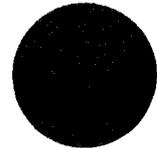


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**PRIMARY DERMAL IRRITATION STUDY OF
IN THE RABBIT**

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FINAL REPORT

**IITRI Project No. L8100
Study No. 48
Test Article No. 14**

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Life Sciences Research
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Chicago, IL 60616**

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April 30, 1980

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PRIMARY DERMAL IRRITATION STUDY OF
IN THE RABBIT

Study No. 48
Test Article No. 14

This report summarizes a primary dermal irritation study conducted by IIT Research Institute for the Standard Oil Co. (Indiana).

Bruce K. Bernard, Senior Toxicologist, served as study director and was responsible for the overall conduct of the study. Gerald King, Assistant Toxicologist, was responsible for the collection of test data. Calvin Reaves, Experimentalist, was responsible for animal care personnel. Josephine M. Reed, Supervisor, Quality Assurance, was responsible for the quality assurance program.

Bruce K. Bernard 4/30/80

Bruce K. Bernard Date
Study Director
Program Director
Life Sciences Research

R. Ehrlich/AS 4/30/80

Richard Ehrlich Date
Director
Life Sciences Research

Josephine M. Reed 4/15/80

Josephine M. Reed Date
Supervisor Quality Assurance
Life Sciences Research

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IITRI Project No. L8100

PRIMARY DERMAL IRRITATION STUDY OF
IN THE RABBIT

Study No. 48

Test Article No. 14

SUMMARY

was applied to the skin of the backs of 3 males and 3 female rabbits. A single dose of 0.5 ml was applied at each of two abraded and two non-abraded test sites. Varying degrees of erythema were seen in 4 rabbits at each observation interval. Slight edema was seen in 5 and 3 rabbits at 24 and 72 hours, respectively. The Primary Irritation Score (PIS) for this test article was calculated to be 1.1.

Under the guidelines of the Federal Hazardous Substances Act,
is not a primary dermal irritant.

IIT RESEARCH INSTITUTE

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PRIMARY DERMAL IRRITATION STUDY OF
IN THE RABBITI. INTRODUCTION

The purpose of this study was to assess the primary dermal irritancy of _____ in rabbits.

II. MATERIALS AND METHODS

- a. Test Article. (lot no. A-013-J9; approximately one gallon (3.8 l); gross weight of 3.54 kg) was received on December 4, 1979. The original polyethylene container and contents were stored in a ventilated cabinet at room temperature (approximately 22°C). A reserve sample of 10 ml was taken on the day of study initiation and stored under identical conditions.
- b. Dosage Formulation. The test article was applied undiluted.
- c. Animals, Housing and Diet. New Zealand albino rabbits (Lesser's Rabbitry, Union Grove, Wisconsin), were used for this study. Upon arrival (January 9, 1980), the rabbits were housed individually in stainless steel cages. The cage size (61.0 x 45.5 x 42.0 cm) conformed to the upper limit weight range recommended in the *Guide for the Care and Use of Laboratory Animals*, DHEW, (NIH) No. 78.23. Air conditioned rooms were maintained at 22 ± 1°C and approximately 40% relative humidity. Fluorescent lighting was provided on a 12 hour light-dark cycle. Purina Rabbit Chow and tap water (supplied by an automatic watering system) were available *ad libitum*.
- d. Experimental Design. The test article was applied to the abraded and intact skin of 3 male and 3 female rabbits; the skin adjacent to the test sites remained untreated as a control.
- e. Method. Prior to study initiation, the rabbits were observed during a quarantine period of one week. Twenty-four hours prior to study initiation, the back of each healthy rabbit was clipped (approximately 240 cm²) and examined for skin anomalies. Three (3) male and three (3) female rabbits were chosen for the study. Each of

the test rabbits received a unique number tag inserted into the right ear. A card on the front of each cage bore the study number, test article number, animal number, dose, sex and date of arrival.

On the day of treatment, four (4) 2.5 cm x 2.5 cm test sites were visualized in the clipped area on the back of each rabbit, two (2) on either side of the midline. The test sites on the right side were abraded with a hypodermic needle in such a way as to penetrate the stratum corneum, but not the dermis. The test sites on the left side were left intact.

One-half milliliter of _____ was applied uniformly to each of the four (4) test sites on January 15, 1980. Each test site was covered with a 1"x1" gauze patch which was secured by a semi-impervious tape. The mid-section of each rabbit was then wrapped securely with a lint-free cotton towel.

f. Animal Weights. The rabbits were weighed and weights recorded immediately prior to dosing. The weight range for the rabbits was 1.6 to 2.4 kg.

g. Mortality. The rabbits were observed daily for mortality and morbidity.

h. Skin Examinations. All wrapping materials and gauze pads were removed 24 hours after application and the test sites washed with normal saline to remove any residual test article. Each test site was scored for irritation according to the method of Draize (Appendix I). The test sites were examined and scored 24, 72 and 168 hours after application for edema and erythema-eschar formation.

Each score was weighted by the frequency of its occurrence; all weighted scores were added together and the sum divided by four (4) to yield the Primary Irritation Score (PIS).

i. Animal Disposition. The rabbits were sacrificed humanely and discarded at the completion of the study.

III. RESULTS

- a. Mortality. No mortality was observed during the 168 hour observation period.
- b. Skin Lesions. The individual irritation scores (Appendix II), were tabulated in Table 1. Varying degrees of erythema were seen in 4 rabbits at each observation interval. Slight edema was seen in 5 and 3 rabbits at 24 and 72 hours, respectively.
- c. Primary Irritation Score. The calculation for the PIS of are presented in Table 2.

According to the Federal Hazardous Substances Act, A PIS of five (5) or more classifies the test article as an irritant. The PIS for this test article is 1.1.

Therefore, is not considered to be a primary irritant.

IV. QUALITY ASSURANCE

Laboratory operations were inspected January 17, 1980. The raw data and final draft report were audited on April 15, 1980. All audits and inspections were conducted by Josephine M. Reed and studies were found to be in compliance with Life Sciences Quality Assurance criteria. Raw data generated during the course of this study will be maintained by the Life Sciences Archives as specified by government regulations.

Study Number: 48

Test Article Number: 14

DOSE 0.5 ml

N= 12

Neat Material

SUMMATIONS OF OBSERVATIONS

TABLE 1

SKIN REACTION:
TEST SITE:

ERYTHEMA & ESCHAR		EDEMA	
ABRADED	INTACT	ABRADED	INTACT

FREQUENCY OF IRRITATION SCORES

SCORES AT
24 HOURS

0	4/12	4/12	7/12	7/12
1	6/12	6/12	5/12	5/12
2	2/12	2/12	0	0
3	0	0	0	0
4	0	0	0	0

SUMMATIONS: 10/12 10/12 5/12 5/12

SCORES AT
72 HOURS

0	4/12	5/12	6/12	8/12
1	8/12	7/12	6/12	4/12
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0

SUMMATIONS: 8/12 7/12 6/12 4/12

Study Number: 48Test Article Number: 14DOSE 0.5 mlN= 12

Neat Material

PRIMARY SKIN IRRITATION SCORE

TABLE 2

SKIN REACTION:
TEST SITE:

ERYTHEMA & ESCHAR		EDEMA	
ABRADED	INTACT	ABRADED	INTACT

24 HOURS

10/12	10/12	5/12	5/12
-------	-------	------	------

SUBTOTAL A 30/12

72 HOURS

8/12	7/12	6/12	4/12
------	------	------	------

SUBTOTAL B 25/12

SUBTOTAL A + SUBTOTAL B = TOTAL SCORE

$$\frac{30}{12} + \frac{25}{12} = \frac{55}{12}$$

TOTAL SCORE / 4 = PRIMARY SKIN IRRITATION SCORE

$$\frac{55}{12} / 4 = \frac{55}{48} = 1.1$$

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APPENDICES

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APPENDIX I

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SCALE FOR SCORING SKIN LESIONS

Evaluation of Skin Reactions

Erythema and eschar formation:

No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Edema formation:

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm extending beyond the area of exposure)	4

The mean scores for erythema and eschar formation for intact skin at 24 and 72 hours are added to the values for abraded skin at 24 and 72 hours. Similarly, the values for edema formation at 24 hours and at 72 hours for the intact and abraded skin will be summed. The primary irritation score is the total of the eight values divided by four. A primary irritant is one which results in a score of five or more as tested by this method.

* Draize, J. H., Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics, Assoc. Food and Drug Officials of the U.S., Austin, Texas, 1959.

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APPENDIX II
PRIMARY SKIN IRRITATION (RABBIT)

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S.N. 48 T.A. 14 SEX M

DOSE 0.5 ml
test material

INITIAL APPLICATION 1/15/80 DATE 1:50 P TIME AKC INITIALS

DATE	TIME	ERYTHEMA & ESCHAR		EDEMA		INITI
		ABRADED	INTACT	ABRADED	INTACT	

INDIVIDUAL IRRITATION SCORES

ANIMAL No. 55
INITIAL Wt. 1.6 Kg

1-16-80	2:00 PM	1, 1	1, 1	1, 1	1, 1	MS,
1-18-80	1:14 PM	1, 1	1, 1	1, 1	1, 1	A.S. =
1-22-80	2:35 P	1, 1	00	00	00	AK

OBSERVATIONS:

ANIMAL No. 56
INITIAL Wt. 1.9 Kg

1-16-80	2:03 PM	2, 2	2, 2	1, 0	2, 0	MS,
1-18-80	1:22 PM	1, 1	0, 1	0, 0	0, 0	A.S. =
1-22-80	2:35 P	00	00	00	00	AK

OBSERVATIONS:

ANIMAL No. 57
INITIAL Wt. 2.0 Kg

1-16-80	2:07 PM	1, 1	1, 1	0, 1	0, 1	MS, 1
1-18-80	1:26 PM	1, 1	1, 1	0, 0	0, 0	A.S. =
1-22-80	2:35 P	00	00	00	00	AK

OBSERVATIONS:

READ AND UNDERSTOOD

PKB
DATE 4/19/82
A-2

REVIEWED BY R. Meyers
3/13/80

APPENDIX II (con't)
PRIMARY SKIN IRRITATION (RABBIT)

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S.N. 48

T.A. 14

SEX F

DOSE 0.5ml
test material

INITIAL APPLICATION 4/5/80
DATE

2:10P
TIME

JK
INITIALS

DATE	TIME	ERYTHEMA & ESCHAR		EDEMA		INITI
		ABRADED	INTACT	ABRADED	INTACT	

INDIVIDUAL IRRITATION SCORES

ANIMAL No. 58
INITIAL Wt. 2.6K

1-16-80	2:14 PM	0,0	0,0	1,0	1,0	MS, K
1-18-80	1:29 PM	0,0	0,0	0,0	0,0	A.S.F.
1-22-80	2:40P	1,1	1,1	0,0	0,0	JK

OBSERVATIONS:

ANIMAL No. 59
INITIAL Wt. 2.3K

1-16-80	2:16 PM	0,0	0,0	0,0	0,0	MS, K
1-18-80	1:33 PM	0,0	0,0	1,1	1,1	A.S.F.
1-22-80	2:40P	1,1	1,1	X 0,0	0,0	JK

OBSERVATIONS:

ANIMAL No. 60
INITIAL Wt. 2.3K

1-16-80	2:21 PM	1,1	1,1	0,0	1,0	MS, K
1-18-80	1:36 PM	1,1	1,1	1,1	0,0	A.S.F.
1-22-80	2:45P	1,1	1,1	0,0	0,0	JK

OBSERVATIONS:

READ AND UNDERSTOOD

PKP
DATE 7/19/80
A-3

REVIEWED BY B. Meyers
3/13/80

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