FOR DU PONT USE ONLY

Du Pont HLR 801-88

Study Title

Skin Irritation Test in Rabbits of [redacted]

Author

William J. Brock

Study Completed On

December 14, 1988

Performing Laboratory

E. I. du Pont de Nemours and Company, Inc.
Haskell Laboratory for Toxicology and Industrial Medicine
Elkton Road, P. O. Box 50
Newark, Delaware 19714

[redacted]

Laboratory Project ID

Haskell Laboratory Report No. 801-88

GENERAL INFORMATION

Material Tested:	[redacted]
Medical Research No.:	[redacted]
Haskell No.:	17,503
Physical Form:	White powder
Purity:	[redacted]
Synonyms:	[redacted]
Contaminants:	[redacted]
Submitter's Notebook No.:	[redacted]
Stability:	The test material was assumed to be stable under the conditions of administration.
Sponsor:	Chemicals and Pigments Department E. I. du Pont de Nemours and Company, Inc. Wilmington, Delaware
Material Submitted By:	[redacted] Chemicals and Pigments Department E. I. du Pont de Nemours and Company, Inc. Jackson Laboratory Deepwater, New Jersey
In-Life Phase Initiated - Completed:	11/15/88 - 11/17/88
Notebook:	[redacted]

There are 7 pages in this report.

Distribution: [redacted]

Skin Irritation Test in Rabbits of

[redacted]

SUMMARY

[redacted] solids) was evaluated for acute skin irritation potential in 4 male and 2 female rabbits. No erythema or edema was observed in any of the treated rabbits throughout the study. Under the conditions of this study, [redacted] was not a skin irritant.

Work by: Cindy H Hahn 12/12/88
Cindy H. Hahn
Technician

Study Director: William J Brock 12/12/88
William J. Brock, Ph.D.
Research Toxicologist
Acute and Developmental Toxicology Division

Reviewed and
Approved for Issue: William J Brock 12/14/88
William J. Brock, Ph.D.
Study Director

WJB:jjb:HLR110.6

QUALITY ASSURANCE DOCUMENTATION

STUDY: [redacted] Skin Irritation Test in Rabbits of [redacted]
H# 17,503

AUDITS:

Items Audited	Audit Dates
Exposure of test system to test article (dosing)	11/15/88

SHORT-TERM AUDIT REPORT NUMBER: [redacted]
DATE FINDINGS REPORTED TO MANAGEMENT AND STUDY DIRECTOR: 12/13/88

Reported by: Joseph C. Hamill 12/13/88
Joseph C. Hamill Date
Quality Assurance Auditor

INTRODUCTION

The purpose of this study was to evaluate the skin irritation potential of [redacted] when applied to the clipped, intact skin of New Zealand White rabbits. This study was conducted according to the applicable EPA Good Laboratory Practice Regulations. Areas of noncompliance are documented in the study records. No deviations existed that significantly 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. Purina Certified High Fiber Rabbit Chow® #5325 and water were available ad libitum except as noted under Protocol. 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%. Any excursions outside these ranges were of small magnitude and/or brief duration and did not adversely affect the validity of the study.

B. Protocol

On the day prior to study initiation, the hair of 4 male and 2 female New Zealand White rabbits was closely clipped to expose the skin from the scapular to the lumbar region of the back. The rabbits weighed from 2942 to 3460 grams on the day of treatment.

Each rabbit was placed into a stock which had been fitted with a piece of rubber sheeting, approximately 8" x 18". The rabbits remained in the stocks throughout the exposure period and during that time did not have access to food or water. A 0.5 gram aliquot of [redacted] moistened with dimethyl phthalate (DMP), was applied directly to a 2-inch gauze square that was then placed on the test site. The patch was held in place with tape. The rubber sheeting was then wrapped around the animal and secured with clips to retard evaporation and to keep the test material in contact with the skin without undue pressure.

Approximately 24 hours after application of the test material, the rubber sheeting was loosened, and the skin at the corners of the gauze squares was marked with a waterproof pen; wrappings and gauze squares were then removed. The test sites were gently washed with warm water to remove excess test material. The skin was gently patted dry and the animals were returned to their cages. The material was moistened with DMP, but did not dissolve in DMP. Therefore, some of the compound may have fallen from the test site during the exposure period.

Approximately 24 and 48 hours after application of the test material, the test sites were evaluated for erythema, edema and other evidence of dermal effects and were scored according to the Draize scale (Table I). The adjacent areas of the untreated skin were used for comparison.

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, Inc., Newark, Delaware or in the Du Pont Records Management Center, Wilmington, Delaware.

RESULTS AND CONCLUSIONS

No erythema or edema was observed in any of the rabbits treated with [redacted]. Under the conditions of this study, [redacted] was not a skin irritant.

TABLE I

DRAIZE[1] SCALE FOR SCORING PRIMARY SKIN IRRITATION

Evaluation of Skin Reactions	Value
Erythema and eschar formation:	
No erythema	0
Very slight erythema (barely perceptible)	1 (Slight)
Well-defined erythema	2 (Mild)
Moderate to severe erythema	3 (Moderate)
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4 (Severe)
Edema formation:	
No edema	0
Very slight edema (barely perceptible)	1 (Slight)
Slight edema (edges of area well defined by definite raising)	2 (Mild)
Moderate edema (raised approximately 1.0 mm)	3 (Moderate)
Severe edema (raised more than 1.0 mm extending beyond the area of exposure)	4 (Severe)

A = Abraded
I = Intact
T = Thickening
C = Eschar
- = No Effect
B = Blanching

F = Fissuring
N = Necrosis
G = Fissuring with Bleeding
S = Epidermal Scaling

L = Sloughing
R = Raw Areas
X = Compound Adhered to Skin
SN = Superficial Necrosis

---

[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.