

Industrial **BIO-TEST Laboratories, Inc.**
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REPORT TO
E. I. DU PONT DE NEMOURS & COMPANY
EYE IRRITATION TESTS WITH
H-8580
IN ALBINO RABBITS

[REDACTED]
FEBRUARY 12, 1974
[REDACTED]

Company Sanitized. Does not contain TSCA CBI

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I. Introduction

At the request of E. I. du Pont de Nemours & Company washed and unwashed eye irritation tests were conducted with a sample identified as H-8580.

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II. Summary

The results of the eye irritation tests conducted with H-8580 are summarized below.

<u>Test Conditions</u>	<u>Maximum Irritation Score</u>	<u>Rating</u>
Washed Eye 20-Second Contact Period	13.0/110.0	Minimally Irritating
Unwashed Eye	19.0/110.0	Mildly Irritating

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by:

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III. Investigational Procedure

Young albino rabbits of the New Zealand strain were used to evaluate the eye irritating properties of the test material. The test method was patterned after that of Draize et al.*

The test material was instilled into the conjunctival sac of the right eye of each of two rabbits. After an exposure period of 20 seconds, the right eye of one animal was rinsed for one minute with 150 ml of tap water while the right eye of the other animal remained unwashed. At each scoring interval the cornea, iris, and palpebral conjunctiva were examined and graded for irritation and injury according to a standard scoring system*. The maximum possible score at any one examination and scoring period is 110 points, which indicates maximal irritation and damage to all three ocular tissues. Zero score indicates no irritation. The scoring system is presented in Table I. In this scoring system, special emphasis is placed upon irritation or damage to the cornea, while less emphasis is placed upon damage to the iris and conjunctiva.

After the completion of the test, the scores were analyzed, and a descriptive eye irritation rating was assigned to the test material. The criteria used for assignment of the descriptive rating are the frequency, the extent, and the persistence of irritation or damage which occur to the three ocular tissues.

* Draize, John H., Woodard, Geoffrey, and Calvery, Herbert O., "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes," J. Pharm. & Exp. Ther. 82, 377 (1944).

TABLE I

Eye Irritation Test - Albino Rabbits

Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Draize Grade
Cornea	<u>Opacity (A)</u>	
	Opacity - Degree of density (area which is most dense is taken for reading).	
	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
	<u>Area of Cornea Involved (B)</u>	
	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 equals A x B x 5		Total maximum = 80
Iris	<u>Values (A)</u>	
	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
Score equals A x 5		Total maximum = 10

TABLE I. continued

Eye Irritation Test - Albino Rabbits

Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Draize Grade
Conjunctiva	<u>Redness (A)</u>	
	Redness (refers to palpebral conjunctiva only).	
	Vessels definitely injected above normal.	1
	More diffuse, deeper crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	<u>Chemosis (B)</u>	
	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
	<u>Discharge (C)</u>	
	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

Note: The maximum total score is the sum of all scores obtained for the cornea, iris, and conjunctiva.

The rating is arrived at by selecting the maximum irritation score at one, 4, 24, 48 or 72 hours after instillation. If the rate of dissipation of injury does not meet the requirements defined for the descriptive rating appropriate for a particular numerical score, the descriptive rating is raised by one or more levels. The rating system is presented in Table II.

TABLE II

Eye Irritation Test - Albino Rabbits

Classification of Test Materials
Based on Eye Irritation Properties

Rating	Range	Definition
Non-Irritating	0.0 - 0.5	To maintain this rating, score at the 24-hour reading must be zero; otherwise, increase rating one level.
Practically Non-Irritating	>0.5 - 2.5	To maintain this rating, score at the 24-hour reading must be zero; otherwise, increase rating one level.
Minimally Irritating	>2.5 - 15.0	To maintain this rating, score at the 72-hour reading must be zero; otherwise, increase rating one level.
Mildly Irritating	>15.0 - 25.0	To maintain this rating, score at the 7-day reading must be zero; otherwise, increase rating one level.
Moderately Irritating	>25.0 - 50.0	To maintain this rating, score at 7 days must be ≤ 10 , otherwise increase rating one level.
Severely Irritating	>50.0 - 80.0	To maintain this rating, score at 7 days must be ≤ 30 , otherwise increase rating one level.
Extremely Irritating	>80.0 - 110.0	

IV. Results

The results of the eye irritation tests are presented in Table III

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TABLE III

Eye Irritation Test - Albino Rabbits

TEST MATERIAL: H-8580

FORM ADMINISTERED: Instillation (0.1 ml, Undiluted)

DESCRIPTIVE RATING:

WASHED EYE: Minimally Irritating

UNWASHED EYE: Mildly Irritating

Test Conditions	Tissue	1 Hour	4 Hours	24 Hours	48 Hours	72 Hours	96 Hours	7 Days
Washed Eye, 20-Second Contact Period*	Cornea (D-A)	0	0	0	0	0	0	0
	Iris	5	0	0	0	0	0	0
	Conjunctiva (R-S-D)	8 (2-1-1)	12 (2-2-2)	8 (2-1-1)	2 (1-0-0)	0	0	0
	Total	13	12	8	2	0	0	0
Unwashed Eye	Cornea (D-A)	0	0	0	0	0	0	0
	Iris	5	5	0	0	0	0	0
	Conjunctiva (R-S-D)	12 (2-2-2)	14 (2-2-3)	8 (2-1-1)	2 (1-0-0)	0	0	0
	Total	17	19	8	2	0	0	0

Note: Sterile sodium fluorescein strips were used at each scoring interval starting with the 24-hour scoring to verify the presence or absence of corneal irritation.

* The eye was washed for one minute with running tap water (approximately 150 ml of water).