



HAZLETON

LABORATORIES AMERICA, INC.

Chemical & BioMedical Sciences Division

3301 KINSMAN BLVD. • P.O. BOX 7545 • MADISON, WISCONSIN 53707 • PHONE (608) 241-4471 • TLX 703956 HAZRAL MDS UD

FINAL REPORT



ROGER G. PERKINS
MINNESOTA MINING & MANUFACTURING COMPANY
TOXICOLOGY SERVICES
ST. PAUL, MN 55101

SAMPLE NUMBER: 61005209
SAMPLE ENTERED: 10/23/86
REPORT PRINTED: 01/13/87

SAMPLE: T-3974 LOT 390

PURCHASE ORDER NUMBER: T757575-TBR 632

ENCLOSED: PRIMARY EYE IRRITATION STUDY IN RABBITS - METHOD, SUMMARY
RAW DATA APPENDIX

SIGNED: *Steven M. Glaza*
.....
STEVEN M. GLAZA
STUDY DIRECTOR
ACUTE TOXICOLOGY

.....1-14-87.....
DATE

BY AND FOR HAZLETON LABORATORIES AMERICA, INC.

RAW DATA FOR THIS STUDY ARE KEPT ON FILE AT HAZLETON LABORATORIES
AMERICA, INC., MADISON, WISCONSIN.





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SAMPLE: T-3974 LOT 390

EYE IRRITATION

Objective: To determine the level of irritation produced following a single exposure of a test material to one eye of albino rabbits according to the U.S. Environmental Protection Agency's Guidelines for Testing Pesticides and Toxic Substances.

Test Material: T-3974 Lot 390

Physical Description: Fine white powder

Purity and Stability: Sponsor assumes responsibility for purity and stability determinations.

Test Animal: Young adult rabbits of the New Zealand White strain were procured, maintained individually in screen-bottom cages in temperature- and humidity-controlled quarters, provided access to water ad libitum and a measured amount of Purina High Fiber Rabbit Chow, and held for an acclimation period of at least 7 days.

Six acclimated animals, weighing from 2340 to 2800 g, were chosen at random for the test. The animals' eyes were examined within 24 hours prior to test material administration using sodium fluorescein dye procedures. Only those animals with no sign of ocular injury or irritation were used on the test. Test animals were identified by animal number and corresponding ear tag.

Reason for Species Selection: The New Zealand White albino rabbit is the animal of choice based upon its large orbit and nonpigmented iris.

Preparation of Test Material: The sample was dosed as received. A bulk density determination was made to determine the weight equivalent of a 0.1 ml dose.

Treatment: Each rabbit received 0.05 g (0.1 ml weight equivalent) of the test material placed on the everted lower lid of one eye, with the contralateral eye serving as the untreated control. The upper and lower lids were gently held together for one second to prevent loss of material and then released. The eyes of the rabbits remained unflushed.

Reason for Route of Administration: Historically, the route of choice based on the method of Draize.



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EYE IRRITATION

(CONTINUED)

Observations: The treated eyes were observed for ocular irritation at 1, 24, 48, 72 and 96 hours, and at 7 days after treatment. Because injury was present at 7 days, observations were continued at 14 and 21 days.

At the 72-hour and 7, 14 and 21-day readings, sodium fluorescein was used to aid in revealing possible corneal injury. Irritation was graded and scored according to the Draize technique.

Animals were weighed just prior to test material administration and at weekly intervals during the study.

Pathology: At study termination all animals were euthanatized and discarded.



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EYE IRRITATION

(CONTINUED)

SUMMARY

Test Animal: Albino rabbits - New Zealand White
Source: Hazleton Research Products, Inc., Denver PA
Date Animals Received: 10/21/86

Date Test Started: 11/17/86 Date Test Completed: 12/09/86

PRIMARY EYE IRRITATION SCORES*

OBSERVATION PERIOD	6 Rabbit Mean 0.05 g (Unwashed)
1 Hour:	39.0
24 Hours:	36.5
48 Hours:	34.8
72 Hours:	33.5
96 Hours:	30.0
7 Days:	35.2
14 Days:	20.8 **
21 Days:	17.5

* The Primary Eye Irritation Score is the total eye irritation score for all the animals divided by the number of animals (6) at each observation period.

**Based on a 5-animal mean.



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EYE IRRITATION

(CONTINUED)

Table 1
Individual Eye Irritation Scores

Animal Number	Observation Period	Cornea		Score	Iris		Conjunctivae			Score
		A	B	AXBX5	A	A X 5	A	B	C	(A+B+C)2
F15615	1 Hour	1	4	20	1	5	2	3	3	16
	24 Hours	1	4	20	1	5	2	3	2	14
	48 Hours	1	4	20	1	5	2	3	2	14
	72 Hours	1	3	15	1	5	2	3	1	12
	96 Hours	1	3	15	1	5	2	3	1	12
	7 Days	2	1	10	1	5	2	3	1	12
	14 Days	1	1	5	1	5	2	3	1	12
	21 Days	1	1	5	0	0	1	2	1	8
F15616	1 Hour	1	4	20	1	5	2	3	3	16
	24 Hours	1	4	20	1	5	2	3	2	14
	48 Hours	1	4	20	1	5	2	3	2	14
	72 Hours	1	4	20	1	5	2	3	2	14
	96 Hours	1	2	10	1	5	2	3	2	14
	7 Days	2	1	10	0	0	2	2	1	10
	14 Days	1	1	5	0	0	1	1	0	4
	21 Days	3	1	15	0	0	0	2	0	4
F15591	1 Hour	1	3	15	1	5	2	2	3	14
	24 Hours	1	3	15	1	5	2	2	2	12
	48 Hours	1	2	10	1	5	2	2	1	10
	72 Hours	1	2	10	1	5	2	2	1	10
	96 Hours	1	1	5	1	5	2	2	1	10
	7 Days	2	2	20	1	5	2	2	1	10
	14 Days	1	1	5	0	0	0	0	0	0
	21 Days	1	1	5	0	0	0	0	0	0
F15618	1 Hour	1	4	20	1	5	2	3	3	16
	24 Hours	1	4	20	1	5	2	1	2	10
	48 Hours	1	4	20	1	5	2	2	2	12
	72 Hours	1	3	15	1	5	2	2	1	10
	96 Hours	1	3	15	1	5	2	2	1	10
	7 Days	2	1	10	1	5	2	2	1	10
	14 Days	0	0	0	0	0	0	0	0	0
	21 Days	0	0	0	0	0	0	0	0	0



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EYE IRRITATION

(CONTINUED)

Table 1 (continued)
Individual Eye Irritation Scores

Animal Number	Observation Period	Cornea		Score	Iris		Conjunctivae			Score
		A	B	AXBX5	A	A X 5	A	B	C	(A+B+C)2
F15619	1 Hour	1	3	15	1	5	2	3	3	16
	24 Hours	1	4	20	1	5	2	2	2	12
	48 Hours	1	3	15	1	5	2	2	2	12
	72 Hours	1	3	15	1	5	2	3	2	14
	96 Hours	1	3	15	1	5	2	3	2	14
	7 Days	1	3	15	1	5	2	3	2	14
	14 Days	3	3	45	1	5	3	3	3	18
	21 Days	4	1	20	0	0	2	3	3	16
F15620	1 Hour	1	4	20	1	5	2	3	3	16
	24 Hours	1	4	20	1	5	2	2	2	12
	48 Hours	1	4	20	1	5	2	2	2	12
	72 Hours	1	4	20	1	5	3	3	2	16
	96 Hours	2	1	10	1	5	3	4	3	20
	7 Days	3	3	45	1	5	3	4	3	20
	14 Days	4	4	80	*	*	3	4	3	20
	21 Days	4	1	20	0	0	1	3	2	12

* Unable to visualize due to severe opacity.

Table 2
Sodium Fluorescein Examination

Animal Number	Pre-initiation	Observation Period			
		72 Hours	7 Days	14 Days	21 Days
F15615	NEG	POS (60%)	POS (25%)	POS (15%)	NEG
F15616	NEG	POS (20%)	POS (10%)	POS (5%)	POS (5%)
F15591	NEG	POS (45%)	POS (30%)	POS (5%)	NEG
F15618	NEG	POS (30%)	POS (15%)	NEG	NEG
F15619	NEG	POS (60%)	POS (70%)	POS (40%)	POS (25%)
F15620	NEG	POS (100%)	POS (60%)	POS (50%)	POS (10%)

NEG = No stain retention

POS = Positive stain retention (area of cornea involved).



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EYE IRRITATION

(CONTINUED)

Comments:

A pain response (vocalization) was elicited from two animals following instillation of the test material. Five animals exhibited excessive pawing at the treated eye following dosing.

Blanching of the conjunctivae was seen in all six animals at 1 hour, in four animals at 24 hours, in all six animals at 48, 72 and 96 hours, and in five animals at 7 days.

Petite hemorrhaging of the conjunctivae was exhibited by two animals at 24 hours, by three animals at 48 hours, by four animals at 72 hours, by all six animals at 96 hours, and by three animals at 7 days.

Hair loss around the eye was seen in one animal at Day 14.

Corneal epithelial peeling was observed in three animals at 24 hours, in three animals at 48 hours, in all six animals at 72 and 96 hours and 7 days, in five animals at 14 days, and in three animals at 21 days.

Corneal neovascularization was seen in five animals at 7 days, in all six animals at 14 days, and in three animals at 21 days.

Pannus was observed in one animal at 96 hours, and in one other animal at 7 days.

Three animals exhibited granulation scar tissue at 21 days.

At the 14-day observation, the iris of one animal (F15620) could not be visualized due to the severe opacity.

References:

1. Hitch, R.K., "Primary Eye Irritation Study," Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals, U.S. Environmental Protection Agency Office of Pesticide and Toxic Substances Series 81-4, pp. 51-55 (November 1982).
2. Draize, J.H., "Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics - Dermal Toxicity." Association of Food and Drug Officials of the U.S., pp. 46-59 (1975).
3. DHHS Publication No. (NIH 85-23 1985) Guide for the Care and Use of Laboratory Animals.

PROTOCOL - APPENDIX I

(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

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*

A x 5

Total Maximum = 10

(3) Conjunctivas

(A) Redness (refers to palpebral conjunctivae only)	
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 (includes 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 (A + B + C) x 2

Total Maximum = 20

The total score for the eye is the sum of all scores obtained for the cornea, iris, and conjunctivas.

* Starred figures indicate positive affect.

PRIMARY EYE IRRITATION TEST

HLA No. 61005209

Initial Sodium Fluorescein Exam and Animal Body Weights

Test Material: Sample: T-3974 Lot 390
 Physical Description: Fine white powder
 pH result: U with NA pH meter No. NA
 Dose: 0.05g (0.1ml WEIGHT EQUIVALENT)
 Review of folder preparation by: SP Date: 11/17/86
 Room Number: 161C, 161D

Date Animals Received: 10-21-86
 Species: RABBIT
 Strain: NEW ZEALAND WHITE
 Source: HAZLETON RESEARCH PRODUCTS, INC.

All animals appeared normal just prior to dosing.

Technician: RFJ Date: 11-17-86

FI- Animal No.	Sex	Initial Sfr	Vocal- ization Following Dosing	Animal Body Weights (g)			
				Initiation	Day 7	Day 14	Day 21
<u>5615</u>	<u>♂</u>	<u>NEG</u>	<u>N⁰</u>	<u>2800</u>	<u>2998</u>	<u>3154</u>	<u>3230</u>
<u>5616</u>	<u>♂</u>	<u>NEG</u>	<u>N⁰</u>	<u>2359</u>	<u>2542</u>	<u>2584</u>	<u>2776</u>
<u>5591</u>	<u>♀</u>	<u>NEG</u>	<u>N⁰</u>	<u>2779</u>	<u>2922</u>	<u>2945</u>	<u>3046</u>
<u>5618</u>	<u>♀</u>	<u>NEG</u>	<u>N</u>	<u>2564</u>	<u>2739</u>	<u>2848</u>	<u>2917</u>
<u>5619</u>	<u>♀</u>	<u>NEG</u>	<u>Y⁰</u>	<u>2515</u>	<u>2672</u>	<u>2746</u>	<u>2790</u>
<u>5620</u>	<u>♀</u>	<u>NEG</u>	<u>Y⁰</u>	<u>2340</u>	<u>2646</u>	<u>2674</u>	<u>2723</u>
TECHNICIAN	<u>SP</u>	<u>SP</u>	<u>RFJ</u>	<u>RFJ</u>	<u>RFJ</u>	<u>RFJ</u>	<u>RFJ</u>
DATE	<u>11/16/86</u>	<u>11/16</u>	<u>11-17</u>	<u>11-17</u>	<u>11/24</u>	<u>12/1</u>	<u>12/8</u>
SCALE USED		<u>KTRON</u>	<u>15019</u>	<u>5008</u>	<u>5008</u>	<u>5008</u>	<u>15019</u>

① Entry error 11-16-86 SP
 ② Excessive pawing at dosed eye. RFJ 11-17-86
 ③ Entry error RFJ 11-17-86
 ④ THE ANIMALS WERE MOVED FROM 161C TO 161 ON 12-3-86. SP 12-3-86

Reviewed by: SP Date: 12-10-86

Dosed in the conjunctival sac. The upper and lower lids were gently held together for one second.

NA Dosed directly on the cornea. The eyelids were re-teased immediately without forced blinking or manipulation.

- * - Sodium Fluorescein Examination.
- NEG - Negative
- POS - Positive
- NA - Not Applicable
- U - Unable to determine pH
- Y - Yes
- N - No
- M - Male
- F - Female

Time of Dosing: 4:15 Date: 11-17-86
 Tech: RFJ Date: 11-17-86

Time of First Observation: 2:15 PM
 Tech: RFJ Date: 11-17-86

Primary Eye Irritation Test Observations

Test Material: Sample: T-3974 Lot 390 HLA No. 61005209
 Test Eye: Right Group: NA

NA Washed: NA seconds following instillation of test material, Unwashed
 the test eye was washed with NA mL of lukewarm tap water for NA seconds.

OBSERVATION PERIOD: 1hr

Animal No.	F1-	5615	5616	5591	5618	5619	5620
Location of Corneal Lesions							
Tail ----- Head							
Cornea - Opacity		1	1	1	1	1	1
Area		4	4	3	4	3	4
Iris		I	I	I	I	I	I
Conjunctivae -		B	B	B	B	B	B
Redness		2	2	2	2	2	2
Chemosis		3	3	2	3	3	3
Discharge		3C	3C	3C	3C	3C	3C
Sodium Fluorescein Exam		NA	NA	NA	NA	NA	NA

Technician JMC

Date 11-17-86

- NA - Not Applicable
- A - Petite hemorrhage
- B - Blanching
- C - Clear discharge
- D - Purulent discharge
- E - Hair loss around the eye
- F - Necrotic Areas
- G - Unable to visualize due to severe swelling
- H - No reaction to light
- I - Injected
- J - Corneal epithelial damage, peeling
- K - Corneal epithelial damage, piling
- L - Corneal epithelial damage, pitting
- M - Hypopyon
- N - Corneal neovascularization
- P - Pannus
- R - Unable to visualize due to severe opacity
- S - Granulation scar tissue
- POS - Positive stain retention
- NEG - Negative stain retention

Reviewed By: JMC Date: 12-10-86 Eye Irritation Score: 39.0
 (4253A) 12-10-86
slu 11-17-86

Primary Eye Irritation Test Observations

Test Material: Sample: T-3974 Lot 390 HLA No. 61005209
 Test Eye: Right Group: NA

NA Washed: NA seconds following instillation of test material, Unwashed
 the test eye was washed with NA mL of lukewarm tap water for NA seconds.

OBSERVATION PERIOD: 24 hrs

Animal No.	5615	5616	5591	5618	5619	5620
Location of Corneal Lesions						
Tail ----- Head						
Cornea - Opacity	1	1 ^{J=20%}	1 ^{J=60%}	1	1	1 ^{J=80%}
Area	4	4	3	4	4	4
Iris	I	I	I	I	I	I
Conjunctivae -						
Redness	2AB	2A	2B	2B	2B	2
Chemosis	3	3	2	1	2	2
Discharge	2c	2c	2c	2c	2c	2c
Sodium Fluorescein Exam	NA	NA	NA	NA	NA	NA

Technician RS/SG
 Date 11-18-86

0 No opacity in this Area. RS 11-18-86

- NA - Not Applicable
- A - Petite hemorrhage
- B - Blanching
- C - Clear discharge
- D - Purulent discharge
- E - Hair loss around the eye
- F - Necrotic Areas
- G - Unable to visualize due to severe swelling
- H - No reaction to light
- I - Injected
- J - Corneal epithelial damage, peeling
- K - Corneal epithelial damage, piling
- L - Corneal epithelial damage, pitting
- M - Hypopyon
- N - Corneal neovascularization
- P - Pannus
- R - Unable to visualize due to severe opacity
- S - Granulation scar tissue
- POS - Positive stain retention
- NEG - Negative stain retention

Reviewed By: SG Date: 12-10-86 Eye Irritation Score: 36.5
 (4253A) SG 11-18-86

Primary Eye Irritation Test Observations

Test Material: Sample: T-3974 Lot 390 HLA No. 61005209
 Test Eye: Right Group: NA

NA Washed: NA seconds following instillation of test material, Unwashed
 the test eye was washed with NA mL of lukewarm tap water for NA seconds.

OBSERVATION PERIOD: 48 hrs

Animal No.	F1-	5615	5616	5591	5618	5619	5620
Location of Corneal Lesions							
Tail ----- Head				I=45%		J=70%	J=80%
Cornea - Opacity		1	1	1	1	1	1
Area		4	4	2	4	3	4
Iris		I	I	I	I	I	I
Conjunctivae -		AB	AB	B	B	B	AB
Redness		2	2	2	2	2	2
Chemosis		3	3	2	2	2	2
Discharge		2C	2D	1D	2D	2D	2D
Sodium Fluorescein Exam		N/A	N/A	N/A	N/A	N/A	N/A

Technician LMC
 Date 11-19-86

- NA - Not Applicable
- A - Petite hemorrhage
- B - Blanching
- C - Clear discharge
- D - Purulent discharge
- E - Hair loss around the eye
- F - Necrotic Areas
- G - Unable to visualize due to severe swelling
- H - No reaction to light
- I - Injected
- J - Corneal epithelial damage, peeling
- K - Corneal epithelial damage, piling
- L - Corneal epithelial damage, pitting
- M - Hypopyon
- N - Corneal neovascularization
- P - Pannus
- R - Unable to visualize due to severe opacity
- S - Granulation scar tissue
- POS - Positive stain retention
- NEG - Negative stain retention

Reviewed By: [Signature] Date: 12-10-86 Eye Irritation Score: 348
 (4253A) slu 11-19-86

Ⓞ Entry error 11-19-86 LMC

Primary Eye Irritation Test Observations

Test Material: Sample: T-3974 Lot 390

HLA No. 61005209

Test Eye: Right

Group: NA

NA Washed: NA seconds following instillation of test material, the test eye was washed with NA mL of lukewarm tap water for NA seconds.

Unwashed

OBSERVATION PERIOD: 72 hrs

Animal No.	F1-	5615	5616	5591	5618	5619	5620
Location of Corneal Lesions							
Tail ----- Head							
Cornea - Opacity		J=60%	J=30%	J=45%	J=30%	J=60%	J=100%
Area		3	4	2	3	3	4
Iris		1 I	1 I	1 I	1 I	1 I	1 I
Conjunctivae -							
Redness		2 AB	2 AB	2 B	2 B	2 AB	3 AB
Chemosis		3	3	2	2	3	3
Discharge		1c	20	1c	1c	2c	20
Sodium Fluorescein Exam		Pos. 10%	Pos. 20%	Pos. 45%	Pos. 30%	Pos. 60%	Pos. 100%

Technician SMC / JG

Date 11-20-86

- NA - Not Applicable
- A - Petite hemorrhage
- B - Blanching
- C - Clear discharge
- D - Purulent discharge
- E - Hair loss around the eye
- F - Necrotic Areas
- G - Unable to visualize due to severe swelling
- H - No reaction to light
- I - Injected

- J - Corneal epithelial damage, peeling
- K - Corneal epithelial damage, piling
- L - Corneal epithelial damage, pitting
- M - Hypopyon
- N - Corneal neovascularization
- P - Pannus
- R - Unable to visualize due to severe opacity
- S - Granulation scar tissue
- POS - Positive stain retention
- NEG - Negative stain retention

Reviewed By: JG

Date: 12-10-86

Eye Irritation Score: 33.5

(4253A)

12-10-86
slm 11-20-86

Primary Eye Irritation Test Observations

Test Material: Sample: T-3974 Lot 390 HLA No. 61005209

Test Eye: Right Group: NA

NA Washed: NA seconds following instillation of test material, Unwashed
 the test eye was washed with NA mL of lukewarm tap water for NA seconds.

OBSERVATION PERIOD: 96 hrs

Animal No.	EI-	5615	5616	5591	5618	5619	5620
Location of Corneal Lesions							
Tail ----- Head							
Cornea - Opacity		S=75%P	S=40%	S=25%	S=75%	S=20%	S=100%
Area		3	2	1	3	3	1
Iris		I	I	I	I	I	I
Conjunctivae -		AB	AB	AB	AB	AB	AB
Redness		2	2	2	2	2	3
Chemosis		3	3	2	2	3	4
Discharge		1C	2D	1C	1D	2D	3D
Sodium Fluorescein Exam		NA	NA	NA	NA	NA	NA

Technician RP

Date 11-21-86

- NA - Not Applicable
- A - Petite hemorrhage
- B - Blanching
- C - Clear discharge
- D - Purulent discharge
- E - Hair loss around the eye
- F - Necrotic Areas
- G - Unable to visualize due to severe swelling
- H - No reaction to light
- I - Injected
- J - Corneal epithelial damage, peeling
- K - Corneal epithelial damage, piling
- L - Corneal epithelial damage, pitting
- M - Hypopyon
- N - Corneal neovascularization
- P - Pannus
- R - Unable to visualize due to severe opacity
- S - Granulation scar tissue
- POS - Positive stain retention
- NEG - Negative stain retention

Reviewed By: [Signature]
 (4253A)

Date: 10-10-86 Eye Irritation Score: 30.0
slu 11-24-86

Primary Eye Irritation Test Observations

Test Material: Sample: T-3974 Lot 390

HLA No. 61005209

Test Eye: Right

Group: NA

NA Washed: NA seconds following instillation of test material, the test eye was washed with NA mL of lukewarm tap water for NA seconds. Unwashed

OBSERVATION PERIOD: 7 days

Animal No.	F1- 5615	5616	5591	5618	5619	5620
Location of Corneal Lesions						
Tail ----- Head						
Cornea - Opacity	J=25%N 2	J=10%N 2	J=30%N 2	J=15%N 2	J=70%N 1	J=60%P 3
Area	1	1	2	1	3	3
Iris	I	O	I	I	I	I
Conjunctivae -						
Redness	2 AB	2 B	2 B	2 AB	2 AB	3
Chemosis	3	2	2	2	3	3 4
Discharge	1C	1C	1D	1C	2C	3T
Sodium Fluorescein Exam	Pos 25%	Pos 10%	Pos 30%	Pos 15%	Pos 70%	Pos 60%

Technician JMC

Date 11-24-80

- NA - Not Applicable
- A - Petite hemorrhage
- B - Blanching
- C - Clear discharge
- D - Purulent discharge
- E - Hair loss around the eye
- F - Necrotic Areas
- G - Unable to visualize due to severe swelling
- H - No reaction to light
- I - Injected

- J - Corneal epithelial damage, peeling
- K - Corneal epithelial damage, piling
- L - Corneal epithelial damage, pitting
- M - Hypopyon
- N - Corneal neovascularization
- P - Pannus
- R - Unable to visualize due to severe opacity
- S - Granulation scar tissue
- POS - Positive stain retention
- NEG - Negative stain retention
- T - Blood-like discharge 11-24-80 JMC

Reviewed By: JMC

Date: 12-10-86

Eye Irritation Score: 35.2

(4253A)

⓪ Entry error 11-24-80 JMC

35.2 12-10-86
slu 11-24-86

Primary Eye Irritation Test Observations

Test Material: Sample: T-3974 Lot 390 HLA No. 61005209

Test Eye: Right Group: NA

NA Washed: NA seconds following instillation of test material, Unwashed
 the test eye was washed with NA mL of lukewarm tap water for NA seconds.

OBSERVATION PERIOD: 14 days

Animal No.	F1- 5615	5616	5591	5618	5619	5620
Location of Corneal Lesions						
Tail ----- Head						
Cornea - Opacity	J=15% N	J=5% N	J=5% N	0 N	J=40% N	J=5% N
Area	1	1	1	0	3	4.20
Iris	I	0	0	0	I	R
Conjunctivae -						
Redness	2	1	0	0	3	3 ^E
Chemosis	3	1	0	0	3	4
Discharge	1D	0	0	0	3D	3D
Sodium Fluorescein Exam	Pos 15%	Pos 5%	Pos 5%	Neg	Pos 40%	Pos 50%

Technician smc / GJ
 Date 12-1-86

- NA - Not Applicable
- A - Petite hemorrhage
- B - Blanching
- C - Clear discharge
- D - Purulent discharge
- E - Hair loss around the eye
- F - Necrotic Areas
- G - Unable to visualize due to severe swelling
- H - No reaction to light
- I - Injected
- J - Corneal epithelial damage, peeling
- K - Corneal epithelial damage, piling
- L - Corneal epithelial damage, pitting
- M - Hypopyon
- N - Corneal neovascularization
- P - Pannus
- R - Unable to visualize due to severe opacity
- S - Granulation scar tissue
- POS - Positive stain retention
- NEG - Negative stain retention

Reviewed By: JDD Date: 12-10-86 Eye Irritation Score: 20.8
 (4253A) ② slu 12-1-86

① Entry error 12-1-86 smc
 ② DUE TO THE INABILITY TO SCORE THE IRIS OF ONE ANIMAL (F15620), THIS SCORE REFLECTS A FIVE-ANIMAL MEAN. slu 12-1-86

Primary Eye Irritation Test Observations

Test Material: Sample: T-3974 Lot 390 HLA No. 61005209
 Test Eye: Right Group: NA

NA Washed: NA seconds following instillation of test material, the test eye was washed with NA mL of lukewarm tap water for NA seconds. Unwashed

OBSERVATION PERIOD: 21 days

Animal No.	F1-	5615	5616	5591	5618	5619	5620
Location of Corneal Lesions							
Tail ----- Head							
Cornea - Opacity		1 00	S=5% NS 3	1	0	S=25% NS 4	S=10% NS 4
Area		1 00	1	1	0	1	1
Iris		0	0	0	0	0	0
Conjunctivae -							
Redness		1	0	0	0	2	1
Chemosis		2	2	0	0	3	3
Discharge		1 ^c	0	0	0	3 ^D	2 ^D
Sodium Fluorescein Exam		Neg	Pos 5%	Neg	Neg	Pos 25%	Pos 10%

Technician PP
 Date 12-8-86

- NA - Not Applicable
- A - Petite hemorrhage
- B - Blanching
- C - Clear discharge
- D - Purulent discharge
- E - Hair loss around the eye
- F - Necrotic Areas
- G - Unable to visualize due to severe swelling
- H - No reaction to light
- I - Injected
- J - Corneal epithelial damage, peeling
- K - Corneal epithelial damage, piling
- L - Corneal epithelial damage, pitting
- M - Hypopyon
- N - Corneal neovascularization
- P - Pannus
- R - Unable to visualize due to severe opacity
- S - Granulation scar tissue
- POS - Positive stain retention
- NEG - Negative stain retention

Reviewed By: QD Date: 12-10-86 Eye Irritation Score: 17.5
12-8-86

① entry errors m 12-8-86