Study Title

Eye Irritation Test with H-20056 in Rabbits

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Performing Laboratory

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[redacted]

Laboratory Project ID

Haskell Laboratory Report No. 309-93

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was conducted according to EPA TSCA Good Laboratory Practice Standards (40 CFR 792). Any areas of noncompliance are documented in the study records. No deviations existed that affected the validity of the study.

Submitter: E. I. du Pont de Nemours and Company

Sponsor: DuPont Chemicals
E. I. du Pont de Nemours and Company

Study Director: John W. Sarver 5/4/93
John V. Sarver
Toxicologist

GENERAL INFORMATION

Substance Tested:	[redacted]
Synonyms/Codes:	• H-20056 [redacted]
Physical Form:	[redacted]
Composition:	[redacted]
Sponsor:	DuPont Chemicals E. I. du Pont de Nemours and Company Wilmington, Delaware
Study Initiated - Completed:	3/22/93 - 5/4/93
In Life Phase Initiated - Completed:	3/23/93 - 3/26/93

Company Sanitized. Does not contain TSCA CBI

Eye Irritation Test with H-20056 in Rabbits

SUMMARY

H-20056 was evaluated for acute eye irritation potential in 2 rabbits. Approximately 0.01 mL of the test substance was instilled into the lower conjunctival sac of the right eye of each rabbit. Approximately 20 seconds after instillation, the treated and control eyes of 1 rabbit were washed. The treated and control eyes of the remaining rabbit were not washed. The eyes of the rabbits were examined on the day of treatment and on days 1, 2, and 3 following treatment.

H-20056 produced mild conjunctival redness and slight chemosis in both treated rabbit eyes and was observed only at the 1 hour evaluation. Both treated eyes were normal by 4 hours after treatment.

Under the conditions of this study, H-20056 was a mild, transient eye irritant.

Work by: Tracy A. Filliben
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Revieved and
Approved for Issue: John W. Sarver 5/4/93
John W. Sarver
Study Director

JWS/alw

Company Sanitized. Does not contain TSCA CBI

QUALITY ASSURANCE DOCUMENTATION

(H-20056)

Dates of Inspection:

Conduct - 3/23/93

Records, Report(s) - 4/30/93

Date(s) Findings Reported to:

Study Director - 4/30/93

Management - 5/4/93

Reported by: Paul Jeffrey Chapman 5/4/93

P. Jeff Chapman
Quality Assurance Auditor

Date

INTRODUCTION

The purpose of this study was to evaluate the acute eye irritation potential of H-20056 in young adult rabbits. This study was conducted according to the applicable EPA Good Laboratory Practice Standards. Areas of noncompliance are documented in the study records. No deviations existed that affected the validity of the study.

MATERIALS AND METHODS

A. Animal Husbandry

Young adult male and female New Zealand White rabbits were received from Hare Marland, Hewitt, New Jersey. The rabbits were housed singly in suspended, stainless steel, wire-mesh cages. Each rabbit was assigned a unique identification number which was recorded on a card affixed to the cage. The rabbits were offered approximately 125 grams of Purina Certified High Fiber Rabbit Chow® #5325 daily during the study. Water was available ad libitum. Rabbits were quarantined, weighed, and observed for general health for approximately 2 weeks. Animal rooms were maintained on a timer-controlled, 12-hour light/12-hour dark cycle. Environmental conditions of the rooms were targeted for a temperature of 20°C ± 2°C and relative humidity of 50% ± 10%. Excursions outside these ranges were judged to have been of insufficient magnitude and/or duration to have adversely affected the validity of the study.

B. Protocol

On the day of treatment, the eyes of 1 male and 1 female New Zealand White rabbits were examined using illumination, magnification, and fluorescein dye. These animals were selected for this study as they showed no evidence of preexisting corneal or conjunctival injury or irritation and were judged to be in good health. These rabbits weighed 2907 and 3303 grams, respectively, on the day of treatment.

Approximately 0.01 mL of H-20056 was introduced into the lower conjunctival sac of each right eye. The left eye of each rabbit was not treated with the test substance and served as a control. Approximately 20 seconds after the test substance was administered, both eyes of 1 rabbit were rinsed for approximately 1 minute with room temperature water. The treated and control eyes of the remaining rabbit were not washed. Each rabbit was observed for approximately 30 to 60 seconds before being returned to its cage and any abnormal behavior was noted. In the absence of visible evidence to the contrary, the test substance was assumed to be stable under the conditions of administration.

Approximately 1 and 4 hours, and 1, 2, and 3 days after H-20056 was administered, the rabbits were examined for evidence of eye irritation. At each of these observation periods, eyes were examined using illumination and magnification and scored for ocular reactions according to the Draize scale (presented in Table 1). Eyes were also observed for any unusual responses to treatment such as pannus, blistering of the conjunctiva, ulceration, or other effects indicative of corrosive action. Control eyes were not scored. These untreated eyes were used for comparison and were considered "normal" relative to the treated eye.

C. Records Retention

All raw data and the final report will be stored in the archives of Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours and Company, Newark, Delaware or in the DuPont Records Management Center, Wilmington, Delaware.

RESULTS

H-20056 produced mild conjunctival redness and slight chemosis in both treated rabbit eyes and was observed only at the 1 hour evaluation. Both treated eyes were normal by 4 hours after treatment. Individual eye irritation scores are presented in Tables 2 and 3.

CONCLUSION

Under the conditions of this study, H-20056 was a mild, transient eye irritant.

If these test scores are to be used for EEC/OECD classification, according to the guide to the labeling of dangerous substances published in the Official Journal of European Communities (EEC Directive 91/325, Annex VI), H-20056 probably could be classified as "NON-IRRITANT" until further data is available.

TABLE 1

DRAIZE[1] SCALE FOR SCORING OCULAR LESIONS

(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 (Slight)
	Easily discernible translucent areas, details of iris slightly obscured	2 (Mild)
	Opalescent areas, no details of iris visible, size of pupil barely discernible	3 (Moderate)
	Opaque, iris invisible	4 (Severe)
	(B) Area of cornea involved	
	One quarter (or less) but not zero	1 (Localized)
	Greater than one quarter, but less than half	2 (Small)
	Greater than one half, but less than three quarters	3 (Moderate)
	Greater than three quarters, up to whole area	4 (Generalized)
(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 (Moderate)
	No reaction to light, hemorrhage, gross destruction (any or all of these)	2 (Severe)
(3)	**Conjunctiva**	
	(A) Redness (refers to palpebral and bulbar conjunctiva excluding cornea and iris)	
	Vessels normal	0
	Vessels definitely injected above normal	1 (Mild)
	More diffuse, deeper crimson red, individual vessels not easily discernible	2 (Moderate)
	Diffuse beefy red	3 (Severe)

TABLE 1 (Cont'd)

DRAIZE SCALE FOR SCORING OCULAR LESIONS

(B)	Chemosis	
	No swelling	0
	Any swelling above normal (includes nictitating membrane)	1 (Slight)
	Obvious swelling with partial eversion of lids	2 (Mild)
	Swelling with lids about half closed	3 (Moderate)
	Swelling with lids about half closed to completely closed	4 (Severe)
(C)	Discharge	
	No discharge	0
	Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)	1 (Minimal)
	Discharge with moistening of the lids and hairs just adjacent to lids	2 (Moderate)
	Discharge with moistening of the lids and hairs, and considerable area around the eye	3 (Copious)

[1] Draize, J. H., "Dermal Toxicity." Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. The Editorial Committee of the Association of Food and Drug Officials of the United States, Austin, Texas, 1959, pp. 46-59.

TABLE 2

EYE IRRITATION REACTIONS OBSERVED IN THE UNWASHED RABBIT EYE AFTER TREATMENT WITH H-20056

Rabbit Number 27857	1 Hour	4 Hours	1 Day	2 Days	3 Days
Cornea					
Opacity	0	0	0	0	0
Area	0	0	0	0	0
Iris	0	0	0	0	0
Conjunctiva					
Redness	1	0	0	0	0
Chemosis	1	0	0	0	0
Discharge	0	0	0	0	0

TABLE 3

EYE IRRITATION REACTIONS OBSERVED IN THE WASHED RABBIT EYE AFTER TREATMENT WITH H-20056

Rabbit Number 27828	1 Hour	4 Hours	1 Day	2 Days	3 Days
Cornea					
Opacity	0	0	0	0	0
Area	0	0	0	0	0
Iris	0	0	0	0	0
Conjunctiva					
Redness	1	0	0	0	0
Chemosis	1	0	0	0	0
Discharge	0	0	0	0	0