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LETTER FROM CIBA-GEIGY CORPORATION TO USEPA SUBMITTING ENCLOSED HEALTH AND SAFETY STUDIES ON o-PHENYLENEDIAMINE WITH ATTACHMENTS		
Chemical Category		
o-PHENYLENEDIAMINE		

AR027-019

29-0090

Dyestuffs & Chemicals
CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419
Telephone 919 292 7100

CIBA-GEIGY

June 24, 1983

CERTIFIED MAIL
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U. S. Environmental Protection Agency
TSCA - 8D 1, P. O. Box 2066
Rockville, Maryland 20852

Gentlemen:

HEALTH AND SAFETY DATA REPORTING UNDER TSCA SECTION 8(d) -
FINAL RULE (ADDITIONAL SUBSTANCES) PUBLISHED MARCH 30, 1983

With this letter, CIBA-GEIGY Corporation submits copies and lists of eligible health and safety studies in compliance with the above referenced Section 8(d) final rule.

File searching among the various Divisional and manufacturing plant units were coordinated (1) to assure all eligible studies and references to such studies have been uncovered and (2) to aggregate these findings into a single CIBA-GEIGY Corporation submission. Copies of nine eligible health and safety studies spanning two Divisions of the Corporation, the Dyestuffs and Chemicals Division and the Plastics and Additives Division, were uncovered in addition to one reference to an eligible study. For all these submitted reports, the Corporation claims no information to be confidential.

All but one of the nine uncovered studies are the responsibility of the Dyestuffs and Chemicals Division, for which I am the technical contact. These eight studies are enumerated in Appendix 1 and are enclosed as Attachments 1-8. These files also reference an acute oral toxicity study in rat for o-phenylenediamine, CAS Number 95-54-5. The cited LD_{50} Value was 1,264 mg/kg. The name and address of the person likely to possess this study is:

Mr. Werner Eich
CIBA-GEIGY Limited
Department FC 2.11
CH-4002 Basle, Switzerland

The Plastics and Additives Division is responsible for the remaining study. This is an Acute Aerosol Inhalation Toxicity of Diethylenetriamine (CAS Number 111-40-0) in Rats (Attachment 9). The technical contact is:

Dr. J. Saunders
Director, Product Safety and Ecology
CIBA-GEIGY Corporation
Plastics and Additives Division
3 Skyline Drive
Hawthorne, New York 10532
(914-347-4700, Extension 249)

Questions which may arise regarding the various studies copied or listed should be directed to the technical contact for the responsible Division.

Sincerely,

Joseph A. LoMenzo

Joseph A. LoMenzo
Manager, Safety & Regulatory Affairs

41/6/23/2K

Enclosures: Copies of Nine Health and Safety Studies

June 24, 1983

APPENDIX 1

Copies of Health and Safety Studies

CIBA-GEIGY Corporation
Dyestuffs and Chemicals Division

CAS Number	Chemical Name	Study Type (Species) [Result]	Attachment Number
95-54-5	o-Phenylenediamine	Acute Vapor Inhalation (Rat) [LC_{50} >1,340 mg/m^3]	1
		Eye Irritation (Rabbit) [Moderately Irritating]	2
		Acute Dermal Toxicity (Rabbit) [LD_{50} >3,000 mg/kg]	3
		Acute Oral Toxicity (Rat) [LD_{50} >1,000 <3,000 mg/kg]	4
1197-37-1	Ethoxyphenylenediamine	Acute Oral Toxicity (Rat) [LD_{50} <5,000 mg/kg]	5
		Acute Dermal Toxicity (Rabbit) [LD_{50} >2,000 mg/kg]	6
		Primary Dermal Irritation (Rabbit) [Non-irritating]	7
		Eye Irritation (Rabbit) [Moderately Irritating]	8

41/6/23/2K

878213656
Attachment 1
CAS # 95-54-5

29-0091

REPORT TO

CIBA-GEIGY CORPORATION

ACUTE VAPOR INHALATION TOXICITY STUDY WITH o-PHENYLENE DIAMINE CAKE IN RATS

FEBRUARY 17, 1975

IBT NO. 663-06061

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Introduction

Test Material: o-Phenylene diamine cake 10/74 Strain: BLU: (LE) BR Rats
Form Administered: Vapor
Acute LC_{50}: The acute vapor inhalation median lethal concentration (LC_{50}) is greater than 1340.0 mg/m^{3}air.
Exposure Time: Four hours
Observation Period: 14 days

Procedure

The vapor was generated by passing a stream of clean dry air (-40°C dew-point) through the undiluted test material in a gas wash bottle and into the test chamber.

Chamber Conditions

Group No.	Size (Liters)	Atmosphere Pressure (Inches Hg)	Temperature (°C)	Air Flow (L/min)
I	80	30.50	23.5	7.5

Results

Group No.	Total Number of Animals Male/Female	Nominal Concentration	Mortality	Weight Gain Male/Female (Grams)
I	5/5	1340.0 mg/m^3*	0/10	76/17

* Maximum attainable concentration at stated conditions.

Remarks

There were no untoward reactions during exposure or the 14-day observation period which followed. The average two-week body weight gain was within the normal limits. Necropsies, performed on all rats at the end of the observation period, did not reveal any gross pathologic alterations.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Prepared by: James C. Kinert
James C. Kinert, B.S.
Assistant Toxicologist

Approved by: John W. Goode
John W. Goode, Ph.D.
Manager, Decatur Research

Attachment 2
CAS # 95-54-5

Industrial BIO-TEST Laboratories, Inc.

REPORT TO

CIBA-GEIGY CORPORATION

Eye Irritation Test - Albino Rabbits

Results

Test Material: O-Phenylenediamine Cake, Batch No. 10/74
Form Administered: Instillation (100 mg, Undiluted)
Special Instructions: Unwashed Eyes

IBT No.: 601-06-60
Descriptive Rating: Moderately Irritating (31.7/110.0)

Tissue	Rabbit Number	1 Hour	24 Hours	72 Hours	7 Days	14 Days
Cornea (D-A)	1	20 (1-4), E	20 (1-4)	20 (1-4)	20 (1-4), U, V	10 (1-2), U, V
Iris		5	5	5	5	0
Conjunctiva (R-S-D)		10 (1-2-2)	8 (2-1-1)	6 (1-1-1)	4 (1-1-0)	2 (1-0-0)
Total		35	33	31	29	12
Cornea (D-A)	2	20 (1-4), E	15 (1-3)	0	0	0
Iris		5	5	0	0	0
Conjunctiva (R-S-D)		10 (1-2-2)	8 (1-1-2)	4 (1-1-0)	0	0
Total		35	28	4	0	0

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Eye Irritation Test - Albino Rabbits

Results

Test Material: O-Phenylenediamine Cake, Batch No. 10/74 IBT No.: 601-06060

Tissue	Rabbit Number	1 Hour	24 Hours	72 Hours	7 Days	14 Days
Cornea (D-A)	3	10 (1-2), E	5 (1-1)	0	0	0
Iris		5	5	0	0	0
Conjunctiva (R-S-D)		10 (1-2-2)	8 (1-1-2)	4 (1-1-0)	0	0
Total		25	18	4	0	0
Means						
Cornea		16.7	13.3	6.7	6.7	3.3
Iris		5.0	5.0	1.7	1.7	0.0
Conjunctiva		10.0	8.0	4.7	1.3	0.7
Total		31.7	26.3	13.1	9.7	4.0

E = Epithelial sloughing
U = Ulceration
V = Vascularization

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Prepared by: Ronald G. Baker
Ronald G. Baker, B.S.
Assistant Toxicologist
Acute Toxicity

Approved by: C. W. Mastri
C. W. Mastri, B.S.
Section Head, Acute Toxicity

February 6, 1975

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Attachment 3
CAS # 95-54-5
878213658
29-0093

REPORT TO

CIBA-GEIGY CORPORATION

Acute Dermal Toxicity Study - Albino Rabbits

Results

Test Material: o-Phenylenediamine Cake, Batch No. 10/74
Physical Description: Brown crystals
Form Administered: Applied in the form of a slurry in warm tap water
Acute Dermal LD_{50} > 3,000 mg/kg

Strain: New Zealand
IBT No.: 601-06060
Classification: Practically Non-Toxic

I. Mortality and Body Weights

Dose Level (mg/kg)	Animal Number and Sex	Individual Body Weights (kg) Test Day Number: 0	7	14	Number Dead / Number Tested	Percent Dead
300	1-F**	2.80	2.74	2.84	0/1	0
1,000	2-F**	2.74	2.62	2.74	0/1	0
3,000	3-F**	2.90	2.80	2.80	0/1	0

* The test material could not be completely removed from the skin with tap water or other innocuous solvents.
** The skin at the site of application was abraded.

II. Reactions

No pharmacotoxic symptoms were noted.
The test material was non-irritating to the skin of the albino rabbit.
Necropsy examination did not reveal any gross pathologic alterations.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES

Report prepared by: Glenn E. Trzyna
Glenn E. Trzyna, B.A.
Technician
Acute Toxicity

Report approved by: C. W. Mastri
C. W. Mastri, B.S.
Section Head, Acute Toxicity

ssk

February 6, 1975

000002

Industrial BIO-TEST Laboratories, Inc.

Attachment 4
CAS # 95-54-5

878213659

INTERMEDIATE

RANGE-FINDING

REPORT TO

CIBA-GEIGY CORPORATION

Acute Oral Toxicity Study - Female Albino Rats

Results

Test Material: o-Phenylenediamine Cake 10/74
Form Administered: 1.0 percent (w/v) aqueous solution.
10.0 and 20.0 percent (w/v)
1.0 percent methylcellulose suspensions
Acute Oral LD_{50} > 1,000 < 3,000 mg/kg

Strain: Charles River
IBT No.: 601-03060
Classification: Slightly Toxic

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I. Mortality and Body Weights

Dose Level (mg/kg)	Animal Number	Individual Body Weights (grams) Test Day Number: 0	14	Number Dead / Number Tested	Percent Dead
10*	1	215	256	0/1	0
30*	2	173	213	0/1	0
100*	3	190	220	0/1	0
300*	4	177	215	0/1	0
1,000**	5	196	227	0/1	0
3,000**	6	191	(2½ hours)	1/1	100
10,000***	7	192	(1½ hours)	1/1	100

Note: Figures in parentheses indicate time of death.

* Dosed with a 1.0 percent (w/v) aqueous solution.
** Dosed with a 10.0 percent (w/v) 1.0 methylcellulose suspension.
*** Dosed with a 20.0 percent (w/v) 1.0 methylcellulose suspension.

II. Reactions

The pharmacotoxic symptoms exhibited by the animals following dosing are presented in pages 2 and 3.

Necropsy examination of the animals that died revealed hemorrhages in the gastro-intestinal tracts. Mottled kidneys were noted in animal No. 6.

Animals sacrificed at the end of the 14-day observation period revealed no gross pathologic alterations.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by: Joyce Zmorzynski
Joyce Zmorzynski
Technician
Acute Toxicity

Report approved by: C. W. Mastri
C. W. Mastri, B.S.
Section Head
Acute Toxicity

Acute Oral Toxicity Study - Female Albino Rats

Summary of Reactions

Test Material: o-Phenylenediamine Cake 10/74 IBT No.: 601-06060

Concentration: 1.0 percent (w/v) aqueous solution at 10, 30, 100, and 300 mg/kg; 10.0 percent (w/v) 1.0 percent methylcellulose suspension at 1,000 and 3,000 mg/kg

Dose Level (mg/kg)	Reaction	Time of Onset Following Dose Administration	Duration of Reaction	Time of Death Following Dose Administration
10	-	-	-	-
30	-	-	-	-
100	Hypoactivity	1 hour	6-22 hours	-
	Ruffled fur	1 hour	6-22 hours	
300	Hypoactivity	15 minutes	6-22 hours	-
	Ruffled fur	1 hour	6-22 hours	
	Ptosis	1 hour	6-22 hours	
1,000	Hypoactivity	10 minutes	1 day	-
	Ptosis	10 minutes	6-22 hours	
	Hyperpnea	10 minutes	6-22 hours	
	Ruffled fur	1 hour	1 day	
3,000	Hypoactivity	5 minutes	Until death	2½ hours
	Ptosis	5 minutes		
	Hyperpnea	5 minutes		
	Muscular weakness	5 minutes		
	Prostration	5 minutes		
	Spasms	5 minutes		
	Convulsions	10 minutes		
	Ruffled fur	1 hour		
	Lacrimation	1 hour		

INTERMEDIATE

RANGE-FINDING

Acute Oral Toxicity Study - Female Albino Rats

Summary of Reactions

Test Material: o-Phenylenediamine Cake 10/74 IBT No.: 601-06060
Concentration: 20.0 percent (w/v) 1.0 percent methylcellulose suspension at 10,000 mg/kg

Dose Level (mg/kg)	Reaction	Time of Onset Following Dose Administration	Duration of Reaction	Time of Death Following Dose Administration
10,000	Hypoactivity	5 minutes	Until death	1½ hours
	Ptosis	5 minutes		
	Hyperpnea	5 minutes		
	Muscular weakness	5 minutes		
	Prostration	5 minutes		
	Spasms	5 minutes		
	Convulsions	10 minutes		
	Ruffed fur	1 hour		
	Lacrimation	1 hour		

INTERMEDIATE

RANGE-FINDING

0782136 59

MBR Research Laboratories, Inc. 29-0094 CAS # 3197-37-1 878213660

steinsburg and wentz roads
post office box 203
spinnerstown, pennsylvania 18968
215-536-4110

ACUTE ORAL TOXICITY IN RATS

FOR: TOMS RIVER CHEMICAL CORPORATION

Code Number : M 42485
Product Name : Ethoxy Phenylenediamine 100 Cake
Concentration:
Mix Number : Ba. 1/78
TR Number : 78-309

Project Number: MB 78-2761 A
Date received : 4/19/78
Test started : 5/12/78
Test ended : 5/12/78
Description : Dark Green Paste-use as 50% suspension in distilled water

This study is designed to determine whether or not the oral LD 50 of a material is greater or less than 5.0 g/kg body weight in rats.

Five male and five female Wistar rats were received from our local supplier. The rats were housed five per sex per cage in elevated wire mesh cages in a temperature controlled room reserved exclusively for rats on acute tests. Each rat was uniquely identified with picric acid dye. The dye marks correspond to numbers 1 - 10. Additional identification as to room and rack location was recorded on the lab work sheet. Complete test identification was also recorded on the cage. Purina Rat Chow and water from bottles was available ad libitum except for approximately 18 hours prior to dosing when food was not available.

After at least seven days equilibration, the rats were dosed at 5.0 g/kg orally by intubation. Following treatment the rats were observed at 1, 2 and 4 hours and daily for 14 days for signs of pharmacologic and/or toxicologic effects and mortality. Body weights were recorded prior to dosing and in the survivors at Day 14. Necropsies were performed on all rats.

RESULTS

The LD 50 was: less than 5.0 g/kg.

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Mortality :

Dead/Treated	Day of Death Hr.1	Hr.2	Hr.4
5/5 Males	1(#4)	4(#1,2,3,5)	
5/5 Females	1(#8)	3(#6,7,9)	1(#10)

(Body Weights, Toxicity and Necropsy Observations are recorded on the following page)

Respectfully submitted,

Oscar M. Moreno

Oscar M. Moreno, Ph.D.
President
5/23/78

29-0095

MB Research Laboratories, Inc.

Attachment 6
CAS # 1197-37-1
878213661

steinsburg and wentz roads
post office box 203
spinnerstown, pennsylvania 18968
215-536-4110

ACUTE DERMAL TOXICITY IN RABBITS

FOR: TOMS RIVER CHEMICAL CORPORATION

Code Number : M 42485
Product Name : Ethoxy Phenylenediamine 100 Cake
Concentration:
Mix Number : Ba.1/78
TR Number : 78-309

Project Number: MB 78-2761 B
Date received : 4/19/78
Test started : 6/01/78
Test ended : 6/15/78
Description : dark green paste

New Zealand White rabbits approximately 8 to 11 weeks of age were received in good health from our local supplier and remained in good health during the equilibration period in this laboratory. The rabbits were equilibrated for at least 7 days. The rabbits were individually housed in elevated wire mesh cages in temperature controlled rooms reserved exclusively for rabbits on acute tests. Purina Rabbit Chow and water from bottles were available ad libitum.

Twenty-four hours prior to dosing the backs of the rabbits were clipped free of fur with an Oster ANG-RA clipper head designed specifically for clipping rabbits. The rabbits were returned to their cages overnight. Just prior to dosing, the backs of even-numbered rabbits were abraded with a 21 gauge bent tip needle. The abrasions, made every 2 to 3 cm longitudinally, scratched the stratum corneum, but did not disturb the derma or produce bleeding.

The test material was applied to the backs of two male and two female rabbits at a dose of 2.0 g/kg. The test site was covered with gauze and the trunk was wrapped with impervious material for 24 hours. Following removal of the binder at 24 hours, the test site was washed with warm tap water. One hour after washing, the test sites were graded for skin irritation according to the attached scale. Skin sites were read again at 7 and 14 days. Body weights were recorded pretest and at 7 and 14 days. The rabbits were observed daily for 14 days for signs of toxicity and mortality. Necropsies were performed on all rabbits.

RESULTS: The Acute Dermal LD 50 is greater than 2.0 g/kg.

MORTALITY: 0/4

TOXICITY : An. #1 had diarrhea on Days 8 to 13. An. #2 had diarrhea on Days 2 to 5 and 7 to 9. An. #4 had diarrhea on Days 3 to 5 and 7 to 10.

At all other times, all rabbits appeared normal.

See following page for body weights, skin reactions and necropsy observations.

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Respectfully submitted,

Oscar M. Moreno

Oscar M. Moreno, Ph.D.
President

000002

Individual Body Weights and Skin Grades

Rabbit number	Sex	Weights - kg 0	7	14	Redness 25h	7	14	Edema 25h	7	14
1	M	2.7	2.9	2.4	0	0	0	0	0	0
2 A	M	2.4	2.3	2.7	0	0	0	0	0	0
3	F	2.6	2.5	2.8	0	1*	0ø	0	0	0
4 A	F	2.3	2.4	2.6	0	0	0	0	0	0

A = Abraded

Necropsy Observations: All animals were normal.

CODE: * = small scab lumps dotted over exposure area, some filled with pus
ø = skin flaking

Evaluation of Skin Reactions

	Value
Erythema & Eschar Formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet 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

29-0096

Attachment 7
.S # 1I97-37-1
878213662

MB Research Laboratories, Inc.

steinsburg and wentz roads
post office box 203
spinnerstown, pennsylvania 18968
215-536-4110

PRIMARY DERMAL IRRITATION IN RABBITS

FOR: TOMS RIVER CHEMICAL CORPORATION

Code Number : M 42485
Product Name : Ethoxy Phenylenediamine 100 Cake
Concentration:
Mix Number : Ba. 1/78
TR Number : 78-309
Description : Dark Green Paste

Project Number : MB 78-2761 C
Material received: 4/19/78
Test started : 6/13/78
Test ended : 6/16/78

This study is designed to determine the primary irritation index of a compound in rabbits.

Six New Zealand white albino rabbits weighing approximately 2.5 kg were housed individually in suspended wire mesh cages in a temperature controlled room. Purina Rabbit Chow and water were freely available. After at least seven days equilibration, the back and sides of each rabbit were clipped free of fur with an electric clipper. Rabbits with dermal lesions or irritation were replaced. One day after clipping, the left side of the spinal column was abraded (minor incisions which did not disturb the derma or produce bleeding). 0.5 g, if solid, or 0.5 ml, if liquid, of the test material was placed on an abraded site and an intact site of each back. The material was covered with dry surgical gauze, one inch square, two layers thick. The patches were secured with adhesive tape; the trunk was wrapped with impervious material. After 24 hours, the patches were removed. The dermal reactions were scored by the Draize technique at 24 and 72 hours. The primary dermal index was calculated.

The individual results are attached.

PRIMARY DERMAL INDEX: 0

CONCLUSION: Non-Irritant

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Respectfully submitted,

Oscar M. Moreno

Oscar M. Moreno, Ph.D.
President
6/16/78

MB

INDIVIDUAL SCORES

	Rabbit Number 1	2	3	4	5	6	Mean Score
Erythema & Eschar Formation							
Intact skin - 24 hours	0	0	0	0	0	0	0
Intact skin - 72 hours	0	0	0	0	0	0	0
Abraded skin - 24 hours	0	0	0	0	0	0	0
Abraded skin - 72 hours	0	0	0	0	0	0	0
Edema							
Intact skin - 24 hours	0	0	0	0	0	0	0
Intact skin - 72 hours	0	0	0	0	0	0	0
Abraded skin - 24 hours	0	0	0	0	0	0	0
Abraded skin - 72 hours	0	0	0	0	0	0	0

Sum of Mean Scores = 0

Primary Dermal Index = Sum of Mean Scores/4 0

Evaluation of Skin Reactions

	Value
Erythema & Eschar Formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet 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

29-0097

Attachment 8
CAS #1197-37-1
878213663

MB Research Laboratories, Inc.

steinsburg and wentz roads
post office box 203
spinnerstown, pennsylvania 18968
215-536-4110

REPORT ON RABBIT EYE IRRITATION

For: Toms River Chemical Corporation

Code Number : M 42485
Product Name : Ethoxy Phenylenediamine 100 Cake
Concentration :
Mix Number : Ba. 1/78
TR Number : 78-309

Project Number: MB 78-2761D
Date received : 4/19/78
Test started : 6/13/78
Test ended : 6/27/78
Description : Dark Green Pas

This stuoy was designed to determine ocular irritation potential of a material when instilled in the rabbit eye.

Six New Zealand White rabbits weighing approximately 2.5 kg were housed individually in suspended wire mesh cages in temperature and light controlled rooms. Purina rabbit chow and water were available ad libitum.

The rabbits were equilibrated in this laboratory for at least seven days. Rabbits with irritated or damaged eyes were not used in this test.

The test material (0.1 ml liquid or 0.1 ml-equivalent solid) was instilled in the lower conjunctival sac of one eye of each rabbit and the lids held closed for approximately one second to insure even distribution of the test material over all surfaces of the eye. The other eye served as an untreated control.

The eyes were examined and graded for irritation and corneal damage at 1, 24, 48 and 72 hours after instillation with a hand slit lamp. Eyes not returning to a score of zero by 72 hours were graded on the seventh day after instillation. Eyes still not returning to a score of zero were graded on the fourteenth day after instillation. All eyes were examined by applying 1 drop of 1% fluorescein sodium ophthalmic solution, U.S.P., to the cornea pre-test, 24, 72 hours and 7 and 14 days after instillation.

The ocular reactions were graded and interpreted as described in "Appraisal of the Safety of Food, Drugs, and Cosmetics", Association of Food and Drug Officials of the United States, 1959 with the assistance of the "Illustrated Guide for Grading Eye Irritation by Hazardous Substances". A copy of the score and interpreting system is attached.

The individual scores are presented on the attached pages.

The mean daily scores are:

Hour 1	37.0
Day 1	23.0
Day 2	22.7
Day 3	20.2
Day 7	5.7
Day 14	3.3

CLASSIFICATION: Moderately Irritating

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Respectfully submitted,

Oscar M. Moreno

Oscar M. Moreno, Ph.D.
President
7/19/78

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Rabbit Eye Irritation Study
Individual Daily Scores

Material: M 42485
Project #: MB 78-2761D

An.No.	Item	Tissue	Reading	Hour 1	Day 1	2	3	7	14
1	A	Cornea	Opacity	0	2	0	0	0	0
	B		Area	0	1	0	0	0	0
		1. Cornea Total = (AxB) x 5		0	10	0	0	0	0
	C	Iris		1	1	1	0	0	0
		2. Iris Total = C x 5		5	5	5	0	0	0
	D	Conjunctiva	Redness	2[a]	3[a,c]	3[c]	2	1	0
	E		Chemosis	3	3	2	2	0	0
	F		Discharge	3	3	3	2	1	0
		3. Conjunctiva Total = (D+E+F) x 2		16	18	16	12	4	0
		Totals added = 1 + 2 + 3		21	33	21	12	4	0
		UV Fluorescein scan			1		0	0	0
2	A	Cornea	Opacity	3	0	0	2	0	0
	B		Area	1	0	0	2	0	0
		1. Cornea Total = (AxB) x 5		15	0	0	20	0	0
	C	Iris		1	1	1	1	0	0
		2. Iris Total = C x 5		5	5	5	5	0	0
	D	Conjunctiva	Redness	2	2[a]	2	2	0	0
	E		Chemosis	3	2	2	2	0	0
	F		Discharge	3	2	2	1	0	0
		3. Conjunctiva Total = (D+E+F) x 2		16	12	12	10	0	0
		Totals added = 1 + 2 + 3		36	17	17	35	0	0
		UV fluorescein scan			3		2	0	0
3	A	Cornea	Opacity	2	0	2	2	2	0
	B		Area	3	0	1	1	1	0
		1. Cornea Total = (AxB) x 5		30	0	10	10	10	0
	C	Iris		1	1	1	1	0	0
		2. Iris Total = C x 5		5	5	5	5	0	0
	D	Conjunctiva	Redness	2	2[a]	2[a]	2[a]	1	1
	E		Chemosis	3	3	2	2	2	2
	F		Discharge	3	2	2	2	1	1
		3. Conjunctiva Total = (D+E+F) x 2		16	14	12	12	8	8
		Totals added = 1 + 2 + 3		51	19	27	27	18	8
		UV fluorescein scan			2		1	1	0

a = material still present in conjunctival sac
c = brown spots

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SCALE OF SCORES FOR GRADING THE SEVERITY OF OCULAR LESIONS*

OCULAR TISSUE	DESCRIPTION	GRADING
CORNEA	A. OPACITY - Degree of Density - Area which is most dense is read	
	Scattered or diffuse area, details of iris clearly visible	1
	Easily descernible 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 one half	2
	Greater than one half but less than three quarters	3
	Greater than three quarters, up to whole area	4
	SCORE: A x B x 5 Total Maximum = 80	
IRIS	A. VALUES	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all or these or a 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: A x 5 Total Maximum = 10	
CONJUNCTIVA	A. REDNESS (refers to palpebral conjunctiva only excluding cornea and iris)	
	Vessels definitely injected above normal	1
	More diffuse, deeper crimson red, individual vessels not easily discernible	2
	Diffuse beefy red	3
	B. CHEMOSIS	
	Any swelling above normal (includes nictitating membrane)	1
	Obvious swelling with partial eversion of the lids	2
	Swelling with lids about half-closed	3
	Swelling with lids about half-closed to completely closed	4
	C. DISCHARGE	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals)	1
	Discharge with moistening of the lids and hairs just adjacent to the lids	2
	Discharge with moistening of the lids and hairs and considerable area around eye	3
	SCORE: (A + B + C) x 2 Total Maximum = 20	

*Draize, John H. Dermal Toxicity. "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics". ASSOCIATION OF FOOD AND DRUG OFFICIALS OF THE U.S., 1959, pp 49-51

RATING OF TEST MATERIALS BASED ON EYE IRRITATION PROPERTIES*

RATING	RANGE	DEFINITION
Non-irritating	0 - 0.5	To maintain this rating all scores at the 24 hour reading must be zero; otherwise, increase rating 1 level.
Practically Non-irritating	Greater than 0.5 - 2.5	To maintain this rating, all scores at the 24 hour reading must be zero; otherwise, increase rating 1 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 rating 1 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 1 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. If 7 day mean score is less than or equal to 20 but less than 60% of the 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 1 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 scores 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 1 level.
Extremely Irritating	Greater than 80.0 -110.0	

*Kay, J.H., Calandra, J.C., J. Soc. Cos. Chem., 13:281 - 289, 1962.

SCALE OF SCORES FOR ULTRAVIOLET FLUORESCEIN SCAN

Reading	Grade
Negative	0
Positive with an area one quarter or less	1
Positive with an area greater than one quarter but less than one half	2
Positive with an area greater than one half but less than three quarters	3
Positive with an area greater than three quarters, up to whole area	4