

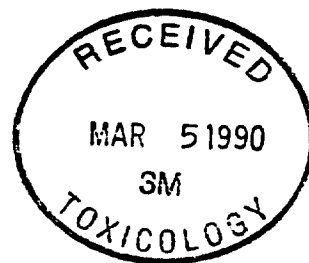
PFOA

Acute Toxicity - 3



HAZLETON
LABORATORIES AMERICA, INC.
3301 KINSMAN BLVD., P.O. BOX 7545
MADISON, WI 53707 USA

FINAL REPORT



HLA Number: 91201741

Karen Armstrong
3M
Toxicology Services
Building 220-2E-02
St. Paul, MN 55144-1000

Sample: T-4416

Enclosed: Primary Eye Irritation/Corrosion Study in Rabbits
(OECD Guidelines)

- o Key Personnel
- o Methodology
- o Summary of Results
- o References
- o Raw Data Appendix

Signed: _____

Steven M. Glaza
Study Director
Acute Toxicology

Date _____

2-28-90



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KEY PERSONNEL

Acute Toxicology

Steven M. Glaza
Study Director
Section Supervisor

Steven R. Sorenson
Study Coordinator

Patricia Padgham
Group Leader

Sharen L. Howery
Report Coordinator

Quality Assurance

Deborah L. Keller
Manager

Laboratory Animal Veterinarian

Cindy J. Cary, DVM
Diplomate, ACLAM



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Sample: T-4416

METHODOLOGY

Objective: To assess the relative level of ocular irritation/corrosion produced following a single exposure of a test substance to one eye of albino rabbits according to the Organisation for Economic Cooperation and Development's Guidelines for Testing Chemicals.¹

Test Material: T-4416

Physical Description: Clear colorless liquid

Purity and Stability: Sponsor assumes responsibility for purity and stability determinations (including under test conditions).

Storage and Retention: The test material was stored at room temperature. Any unused material will be returned to Sponsor according to HLA Standard Operating Procedure.

Safety Precautions: Normal handling procedures were used according to HLA Standard Operating Procedure.

Test Animal: Adult albino rabbits, Hra:(NZW)SPF, 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 High Fiber Rabbit Chow® 5326, Purina Mills, Inc., and held for an acclimation period of at least 7 days. Animal husbandry and housing at HLA comply with standards outlined in the "Guide for the Care and Use of Laboratory Animals".² If variations from the prescribed environmental conditions existed, they were documented and considered to have no effect on the study outcome. No contaminants were expected to have been present in the feed or water which would have interfered with or affected the results of the study.

One male and two female acclimated animals, weighing from 2148 to 2500 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. Test animals were identified by animal number and corresponding ear tag.

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

Preparation and Administration of Test Material: The sample was dosed as received. The pH was determined to be 9.9.



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Treatment: Each rabbit received 0.1 mL of the test material placed into 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 1 second to prevent loss of material and then released. The eyes of the rabbits remained unflushed.

Reason for Route of Administration: Historically, the ocular route is the route of choice based on the method of Draize.³

Observations: The treated eyes were observed for ocular irritation at 1, 24, 48, 72 and 96 hours, and Days 7, 14 and 21 after treatment.

At the 24- and 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 throughout the study.

Termination: At termination of the experimental phase, all animals were euthanatized and discarded.

Statistical Methods: No statistical method was performed.

Location of Raw Data and Final Report: The raw data and a copy of the final report will be retained in the archives of HLA.



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SUMMARY OF RESULTS

Test Animal: Albino Rabbits - Hra:(NZW)SPF
Source: Hazleton Research Products, Inc., Denver PA
Date Animals Received: 12/19/89

Start Date (In-life): 01/10/90

End Date (In-Life): 01/31/90

Average Primary Eye Irritation Scores*

<u>Observation Period</u>	<u>Average Score</u>
1 Hour	41.0
24 Hour	49.0
48 Hour	36.0
72 Hour	38.3
96 Hour	34.3
Day 7	16.0
Day 14	6.0
Day 21	0.0

- * The average primary eye irritation score is the total eye irritation score for all the animals divided by the number of animals (3) at each observation period.



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Sample: T-4416

Table 1
Individual Eye Irritation Scores

Animal Number	Observation Period	Cornea		Score AXBX5	Iris A	Score A X 5	Conjunctivae			Score (A+B+C)2
		A	B				A	B	C	
F31165	1 Hour	1	4	20	1	5	2	3	3	16
	24 Hour	1	4	20	1	5	3	3	3	18
	48 Hour	1	3	15	1	5	3	2	2	14
	72 Hour	1	4	20	1	5	3	2	2	14
	96 Hour	1	3	15	1	5	3	2	1	12
	Day 7	2	1	10	0	0	2	1	0	6
	Day 14	0	0	0	0	0	1	0	0	2
	Day 21	0	0	0	0	0	0	0	0	0
F31127	1 Hour	1	4	20	1	5	2	3	3	16
	24 Hour	1	4	20	1	5	3	3	3	18
	48 Hour	1	4	20	1	5	3	2	1	12
	72 Hour	1	4	20	1	5	3	2	2	14
	96 Hour	1	4	20	1	5	3	2	2	14
	Day 7	1	1	5	1	5	2	1	0	6
	Day 14	1	1	5	1	5	2	1	0	6
	Day 21	0	0	0	0	0	0	0	0	0
F31194	1 Hour	1	4	20	1	5	2	3	3	16
	24 Hour	2	4	40	1	5	3	3	2	16
	48 Hour	1	4	20	1	5	3	2	1	12
	72 Hour	1	4	20	1	5	3	2	1	12
	96 Hour	1	3	15	1	5	3	2	1	12
	Day 7	1	2	10	0	0	2	1	0	6
	Day 14	0	0	0	0	0	0	0	0	0
	Day 21	0	0	0	0	0	0	0	0	0

Cornea

A - Degree of opacity
B - Area of involvement

Conjunctivae

A - Redness
B - Chemosis
C - Discharge



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Table 2
Sodium Fluorescein Examination

Animal Number	Observation Period					
	Pre-initiation	24 Hour	72 Hour	Day 7	Day 14	Day 21
F31165	NEG	POS (80%)	POS (55%)	POS (15%)	NEG	NEG
F31127	NEG	POS (100%)	POS (80%)	POS (5%)	POS (5%)	NEG
F31194	NEG	POS (75%)	POS (80%)	NEG	NEG	NEG

NEG - No stain retention

POS - Positive stain retention (area of cornea involved)

Comments:

A pain response (excessive pawing of the treated eye) was elicited in all three animals following instillation of the test material.

Blanching of the conjunctivae was observed in all three animals at 1, 24, 48, 72 and 96 hours, and Day 7.

Petite hemorrhaging of the conjunctivae was observed in two animals at 24 hours.

Corneal epithelial peeling was seen in all three animals at 24, 48, 72 and 96 hours, in two animals at Day 7, and in one animal at Day 14.

REFERENCES

1. "Acute Eye Irritation/Corrosion," *Organisation for Economic Cooperation and Development's Guidelines for Testing of Chemicals*, Section 405 (adopted May 12, 1981).
2. NIH Publication No. 86-23 (revised 1985).
3. Draize, J. H., "Eye Mucosa," In: *Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics - Dermal Toxicity*, Association of Food and Drug Officials of the U.S., pp. 49-50 (1975).

HLA: 91201741

PERSONNEL SIGNATURE SHEET
ACUTE TOXICOLOGY

<u>Name</u>	<u>Job Title</u>	<u>Signature</u>	<u>Initials</u>
Becky Beckwith	Lab Animal Technician	<u>Becky Beckwith</u>	<u>B/B</u>
Ann Bursaw	Sr. Clerk	<u>Ann Bursaw</u>	<u>AmB</u>
Anthony Cass	Lab Animal Assistant	<u>Anthony Cass</u>	<u>ac</u>
Cindy J. Cary, DVM	Lab Animal Veterinarian	<u>Cindy J. Cary</u>	<u>CJ</u>
Kari Gassen	Sr. Lab Animal Assistant	<u>Kari Gassen</u>	<u>KG</u>
Steven M. Glaza	Section Supervisor	<u>Steven M. Glaza</u>	<u>SG</u>
Ben Haley	Sr. Lab Animal Assistant	<u>Ben Haley</u>	<u>BH</u>
Jeff Hicks	Lab Animal Technician	<u>Jeff Hicks</u>	<u>JH</u>
Sharen L. Howery	Research Assistant	<u>Sharen L. Howery</u>	<u>SLH</u>
Jim Jirschele	Lab Animal Assistant	<u>Jim Jirschele</u>	<u>JJ</u>
Wayne Madison	Senior Section Supervisor	<u>Wayne A. Madison</u>	<u>WAM</u>
Bud McDonald	Sr. Lab Animal Assistant	<u>Bud McDonald</u>	<u>BMD</u>
Eileen McConnell	Administrative Clerk	<u>Eileen McConnell</u>	<u>EMC</u>
Henry Mikula	Lab Animal Assistant	<u>Henry Mikula</u>	<u>HM</u>
Albert Oleson	Sr. Lab Animal Assistant	<u>Albert Oleson</u>	<u>AO</u>
Patricia Padgham	Group Leader	<u>Patricia Padgham</u>	<u>PP</u>
Jane Polnow	Lab Animal Technician	<u>Jane Polnow</u>	<u>JP</u>
Steven R. Sorenson	Study Coordinator	<u>Steven R. Sorenson</u>	<u>SRS</u>
Dawn Thieding	Clerk	<u>Dawn Thieding</u>	<u>DT</u>
Annette R. Turner	Sr. Clerk	<u>Annette R. Turner</u>	<u>AT</u>
<u>KEVIN BRIDGES</u>	<u>Sr. Lab Animal Asst.</u>	<u>Kevin Bridges</u>	<u>KB</u>

(09/11/89)

000855

HLA: 91201741

BODY WEIGHT/DOSE RECORD

Study title: Primary Eye IrritationTest material: T-9416Physical description: CLEAR COLORLESS LIQUIDpH result: 9.9 with CORNING PH METER NO. 05510Dose: 0.1 mL/NA g (NA mL equivalent)✓ dosed with a 1-mL disposable syringe/ NA each dose
individually drawn up with a NA -mL Hamilton SyringeDate animals received: 12/19/89Species/strain: Rabbit/new Zealand whiteSource: Hazleton Research Products, Inc.Room No: 104/111Review of folder preparation by: CRS Date: 1-13-90

Animal No.	Group	Sex	Pain Response		Animal Body Weights (g)			
			Initial SF*	Following Dosing	Initiation	Day 7	Day 14	Day 21
F3 1165	1	♂	NEG	E	2500	2700	2679 ^{AB}	2858
1127	1	♀	NEG	E	2238	2490	2488 ^{AB}	2634
1194	1	♀	NEG	E	2148	2338	2392	2514
Technician	AB	AB	AB	AB	AB	AB	AB	K
Date 1990	1/10	1/10	1/10	1/10	1/17	1/24	1/31	
Scale Used	KTRON				40021	40021	5228	40021

All animals appeared normal just prior to dosing.

Technician: AB Date: 1/10/90

• - Sodium fluorescein examination.

NEG - Negative.

POS - Positive.

NA - Not applicable.

U - Unable to determine pH.

V - Vocalization.

E - Excessive pawing of treated eye.

H - None

NA Dosed directly on the cornea.

The eyelids were released immediately without forced blinking or manipulation.

✓ Dosed in the conjunctival sac. The upper and lower lids were gently held together for one second.Time of dosing: 10:50 AMTechnician AB Date: 1/10/90Time of first observation: 11:50 AMTechnician: AB Date: 1/10/90Surviving animals designated for sacrifice and discard. Technician K Date 1-31-90Reviewed by: K Date: 2-5-90

(C0261/vmt)

Approximately 5 minutes prior to test material administration _____ drops of proparacaine 0.5% (_____)

Lot # _____ was instilled into _____ eye(s) of each rabbit.

Technician _____ Date _____

000856

HLA: 91201741

PRIMARY EYE IRRITATION TEST OBSERVATIONS

Group: 1
 Test material: T-4416
 Test eye: Right

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

Observation Period: 1 Hour

Animal No.	<u>F3</u>	<u>1165</u>	<u>1127</u>	<u>1194</u>			
Location of corneal lesions							
Tail ----- Head							
Cornea - Opacity		<u>1</u>	<u>1</u>	<u>1</u>			
Area		<u>4</u>	<u>4</u>	<u>4</u>			
Iris		<u>1^I</u>	<u>1^I</u>	<u>1^I</u>			
Conjunctivae - Redness		<u>2^B</u>	<u>2^B</u>	<u>2^B</u>			
Chemosis		<u>3</u>	<u>3</u>	<u>3</u>			
Discharge		<u>3^C</u>	<u>3^C</u>	<u>3^C</u>			
Sodium fluorescein exam		<u>NA</u>	<u>NA</u>	<u>NA</u>			

Technician: AB/JN
 Date: 1/10/90

EYE IRRITATION SCORE: 410
 Calculated By: K Date 1-14-90
 Verified By: AB Date 1/24/90

NA - Not applicable.
 A - Petite hemorrhaging.
 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.
 PDS - Positive stain retention.
 NEG - Negative stain retention.

Reviewed by: K Date: 2-5-90

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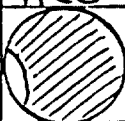
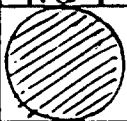
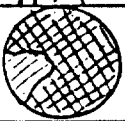
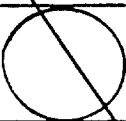
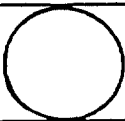
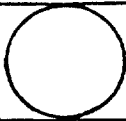
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PRIMARY EYE IRRITATION TEST OBSERVATIONS

Group: 1Test material: T-4416Test eye: Right

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 Hours

Animal No.	<u>F3</u>	<u>1165</u>	<u>1127</u>	<u>1194</u>			
Location of corneal lesions							
Tail ----- Head							
Cornea - Opacity		<u>J = 80%</u>	<u>J = 100%</u>	<u>J = 75%</u>			
Area		<u>1</u>	<u>1</u>	<u>2</u>			
Iris		<u>1F</u>	<u>1F</u>	<u>1F</u>			
Conjunctivae - Redness		<u>3B</u>	<u>3AB</u>	<u>3AB</u>			
Chemosis		<u>3</u>	<u>3</u>	<u>3</u>			
Discharge		<u>3^c</u>	<u>3^c</u>	<u>2^c</u>			
Sodium fluorescein exam		<u>POS 80%</u>	<u>POS 100%</u>	<u>POS 75%</u>			

EYE IRRITATION SCORE: 44.0Technician: GCalculated By: K Date 1-14-90Date: 1-11-90Verified By: GB Date 1/22/90

NA - Not applicable.
 A - Petite hemorrhaging.
 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.

① ENTRY ERROR K 1-11-90② CALCULATION ERROR K 1-14-90Reviewed by: SGDate: 2-9-90

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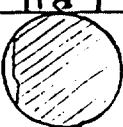
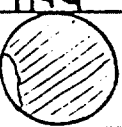
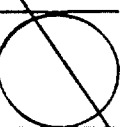
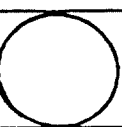
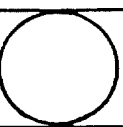
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PRIMARY EYE IRRITATION TEST OBSERVATIONS

Group: 1Test material: T-4416Test eye: Right

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

Observation Period: 48 Hrs

Animal No.	<u>F3</u>	<u>1165</u>	<u>1127</u>	<u>1194</u>			
Location of corneal lesions							
Tail ----- Head	<u>J=75%</u>	<u>J=95%</u>	<u>J=95%</u>				
Cornea - Opacity	<u>1</u>	<u>1</u>	<u>1</u>				
Area	<u>3</u>	<u>4</u>	<u>4</u>				
Iris	<u>1I</u>	<u>1I</u>	<u>1I</u>				
Conjunctivae - Redness	<u>3B</u>	<u>3B</u>	<u>3B</u>				
Chemosis	<u>2</u>	<u>2</u>	<u>2</u>				
Discharge	<u>2C</u>	<u>1C</u>	<u>1C</u>				
Sodium fluorescein exam	<u>NA</u>	<u>NA</u>	<u>NA</u>				

EYE IRRITATION SCORE: 36.0Technician: JHCalculated By: KJ Date 1-14-90Date: 1-12-90Verified By: AB Date 1/23/90

NA - Not applicable.

A - Petite hemorrhaging.

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: KJ Date: 2-5-90

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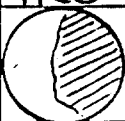
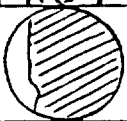
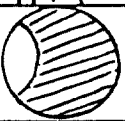
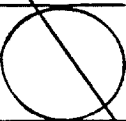
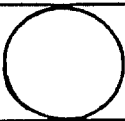
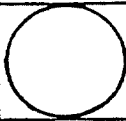
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PRIMARY EYE IRRITATION TEST OBSERVATIONS

Group: I
 Test material: T-4416
 Test eye: Right

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

Observation Period: 72 Hours

Animal No.	<u>F3</u>	<u>1165</u>	<u>1127</u>	<u>1194</u>			
Location of corneal lesions							
Tail ----- Head							
Cornea - Opacity		<u>J=55%</u>	<u>J=80%</u>	<u>J=80%</u>			
Area		<u>4</u>	<u>4</u>	<u>4</u>			
Iris		<u>15</u>	<u>15</u>	<u>15</u>			
Conjunctivae - Redness		<u>38</u>	<u>38</u>	<u>38</u>			
Chemosis		<u>2</u>	<u>2</u>	<u>2</u>			
Discharge		<u>2c</u>	<u>2c</u>	<u>1c</u>			
Sodium fluorescein exam		<u>Pos 55%</u>	<u>Pos 80%</u>	<u>Pos 80%</u>			

EYE IRRITATION SCORE: 38.3Technician: JHCalculated By: KJ Date 1-14-90Date: 1-12-90Verified By: JB Date 1/24/90

NA - Not applicable.
 A - Petite hemorrhaging.
 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.
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 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: KJ Date: 2-5-90

000860

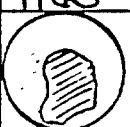
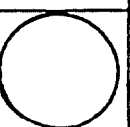
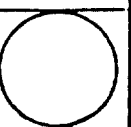
HLA: 91201741

PRIMARY EYE IRRITATION TEST OBSERVATIONS

Group: 1
 Test material: T-4416
 Test eye: Right

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

Observation Period: 96 Hours

Animal No.	<u>F3</u>	<u>1165</u>	<u>1127</u>	<u>1194</u>			
Location of corneal lesions							
Tail ----- Head	<u>J = 25%</u>	<u>J = 75%</u>	<u>J = 25%</u>				
Cornea - Opacity	<u>1</u>	<u>1</u>	<u>1</u>				
Area	<u>3</u>	<u>4</u>	<u>3</u>				
Iris	<u>1I</u>	<u>1I</u>	<u>1F</u>				
Conjunctivae - Redness	<u>3AB</u>	<u>3B</u>	<u>3AB</u>				
Chemosis	<u>2</u>	<u>2</u>	<u>2</u>				
Discharge	<u>1C</u>	<u>2C</u>	<u>1C</u>				
Sodium fluorescein exam	<u>NA</u>	<u>NA</u>	<u>NA</u>				

EYE IRRITATION SCORE: 34.3Technician: KCalculated By: KG Date 1-14-90Date: 1-14-90Verified By: GB Date 1/23/90

NA - Not applicable.

A - Petite hemorrhaging.

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.

ENTRY ERRORS KG 2-5-90Reviewed by: SG KG Date: KG 2-9-90

000861

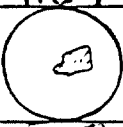
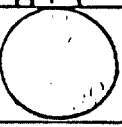
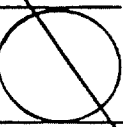
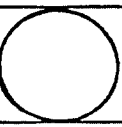
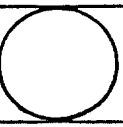
HLA: 91201741

PRIMARY EYE IRRITATION TEST OBSERVATIONS

Group: 1
 Test material: T-4416
 Test eye: Right

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: 7 DAYS

Animal No.	<u>F3</u>	<u>1165</u>	<u>1127</u>	<u>1194</u>			
Location of corneal lesions							
Tail ----- Head							
Cornea - Opacity	<u>J-15%</u> <u>2N</u>	<u>J-5%</u> <u>1</u>	<u>1N</u>				
Area	<u>1</u>	<u>1</u>	<u>2</u>				
Iris	<u>0</u>	<u>1I</u>	<u>0</u>				
Conjunctivae - Redness	<u>2B</u>	<u>2B</u>	<u>2B</u>				
Chemosis	<u>1</u>	<u>1</u>	<u>1</u>				
Discharge	<u>0</u>	<u>0</u>	<u>0</u>				
Sodium fluorescein exam	<u>Pos 15%</u>	<u>Pos 5%</u>	<u>NEG</u>				

Technician: W/NA
 Date: 1-17-90

EYE IRRITATION SCORE: 16.0
 Calculated By: SW Date 1-19-90
 Verified By: GB Date 1/23/90

NA - Not applicable.
 A - Petite hemorrhaging.
 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: K Date: 2-5-90

000862

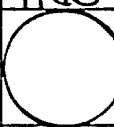
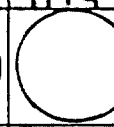
HLA: 91201741

PRIMARY EYE IRRITATION TEST OBSERVATIONS

Group: 1
 Test material: T-4416
 Test eye: Right

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.	<u>E3</u>	<u>1165</u>	<u>1127</u>	<u>1194</u>			
Location of corneal lesions							
Tail ----- Head							
Cornea - Opacity	<u>0</u>	<u>1</u>	<u>0</u>				
Area	<u>0</u>	<u>1</u>	<u>0</u>				
Iris	<u>0</u>	<u>I</u>	<u>0</u>				
Conjunctivae - Redness	<u>1</u>	<u>2</u>	<u>0</u>				
Chemosis	<u>0</u>	<u>1</u>	<u>0</u>				
Discharge	<u>0</u>	<u>0</u>	<u>0</u>				
Sodium fluorescein exam	<u>NEG</u>	<u>5% POS</u>	<u>NEG</u>				

Technician: AB
 Date: 1/24/90

EYE IRRITATION SCORE: 6.0
 Calculated By: GB Date 1/24/90
 Verified By: K Date 1-26-90

NA - Not applicable.
 A - Petite hemorrhaging.
 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: K Date: 2-5-90

000863

HLA: 91201741

PRIMARY EYE IRRITATION TEST OBSERVATIONS

Group: 1
 Test material: T-4416
 Test eye: Right

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

Observation Period: 21 DAYS

Animal No.	F3	1165	1127	1194			
Location of corneal lesions							
Tail ----- Head							
Cornea - Opacity	0	0	0				
Area	0	0	0				
Iris	0	0	0				
Conjunctivae - Redness	0	0	0				
Chemosis	0	0	0				
Discharge	0	0	0				
Sodium fluorescein exam	NEG	NEG	NEG				

Technician: K9
 Date: 1-31-90

EYE IRRITATION SCORE: 0.0
 Calculated By: K9 Date 1-31-90
 Verified By: NA Date 2-1-90

NA - Not applicable.
 A - Petite hemorrhaging.
 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: 2-9-90

000864