

FINAL REPORT

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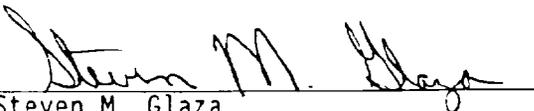
HWI Number: 01104198

Sample: T-5298

Study Title:

Primary Eye Irritation/Corrosion
Study of T-5298 in Rabbits
(OECD Guidelines)

Signed:


Steven M. Glaza
Study Director
Acute Toxicology

Date

1-25-91

Exhibit
2787

State of Minnesota v. 3M Co.,
Court File No. 27-CV-10-28862

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OBJECTIVE

The objective of this study was to assess the relative level of irritation/corrosion produced following a single exposure of a test material to one eye of albino rabbits.¹

TEST MATERIAL

Identification

The test material was identified as T-5298 and described as an off-white 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 discarded according to Hazleton Wisconsin (HWI) Standard Operating Procedure (SOP).

Safety Precautions

Normal handling procedures were used according to HWI SOP.

TEST SYSTEM

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 HWI 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.

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Two male and one female acclimated animals, weighing from 2,502 to 2,594 g, were chosen at random and maintained during the study in the same manner as for the acclimation period. The animals' eyes were examined on the day before test material administration using sodium fluorescein dye procedures. Only those animals with no sign of ocular injury or irritation were used. Animals were identified by animal number and corresponding ear tag.

Justification for Species Selection

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

PROCEDURES

Preparation of Test Material

The test material was administered as received. The pH of the test material was determined to be 6.8.

Treatment

Each rabbit received 0.1 mL of the undiluted test material placed into the everted lower lid of the right eye, with the left 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.

Observations

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

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

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Animals were weighed just before test material administration and at weekly intervals throughout the study.

Termination

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

Statistical Analyses

No statistical analysis 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 HWI.

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SUMMARY OF RESULTS

Test Animal: Albino Rabbits - Hra:(NZW)SPF
Source: Hazleton Research Products, Inc., Kalamazoo MI
Date Animals Received: 12/05/90

Start Date (In-life): 12/27/90

End Date (In-Life): 01/10/91

Average Primary Eye Irritation Scores*

<u>Observation Period</u>	<u>Average Score</u>
1 Hour	15.0
24 Hour	8.0
48 Hour	7.3
72 Hour	4.7
96 Hour	4.7
Day 7	1.3
Day 14	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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Table 1
Individual Eye Irritation Scores

Animal Number	Sex	Cornea		Iris	Conjunctivae			Total Score*
		A	B	C	D	E	F	
<u>1 Hour</u>								
F35136 ^u	M	0	0	1 ⁱ	2 ^b	1	2 ^c	15
F35137 ^u	M	0	0	1 ⁱ	2 ^b	2	1 ^c	15
F35133 ^t	F	0	0	1 ⁱ	2 ^b	2	1 ^c	15
							Mean	15.0
<u>24 Hours</u>								
F35136	M	0	0	0	2	1	1 ^c	8
F35137	M	0	0	0	2 ^b	1	2 ^c	10
F35133	F	0	0	0	2 ^b	0	1 ^c	6
							Mean	8.0
<u>48 Hours</u>								
F35136	M	0	0	0	2	1	2 ^c	10
F35137	M	0	0	0	2	1	2 ^c	10
F35133	F	0	0	0	1	0	0	2
							Mean	7.3

Cornea

A - Degree of opacity
B - Area of involvement

Iris

C - Degree of iridal irritation

Conjunctivae

D - Redness
E - Chemosis
F - Discharge

* = (A x B x 5) + (C x 5) + (D + E + F) x 2.

b - Blanching.

c - Clear discharge.

i - Injected iris.

t - No pain response after test material instillation.

u - Excessive pawing at the treated eye after test material instillation.

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Table 1 (Continued)
 Individual Eye Irritation Scores

Animal Number	Sex	Cornea		Iris	Conjunctivae			Total Score*
		A	B	C	D	E	F	
<u>72 Hours</u>								
F35136	M	0	0	0	2	1	1 ^c	8
F35137	M	0	0	0	2	1	0	6
F35133	F	0	0	0	0	0	0	0
							Mean	4.7
<u>96 Hours</u>								
F35136	M	0	0	0	2	1	1 ^c	8
F35137	M	0	0	0	2	1	0	6
F35133	F	0	0	0	0	0	0	0
							Mean	4.7
<u>Day 7</u>								
F35136	M	0	0	0	1	0	0	2
F35137	M	0	0	0	1	0	0	2
F35133	F	0	0	0	0	0	0	0
							Mean	1.3
<u>Day 14</u>								
F35136	M	0	0	0	0	0	0	0
F35137	M	0	0	0	0	0	0	0
F35133	F	0	0	0	0	0	0	0
							Mean	0.0

Cornea

A - Degree of opacity
 B - Area of involvement

Iris

C - Degree of iridal
 irritation

Conjunctivae

D - Redness
 E - Chemosis
 F - Discharge

* = (A x B x 5) + (C x 5) + (D + E + F) x 2.
 c - Clear discharge.



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Table 2
Sodium Fluorescein Examination

Animal Number	Observation Period			
	Preinitiation	72 Hour	Day 7	Day 14
F35136	NEG	NEG	NEG	NEG
F35137	NEG	NEG	NEG	NEG
F35133	NEG	NEG	NEG	NEG

NEG - No stain retention.

DISCUSSION

The test material, T-5298, when evaluated for its primary eye irritation potential in rabbits, produced iridal involvement and moderate conjunctival irritation. All eyes had returned to a normal appearance by Day 14 after treatment.

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).