evidence of multifocal necrosis of the liver appeared in each of the three dose levels and varied in severity from very slight to severe. Centrilobular vacuolar degeneration of hepatocytes was recognized also in each dose level and varied in severity from slight to moderate. One of eight animals exposed to 2.5 ml/kg of the test material revealed evidence of transitional epithelial hyperplasia in the urinary bladder. Two animals exposed to 2.0 ml/kg of the test material had evidence of inflammatory response in the heart that varied in severity from slight to moderate.

CONCLUSIONS:

The test material, API 79-2, #6 Heavy Fuel Oil (API Gravity 5.2/1.2% S), caused dermal irritation and resulted in obvious treatment-related signs in all treatment groups during the 14 day observation period and at necropsy in the species examined.

The histopathologic observations of tissues from rabbits exposed to the three dose levels of the test material (API 79-2) revealed evidence of dermal and hepatic toxicity. Heart and urinary bladder microscopic observations were not present in sufficient numbers or severity to conclude their significance in this study.

The dermal LD₅₀ for the test material is calculated to be 1.90 ml/kg with a 95% confidence of 0.39 to 9.24.

BIORESEARCH LABORATORIES
Subacute Dermal Toxicity
API 79-2

5

Project No. 1443-F
August 15, 1980

PERSONNEL:

Personnel responsible for the collection and interpretation of data generated in the course of this study were Vicki J. Mills, B.S., Toxicology Technician and Study Coordinator; L. Steven Beck, D.V.M., M.S., Assistant Director of Toxicology and Study Director; Denice E. Morita, B.S., Kris L. Hansen, B.S., M.S., Irma Albirana, Toxicology Technicians; Terry A. Hewett, B.S., Laboratory Assistant; Douglas I. Hepler, Ph.D., Director of Toxicology; and William H. Halliwell, D.V.M., Ph.D., ACVP, Pathologist.

RAW DATA:

Raw data regarding this study are to be found in Elars' notebooks #239 and #1505 in file #1443-F.



BIORESEARCH LABORATORIES
Subacute Dermal Toxicity
API 79-2

6

Project No. 1443-F
August 13, 1980

Table 1
Individual Animal Weights and Dosages
Dose Level 1 ml/kg, 0% Mortality
May 26, 1980

Animal Number	Sex	Body Wt. Day 0 (kg)	Dose (ml)	Body Wt. Terminal	Weight Gain (kg)	Termination Day
953	M	3.6	3.6	3.4	-0.2	14
955	M	2.7	2.7	2.4	-0.3	14
961	M	2.6	2.6	2.4	-0.2	14
963	M	3.6	3.6	2.9	-0.7	14
942	F	3.3	3.3	2.7	-0.6	14
946	F	4.2	4.2	3.1	-1.1	14
1122	F	3.4	3.4	3.1	-0.3	14
1124	F	2.9	2.9	2.6	-0.3	14

Table 2
Individual Animal Weights and Dosages
Dose Level 2 ml/kg, 62.5% Mortality
March 17, 1980

Animal Number	Sex	Body Wt. Day 0 (kg)	Dose (ml)	Body Wt. Terminal	Weight Gain (kg)	Termination Day
931	M	2.9	5.8	2.7	-0.2	10
933	M	2.6	5.2	2.3	-0.3	11
935	M	2.5	5.0	2.2	-0.3	14
937	M	2.6	5.2	2.0	-0.6	14
916	F	3.2	6.4	2.5	-0.7	14
918	F	3.5	7.0	2.9	-0.6	10
920	F	3.0	6.0	2.4	-0.6	14*
922	F	3.0	6.0	2.6	-0.4	9

* Found dead on day 14.

BIORESEARCH LABORATORIES
Subacute Dermal Toxicity
API 79-2

7

Project No. 1443-F
August 15, 1980

Table 3
Individual Animal Weights and Dosages
Dose Level 2.5 ml/kg, 75% Mortality
May 26, 1980

Animal Number	Sex	Body Wt. Day 0 (kg)	Dose (ml)	Body Wt. Terminal	Weight Gain (kg)	Termination Day
957	M	3.5	8.8	3.0	-0.5	6
965	M	3.2	8.0	2.3	-0.9	14
979	M	3.2	8.0	2.8	-0.4	6
991	M	3.0	7.5	2.4	-0.6	9
948	F	3.7	9.3	*	*	5
950	F	3.2	8.0	2.5	-0.7	9
968	F	3.7	9.3	3.2	-0.5	6
1198	F	3.0	7.5	2.7	-0.3	14

* Terminal weight not taken.

Table 4
Individual Animal Weights and Dosages
Dose Level Control, 0% Mortality
May 21, 1979

Animal Number	Sex	Body Wt. Day 0 (kg)	Dose (ml)	Body Wt. Terminal	Weight Gain (kg)	Termination Day
421	M	2.4	0	2.5	0.1	14
423	M	2.3	0	2.7	0.4	14
425	M	2.4	0	2.5	0.1	14
427	M	2.5	0	2.7	0.2	14
422	F	2.7	0	2.9	0.2	14
424	F	2.7	0	3.0	0.3	14
426	F	2.7	0	2.9	0.2	14
428	F	2.4	0	2.5	0.1	14

Westpath Laboratories, Inc.
Project Number 1014

5
Table 5

Elars Bioresearch Laboratories
Project Number 144J-F
API 79-2

INDIVIDUAL HISTOLOGIC OBSERVATIONS

1.0 ml/kg/day

Accession Number (80-)	1126	1127	1128	1129	1130	1131	1132	1133
Animal Number	955	961	963	953	1124	1122	946	942
Sex	M	M	M	M	F	F	F	F
Reason Discontinued	FS							
Days on Test	14	14	14	14	14	14	14	14
Test Site (Skin)								
Acanthosis	3	3	3	3	3	3	3	3
Acute Inflammation			2	2	2	2	3	2
Chronic Inflammation							1	1
Crusting		2						
Deep Pioderma						2		
Dermal Congestion	2	3	2	2	3	2	2	2
Dermal Edema	3	3	3	2	3	2	2	2
Hyperkeratosis	2	3	2	2	2	2	3	3
Necrosis, Epidermal								
Kidney								
Congested								
Mineralization, Focal								
Mononuclear Cell Infiltrate, Diffuse	2	3			1			
Liver								
Congested								
Cyst, Parasitic								4
Mineralization								
Necrosis, Multifocal								4
Pericholangitis	2	2	1	2	1	2	2	2
Vacuolar Degeneration, Centrilobular			2					2
Spleen								
Congested	NR	2						
Urinary Bladder								
Degeneration, Ballooning	NR							
Hyperplasia, Epithelial								
Other Tissues								
Heart								
Hemorrhage								
Inflammation, Acute								
Mineralization								
Stomach								
Congested								

KEY: Acc = Accidental Death
DOT = Died on Test
FS = Final Sacrifice
MS = Moribund Sacrifice
SS = Scheduled Sacrifice
NDT = Tissue Present, No
Diagnosis Tendered

TNP = Tissue Not Present
NR = Tissue Present, Not
Remarkable
AUT = Autolysis
O-NR = Paired Organ, Unilateral
Absence, Tissue Present,
Not Remarkable
O- = Unilateral Lesion

Severity
1 = Very Slight
2 = Slight or Small
3 = Moderate
4 = Severe

Westpath Laboratories, Inc.
Project Number 1014

9
Table 6

Elars Bioresearch Laboratories
Project Number 1443-F
API 79-2

INDIVIDUAL HISTOLOGIC OBSERVATIONS

2.0 ml/kg/day

Accession Number (80-)	821	822	823	825	818	819	820	824
Animal Number	933	935	937	931	916	918	920	922
Sex	M	M	M	M	F	F	F	F
Reason Discontinued	DOT	FS	FS	DOT	FS	DOT	DOT	DOT
Days on Test	11	14	14	10	14	10	14	9
Test Site (Skin)								
Acc. basis	2	3	2	3	4	3	2	3
Acute Inflammation	2	3	2	2	2	3	3	2
Chronic Inflammation	2	3	1	2	2	1	1	2
Crusting	3	3		1	3	2	3	2
Deep Pyoderma								
Dermal Congestion	2	3	3	3	1			2
Dermal Edema								
Hyperkeratosis	4	4	2	3	4	3	4	2
Necrosis, Epidermal	3	4	1	3		2		1
Kidney								
Congested		2						2
Mineralization, Focal						3		3
Mononuclear Cell Infiltrate, Diffuse								
Liver								
Congested								
Cyst, Parasitic								
Mineralization	2			2			3	3
Necrosis, Multifocal	4	2	1	2		4	4	4
Pericholangitis		1	2	2	1	2	3	2
Vacuolar Degeneration, Centrilobular		2		3	3			3
Spleen								
Congested	NR	NR	NR	NR	NR	AUT	AUT	AUT
Urinary Bladder								
Degeneration, Ballooning	NR	NR	NR		NR	AUT	NR	TNP
Hyperplasia, Epithelial				2				
Other Tissues								
Heart								
Hemorrhage	3							3
Inflammation, Acute	3							2
Mineralization	2							
Stomach								
Congested								

KEY: Acc = Accidental Death
DOT = Died on Test
FS = Final Sacrifice
MS = Moribund Sacrifice
SS = Scheduled Sacrifice
NDT = Tissue Present, No
Diagnosis Tendered

TNP = Tissue Not Present
NR = Tissue Present, Not
Remarkable
AUT = Autolysis
O-NR = Paired Organ, Unilateral
Absence, Tissue Present,
Not Remarkable
O- = Unilateral Lesion

Severity
1 = Very Slight
2 = Slight or Small
3 = Moderate
4 = Severe

Westpath Laboratories, Inc.
Project Number 1014

10
Table 7

Elara Bioresearch Laboratories
Project Number 1443-F
API 79-2

INDIVIDUAL HISTOLOGIC OBSERVATIONS

2.5 ml/kg/day

Accession Number (80-)	1134	1135	1136	1137	1138	1139	1140	1141
Animal Number	957	965	979	991	950	948	968	1198
Sex	M	M	M	M	F	F	F	F
Reason Discontinued	DOT	FS	DOT	DOT	DOT	DOT	DOT	FS
Days on Test	6	14	6	9	9	5	6	14
Test Site (Skin)								
Acanthosis	2	3	2	5	2	2	2	1
Acute Inflammation								
Chronic Inflammation				2		2		2
Crusting	3	2	2	2	2	1	2	2
Deep Pyoderma								
Dermal Congestion	4	2	3	3	3	3	2	3
Dermal Edema	2	1	2	2	2	2	1	2
Hyperkeratosis	2	2	3	2	3	2	2	2
Necrosis, Epidermal					3			
Kidney		NR						NR
Congested	2		2	3	3	2	3	
Mineralization, Focal								
Mononuclear Cell Infiltrate, Diffuse							2	
Liver						AUT		
Congested					1			
Cyst, Parasitic								
Mineralization		2		2				
Necrosis, Multifocal	4	3	4	3	2		4	3
Pericholangitis	2	2	2	2	2		2	3
Vacuolar Degeneration, Centrilobular			2	2				
Spleen		NR	AUT		NR			NR
Congested	4			3		2	3	
Urinary Bladder	NR	NR	AUT	NR	NR	NR		NR
Degeneration, Ballooning								
Hyperplasia, Epithelial							3	
Other Tissues								
Heart								
Hemorrhage								
Inflammation, Acute								
Mineralization								
Stomach								
Congested							2	

KEY: Acc = Accidental Death TNP = Tissue Not Present Severity
 DOT = Died on Test NR = Tissue Present, Not 1 = Very Slight
 FS = Final Sacrifice Remarkable 2 = Slight or Small
 MS = Moribund Sacrifice AUT = Autolysis 3 = Moderate
 SS = Scheduled Sacrifice O-NR = Paired Organ, Unilateral 4 = Severe
 NOT = Tissue Present, No Absence, Tissue Present, Not Remarkable
 Diagnosis Tendered Not Remarkable
 O- = Unilateral Lesion

Westpath Laboratories, Inc.
Project No. 1014

11
Table 8

Elars Bioresearch Laboratories
Project Number 1443-F
API 79-2

INDIVIDUAL HISTOLOGIC OBSERVATIONS

Control

	N225	N226	N227	N228	N229	N230	N231	N232
Accession Number	421	422	423	424	425	426	427	428
Animal Number	M	F	M	F	M	F	M	F
Sex	FS							
Reason Discontinued	14	14	14	14	14	14	14	14
Days on Test			NR		NR	NR		
LIVER				4			4	
Abscess, focal								
Congested								
Mineralization								
Necrosis, multifocal								
Pericholangitis	1	3						1
Vacuolar Degeneration, centrilobular	3							
KIDNEY	NR							
Congested								
Mineralization, focal								
Mononuclear Cell Infiltrate, focal								
Mononuclear Cell Infiltrate, diffuse								
Nephrosis, tubular								
SPLEEN				NR	NR	NR		NR
Congested							3	
Hyperplasia, reactive	2	1		2			2	
URINARY BLADDER	NR							
SKIN (Test Site)	NR							
Acanthosis								
Acute Inflammation								
Chronic Inflammation								
Crusting								
Deep Psoderma								
Dermal Congestion								
Dermal Edema								
Epidermal Microabscesses, multifocal								
Hyperkeratosis								
Liquefactive Degeneration								
Necrosis, epidermal								
Parakeratosis								
OTHER LESIONS								
LUNG	TNP							
Atelectasis								
STOMACH	NR	NR	NR		NR	NR	NR	NR
Congestion, mucosal								
Lymphoid Hyperplasia, submucosal				2				

KEY: Acc = Accidental Death
DOT = Died on Test
FS = Final Sacrifice
MS = Moribund Sacrifice
SS = Scheduled Sacrifice
NDT = Tissue Present, No
Diagnosis Tendered

TNP = Tissue Not Present
NR = Tissue Present, Not
Remarkable
AUT = Autolysis
O-NR = Paired Organ, Unilateral
Absence, Tissue Present,
Not Remarkable
O- = Unilateral Lesion

Severity
1 = Very Slight
2 = Slight or Small
3 = Moderate
4 = Severe

BIORESEARCH LABORATORIES
Acute Toxicity Tests

Project No. 1443

Analysis of Feed

The guaranteed analyses of feed for Purina Guinea Pig Chow[®], Purina Formulab Chow[®], and Purina Rabbit Chow[®], as provided on the manufacturer's labels, are listed below. No additional analyses of feed were made.

Guaranteed Analysis of Feed

Nutritional Content	-----Type of Purina [®] Chow-----		
	Purina Guinea Pig Chow [®] 5025 (%)	Purina Formulab Chow [®] 5008 (%)	Purina Rabbit Chow, Checkers [®] 5301 (%)
Crude protein, minimum	18.0	23.0	16.0
Crude fat, minimum	4.0	6.5	2.0
Crude fiber, maximum	16.0	4.0	18.0
Ash, maximum	9.0	8.0	9.0
<u>Added minerals, maximum</u>	3.5	2.5	3.0

Triage of 8(e) Submissions

Date sent to triage: 2/5/96

NON-CAP

CAP

Submission number: 12526A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

~~ATOX~~ ~~SBTOX~~ ~~SEN~~ w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX
STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only	
entire document: <u>0</u> 1 2 pages <u>1</u>	pages <u>1, 2, tabs</u>
Notes:	
Contractor reviewer: <u>LPS</u>	Date: <u>5/11/95</u>

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:

Submission # SEHQ: 0992-12526 SEQ. A

TYPE INT. SUPP FLWP

SUBMITTER NAME: Phillips Petroleum Company

INFORMATION REQUESTED: FLWP DATE:

- 0501 NO INFO REQUESTED
- 0502 INFO REQUESTED (TECH)
- 0503 INFO REQUESTED (VOL. ACTIONS)
- 0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

- 0670 REFER TO CHEMICAL SCREENING
- 0676 CAP NOTICE

VOLUNTARY ACTIONS:

- 0401 NO ACTION REPORTED
- 0402 STUDIES PLANNED/IN PROGRESS
- 0403 NOTIFICATION WORKING
- 0404 LABELS/MSDS (TANKS)
- 0405 PROCEEDING (TANKS)
- 0406 APPROX. DISCONTINUED
- 0407 PRODUCTION DISCONTINUED
- 0408 CONFIDENTIAL

SUB. DATE: 08/24/92 OTS DATE: 09/02/92 CSRAD DATE: 03/21/95

CHEMICAL NAME:

CASE

68553-00-4

INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	<u>0243</u> CHEMPHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/ITERATO (HUMAN)	01 02 04	0221 ENV. OCCUREL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/ITERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQEST DELAY	01 02 04	0248 PRODUCE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
<u>0212</u> ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
<u>0213</u> SUB ACUTE TOX (ANIMAL)	01 02 04	<u>0228</u> ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN	USE	PRODUCTION:
CAS SR	<u>YES</u>	YES (DROP/REFER)	<u>RBT</u> <u>GP</u> <u>Rat</u>	<u>LOW</u> Dermal Sensitization, Ocular Irritation, Acute Oral Toxicity <u>MED</u> Acute Dermal Toxicity, Dermal Irritation <u>HIGH</u> Dermal Irritation (acute toxicity test), Subacute Dermal Toxicity		
	NO	NO (CONTINUE)				
	IN TRAINING	REFER				

COMMENTS:

#12526A

M

Subacute dermal toxicity is of medium concern based on lethality in rabbits (4/sex/dose) exposed 5 days/week for 2 weeks. Mortality and corresponding doses (ml/kg converted to mg/kg, assuming density of 1) were 0/8 (1000), 5/8 (2000) and 6/8 (2500). Clinical signs included progressive loss of activity and anorexia. Necropsy revealed abnormalities in the liver, spleen, and kidneys (all doses), hemorrhagic intestines and heart inflammation (2000), and hemorrhagic stomachs and bladder hyperplasia (2500). Dermal irritation included very slight to severe changes at the test site.

M

Dermal irritation is of medium concern based on moderate irritation in rabbits exposed to 5000 mg/kg (5 ml/kg conversion, assuming density of 1).

L

Dermal irritation is of low concern based on slight to mild erythema and edema in 6 rabbits, which persisted in 1/6 through the 14 day observation.

L

Acute dermal toxicity is of low concern based on 3/8 deaths in rabbits exposed to 5000 mg/kg (5 ml/kg conversion, assuming density of 1). Clinical signs included lethargy, anorexia and ataxia; necropsy revealed mottled, congested livers in 7/8, gastric and intestinal irritation, and congested lungs.

L

Acute oral toxicity is of low concern based on a calculated LD₅₀ of 5130 mg/kg (5.13 ml/kg conversion, assuming density of 1) in rats (5/sex/dose). Mortality and corresponding doses (mg/kg) were 1/10 (3000), 3/10 (5000), 9/10 (6500), 8/10 (7500) and 10/10 (10000, 25000). Clinical signs included lethargy; necropsy revealed congested livers and intestinal irritation in the decedents.

L

Ocular irritation is of low concern based on reversible conjunctival irritation in 6/6 rabbits.

L

Dermal sensitization is of low concern based on no evidence of sensitization in 10 guinea pigs.