AR226-0244

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

SAMPLE NUMBER: 50503501
SAMPLE ENTERED: 05/15/85
REPORT PRINTED: 06/21/85

JANINE GLEASON
MINNESOTA MINING & MANUFACTURING COMPANY
TOXICOLOGY SERVICES
ST. PAUL, MN 55101

SAMPLE: T-3752

PURCHASE ORDER NUMBER: T357842, REL. #513

ENCLOSED: PRIMARY EYE IRRITATION - METHOD, SUMMARY
QAU REPORT
RAW DATA APPENDIX

SIGNED: Steven M. Glaza ..... 6-24-85 .....
STEVEN M. GLAZA DATE
STUDY DIRECTOR
ACUTE TOXICOLOGY

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 NUMBER: 50503501

SAMPLE: T-3752

OECD EYE IRRITATION

Objective: To determine the level of ocular irritation 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, Section 405, Acute Eye Irritation/ Corrosion, adopted May 12, 1981.

Test Material: T-3752
Physical Description: Brown granular solid
Purity and Stability: Sponsor has purity and stability determinations on file.

Test animal: Young adult rabbits (approximately 14 weeks of age) of the New Zealand White strain were procured, maintained individually in screen-bottom cages in temperature- and humidity-controlled quarters, provided continuous access to Purina High Fiber Rabbit Chow and water, and held for an acclimation period of at least 7 days.

Three acclimated animals, weighing from 2333 to 2504 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: 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. A bulk density determination was made to determine the weight equivalent of a 0.1 ml dose. Because individual doses should not exceed 0.10 g and the weight equivalent of 0.1 ml was 0.12 g, an individual dose of 0.1 g was weighed out for each animal.

Treatment: Each rabbit received 0.1 g 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.

SAMPLE NUMBER: 50503501

SAMPLE: T-3752

OECD EYE IRRITATION (CONTINUED)

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

At the 72-hour reading, 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.

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

*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., Topeka, Kansas, pp. 49-51 (1959).

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SAMPLE NUMBER: 50503501

SAMPLE: T-3752

OECD EYE IRRITATION (CONTINUED)

SUMMARY

Test Animal: Albino rabbits - New Zealand White
Source: Hazleton Research Products, Inc., Denver PA
Date Animals Received: 05/21/85

Temperature and Humidity of Animal Room: 21 to 23 Degrees C.; 46 to 64% Relative Humidity

Test Material: T-3752

Date Test Started: 05/29/85 Date Test Completed: 06/01/85

PRIMARY EYE IRRITATION SCORES*

OBSERVATION PERIOD	3 Rabbit Mean 0.1 g (Unwashed)
1 Hour:	10.7
24 Hours:	0.0
48 Hours:	0.0
72 Hours:	0.0

* The 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.

Comments: No pain response (vocalization) was elicited from any animal following instillation of the test material.

No corneal irritation was observed during the study.

SAMPLE NUMBER: 50503501

SAMPLE: T-3752

OECD EYE IRRITATION (CONTINUED)

Table 1
Individual Eye Irritation Scores

Animal Number	Observation Period	Cornea A	Cornea B	Score AXBX5	Iris A	Score A X 5	Conjunctivae A	Conjunctivae B	Conjunctivae C	Score (A+B+C)2
F08711	1 Hour	0	0	0	1	5	1	2	0	6
	24 Hours	0	0	0	0	0	0	0	0	0
	48 Hours	0	0	0	0	0	0	0	0	0
	72 Hours	0	0	0	0	0	0	0	0	0
F08705	1 Hour	0	0	0	0	0	1	1	0	4
	24 Hours	0	0	0	0	0	0	0	0	0
	48 Hours	0	0	0	0	0	0	0	0	0
	72 Hours	0	0	0	0	0	0	0	0	0
F08721	1 Hour	0	0	0	1	5	1	2	3	12
	24 Hours	0	0	0	0	0	0	0	0	0
	48 Hours	0	0	0	0	0	0	0	0	0
	72 Hours	0	0	0	0	0	0	0	0	0

Table 2
Sodium Fluorescein Examination

Animal Number	Observation Period: Pre-initiation	Observation Period: 72 Hours
F08711	NEG	NEG
F08705	NEG	NEG
F08721	NEG	NEG

NEG = No stain retention
POS = Positive stain retention (area of cornea involved).

References:

1. Organisation for Economic Cooperation and Development's Guidelines for Testing Chemicals, Section 405, Acute Eye Irritation/Corrosion, adopted May 12, 1981.

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 United States, Topeka, Kansas, pp. 49-51 (1959).

QUALITY ASSURANCE STATEMENT

Primary Eye Irritation Study in Rabbits

Study No. 50503501

The report as herein attached for the above-mentioned study has been reviewed by the assigned Quality Assurance Unit of Hazleton Laboratories America, Inc. in accordance with the Good Laboratory Practice Regulations as set forth in 21 CFR 58.35 (b) (6) (7). It has been found to accurately identify and/or describe the authorized methods and standard operating procedures followed in the conduct of the study and that the reported data accurately reflect the raw data of the laboratory study. Furthermore, the Quality Assurance Unit has conducted the following inspections of the testing facilities utilized in the conduct of this study and has submitted written reports of said inspections to the study director and/or management.

Date of Inspection	Type of Inspection	Date Issued to Management
5/21-23/85	Process Audit	5/23/85
6/10/85	Report Review	6/10/85

Diana E. Skalitzky

Diana E. Skalitzky
Inspector, Quality Assurance Unit

6/12/85
Date

PROTOCOL - ATTACHMENT 1

(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) Conjunctivae

(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 conjunctivae.

Primary Eye Irritation Test

Initial Sodium Fluorescein Exam and Animal Body Weights

Test Compound T-3752 RT No. 50503501

pH Result NA

Dose (g) 0.1g/Eye Room No. 161-3

Dose (ml) NA Dosed By CK Date 5/29/85

Date Animals Received 5-21-85 Reviewed By pgr Date 5/29/85

Source: Hazleton Research Products

Animal No.	Sex	Initial SF*	Vocalization Following Dosing	Animal Body Weights (g) Initiation	Day 7	Day 14	Day 21
FO-8711	♂	NEG	N	2333			
8705	♂	NEG	N	2427			
8721	♀	NEG	N	2504			
TECHNICIAN	CK	SRAM	CK	CK			
RECORDED BY	CK	SRAM	CK	CK			
DATE 1985	5/29	5-28	5-29	5-29			
SCALE USED			Ktron	15019			

* Sodium Fluorescein Examination

NEG = Negative

POS = Positive

NA = Not Applicable

Y = Yes

N = No

Time of Dosing: 10:45 AM CK 5-29-85

Time of first observation: 11:45 AM CK 5-29-85

Primary Eye Irritation Test Observations

Test Compound I-3752 RT No. 50503501

Test Eye Right Group NA

NA Washed NA Seconds following instillation of test material, the test eye was washed with NA ml of NA for NA seconds ✓ Unwashed

OBSERVATION PERIOD: 1 hour

Animal No./ Ear Tag No. F0-	8711	8705	8721			
Location of Corneal Lesions Tail <----------> Head	○	○	○	○	○	○
Ocular Structure						
Cornea - Opacity	0	0	0			
Area	0	0	0			
Iris	1 INJ	0	1 INJ			
Conjunctivae -						
Redness	1	1	1			
Chemosis	2	1	2			
Discharge	0	0	3 A			
Sodium Fluorescein Exam	NA	NA	NA			
Technician	CK	CK	CK			
Recorded By	CK	CK	CK			
Date 1985	5/29	5/29	5/29			

A = Purulent Discharge
B = Clear Discharge
C = Petite Hemorrhage
D = Blanching
INJ = Injected
NEG = Negative
POS = Positive

E = Corneal Epithelial Damage, Peeling
F = Corneal Epithelial Damage, Piling
G = Corneal Epithelial Damage, Pitting
H = Pannus
I = Corneal Neovascularization
NA = Not Applicable

Reviewed By: slh Date: 6-3-85 Eye Irritation Score: 10.7 slh 6-3-85

(1311A)

Primary Eye Irritation Test Observations

Test Compound T-3752 RT No. 50503501

Test Eye Right Group NA

NA Washed NA Seconds following instillation of test material, the test eye was washed with NA ml of NA for NA seconds ✓ Unwashed

OBSERVATION PERIOD: 24 hours

Animal No./ Ear Tag No. FO-	8711	8705	8701			
Location of Corneal Lesions Tail <----------> Head	○	○	○	○	○	○
Ocular Structure						
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	NA	NA	NA			
Technician	MP	MP	MP			
Recorded By	MP	MP	MP			
Date 1985	5/30	5/30	5/30			

A = Purulent Discharge
B = Clear Discharge
C = Petite Hemorrhage
D = Blanching
INJ = Injected
NEG = Negative
POS = Positive

E = Corneal Epithelial Damage, Peeling
F = Corneal Epithelial Damage, Piling
G = Corneal Epithelial Damage, Pitting
H = Pannus
I = Corneal Neovascularization
NA = Not Applicable

Reviewed By: slh Date: 6-3-85 Eye Irritation Score: D.O slh

(1311A)

Primary Eye Irritation Test Observations

Test Compound I-3752 RT No. 50503501

Test Eye Right Group N/A

N/A Washed N/A Seconds following instillation of test material, the test eye was washed with N/A ml of N/A for N/A seconds ✓ Unwashed

OBSERVATION PERIOD: 48 hours

Animal No./ Ear Tag No. FO-	8711	8705	8721			
Location of Corneal Lesions Tail <----------> Head	○	○	○	○	○	○
Ocular Structure						
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	NA	NA	NA			
Technician	CK	CK	CK			
Recorded By	CK	CK	CK			
Date 1985	5-31	5-31	5-31			

A = Purulent Discharge
B = Clear Discharge
C = Petite Hemorrhage
D = Blanching
INJ = Injected
NEG = Negative
POS = Positive

E = Corneal Epithelial Damage, Peeling
F = Corneal Epithelial Damage, Piling
G = Corneal Epithelial Damage, Pitting
H = Pannus
I = Corneal Neovascularization
NA = Not Applicable

Reviewed By: slh Date: 6-3-85 Eye Irritation Score: D.D slh

(1311A)

001088

Primary Eye Irritation Test Observations

Test Compound T-3752 RT No. 50503501

Test Eye Right Group N/A

N/A Washed N/A Seconds following instillation of test material, the test eye was washed with N/A ml of N/A for N/A seconds ✓ Unwashed

OBSERVATION PERIOD: 72 hours

Animal No./ Ear Tag No. FO-	8711	8705	8721			
Location of Corneal Lesions Tail <----------> Head	○	○	○	○	○	○
Ocular Structure						
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	SAM	SAM	SAM			
Recorded By	SAM	SAM	SAM			
Date 1985	6/1	6/1	6/1			

A = Purulent Discharge
B = Clear Discharge
C = Petite Hemorrhage
D = Blanching
INJ = Injected
NEG = Negative
POS = Positive

E = Corneal Epithelial Damage, Peeling
F = Corneal Epithelial Damage, Piling
G = Corneal Epithelial Damage, Pitting
H = Pannus
I = Corneal Neovascularization
NA = Not Applicable

Reviewed By: SLH Date: 6-3-85 Eye Irritation Score: 0.0 SLH

(1311A)

HAZLETON LABORATORIES AMERICA, INC.
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PROTOCOL TP2072

Primary Eye Irritation Study in Rabbits (OECD Guidelines)

Study No. 50503501

for

3M
St. Paul, Minnesota

by

Hazleton Laboratories America, Inc.
Life Sciences Division
3301 Kinsman Boulevard
Madison, Wisconsin 53704

May 21, 1985

PROTOCOL TP2072

Primary Eye Irritation Study in Rabbits
(OECD Guidelines)

Study No.	50503501
Study Location	Hazleton Laboratories America, Inc. Life Sciences Division 3301 Kinsman Boulevard Madison, Wisconsin 53704
Test Material	T-3752
Sponsor's Representative	Janine Gleason
Study Director	Steven M. Glaza
Proposed Timetable	
Starting Date	Week of May 27, 1985
Completion Date	Week of June 3, 1985
Final Report Date	Week of June 24, 1985

OBJECTIVE

The objective of this study is to determine the level of irritation produced following a single exposure of a test material to one eye of albino rabbits. All aspects of this study will conform to the Organisation for Economic Cooperation and Development's Guidelines for Testing Chemicals, Section 405, Acute Eye Irritation/Corrosion, Adopted May 12, 1981[1] and the Principles of Good Laboratory Practice.[2] All procedures will be done according to Hazleton Laboratories America, Inc. (HLA) Standard Operating Procedures (SOPs) referenced in this protocol.

TEST MATERIAL

Identification

Test Material:	T-3752.
Physical Description:	Brown granular solid.
Purity and Stability:	Sponsor has purity and stability determinations on file.
Storage Conditions:	Store at room temperature.
Test Material Retention:	Any unused test material will be returned to the Sponsor 30 days after issuance of final report.
Safety Precautions:	Laboratory personnel will take the normal necessary precautions in handling a substance of unknown toxicity. Laboratory clothing, latex gloves, safety glasses, and a particle mask approved for toxic dusts must be worn.

TEST SYSTEM

Test Animal

Young adult albino rabbits of either sex of the New Zealand White strain, approximately 14 weeks of age, will be obtained from Hazleton Research Products, Inc., Denver, Pennsylvania. An adequate number of extra animals will be purchased so that no animal in obviously poor health is placed on test. The New Zealand White albino rabbit is the animal of choice based upon its large orbit and nonpigmented iris.

Acclimation

Upon receipt, the animals will be taken to a designated animal room where they will be acclimated for at least 1 week before being placed on test (OP-GENB 36). During acclimation, the animals will be examined for clinical abnormalities indicative of health problems (e.g., diarrhea, ectoparasites, rough hair coat, nasal or ocular discharge, evidence of injury, etc.). Any animals regarded as unsuitable for the study purposes because of poor physical condition will not be released from acclimation and the reason(s) will be documented.

Identification

Each animal in the study will be assigned a permanent identification number and will be identified with a metal ear tag (OP-GENB 24). All data collected from an animal will be recorded and filed under its identification number.

Housing and Maintenance

The following environmental conditions will be maintained in the animal room used for this study (OP-TARC 230).

- Temperature: 21°C ±2°
- Relative humidity: 50% ±20%
- Air change: At least 10 changes an hour of filtered 100% outside air
- Light cycle: 12 hours light/12 hours dark

Temperature and humidity will be monitored throughout the study. Variations from prescribed environmental conditions will be documented.

Animal husbandry and housing at HLA comply with standards outlined in the "Guide for the Care and Use of Laboratory Animals."[3] Care will be taken to ensure that the animals are not disturbed for reasons other than data collection and routine maintenance. The animals will be housed individually in screen-bottom stainless steel cages (heavy gauge) held on racks, with absorbent pan liners in the urine- and feces-collecting pans. Pan liners will be changed at least three times each week.

Feed and water will be provided ad libitum. The diet will be Purina High Fiber Rabbit Chow. No contaminants are expected to be present in the feed or water which would interfere and affect the results of the study.

Study Design

Three rabbits will be selected at random based upon health and a body weight of 2.0 to 3.5 kg.

PROCEDURES

Preparation and Administration of Test Material

The rabbits' eyes will be examined using fluorescein dye procedures within 24 hours prior to test material administration. Only animals with no sign of

corneal injury or eye abnormalities will be utilized. One eye of each animal will be treated with the test material and the other eye will serve as the untreated control.

Each rabbit will receive 0.1 g (or the weight equivalent of 0.1 mL) of solid test material. If necessary, the solid test materials will be finely ground into a dust or powder. The test material will be placed into the everted lower lid of the rabbit's eye. The upper and lower lids are then to be gently held together for 1 second before releasing to prevent loss of material. The eyes of the rabbits will remain unflushed for 24 hours following instillation of the test material. After 24 hours, a washout may be used if considered appropriate.

Reason for Route of Administration

Historically, the route of choice based on the method of Draize.[4]

Observations

The treated eyes of all animals will be examined for ocular irritation at 1, 24, 48, and 72 hours after treatment. If no irritation or injury is present at 72 hours, the study will be terminated. If irritation is present at 72 hours, additional observations will be made at 96 hours and at 7, 14, and 21 days. If at any of these time points there is no irritation, the study will be terminated. If injury is still present at 21 days, the Sponsor will be contacted to determine whether the study should continue or be terminated. After recording the 24-hour observations, sodium fluorescein may be used to aid in revealing possible corneal injury. Irritation will be graded and scored using the Draize technique (Attachment 1).[4] All eye abnormalities will be recorded.

All animals that have a damaged eye producing undue stress or discomfort will be sacrificed for humane reasons after consulting with the Sponsor.

Body weights will be recorded prior to test material administration and at weekly intervals throughout the study. Observations and body weights will be recorded in the study notebook.

Pathology

All animals, whether dying or sacrificed at study termination, will be discarded.

Report

The final report will present a description of the test material, a description of the test system, dates of study initiation and termination, a summary table showing the irritation data at each observation period, and any special observations that were recorded.

Maintenance of Raw Data and Records

Original data or copies thereof will be available at HLA to facilitate auditing the study during its progress and prior to acceptance of the final report. When the final report is completed, all original paper data, as well as the final report, will be retained in the archives of HLA, Madison, Wisconsin (OP-GEN 44).

REFERENCES

1. "Acute Eye Irritation/Corrosion," OECD Guidelines for Testing Chemicals, Section 405 (May 12, 1981).

2. Organisation for Economic Cooperation and Development's Principles of Good Laboratory Practice, Annex 2, 1981.

3. DHEW Publications No. (NIH) 78-23 (1978).

4. 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., Topeka, Kansas, pp. 49-51 (1959).

PROTOCOL APPROVAL

Janine Gleason

Janine Gleason
Sponsor's Representative
3M

5/24/85
Date

Steven M. Glaza

Steven M. Glaza
Study Director
Group Leader, Acute Toxicology
Hazleton Laboratories America, Inc.

5-22-85
Date

(1109S/tji)

PROTOCOL - ATTACHMENT 1

(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) Conjunctivae

(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 conjunctivae.