

(b) (4)

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REPORT

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ACUTE SKIN IRRITATION STUDY IN THE RABBIT

GU PROJECT NO. (b) (4)

TINUVIN 770 (US-sample)

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1. **INTRODUCTION**

At the request of the Plastics & Additives Division an acute study in rabbits was conducted. The purpose was to determine the skin irritating potency of (b) (4)

This report presents the results of the laboratory investigation as compiled by the undersigned.

Study Director

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2. SUMMARY AND CONCLUSIONS

Under the conditions of the present experiment (b) (4) was found to cause minimal irritation when applied to intact and abraded rabbit skin.

The calculated primary irritation index was 0.5.

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4. MATERIALS AND METHODS

4.1 Test Article

Code No

(b) (4)

Batch No.

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Stability

stable

Description

solid

Content of Active Ingredient

not determined

Test Article Received:

30.07.82

4.2 Experimental Animals

Rationale

The albino rabbit has been selected for this test as being a standard species for the determination of an acute skin irritation.

Species and Strain

New Zealand White Rabbits

Source

Kleintierfarm Madoerin AG, CH-4414
Fuellinsdorf

Number of animals

3 male / 3 female

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Initial Body Weight Range

2 - 3 kgs

Individual Identification

ear numbers

Husbandry

Animals were housed individually in metal cages.

The animal room was air conditioned: temperature 22±3° C, relative humidity 55±15%; 12 hours light/day, approximately 15 air changes/h.

Diet

Rabbit food, NAFAG, No. 814 Tox, NAFAG AG, Gossau, SG (Switzerland), and water were provided ad libitum.

4.3 Design

Basis

The procedure used is based, but not in every part identical with the Proposed Guidelines of the United States Environmental Protection Agency (EPA), Paragraph 163.81-5 "Primary dermal irritation study", Federal Register, Vol 43 No. 163, August 22, 1978.

Application of the substance

Before treatment the entire back and the flank of the rabbits were shaved with an electric clipper and immediately before treatment the shaven skin on one side was slightly scarified with the help of a "Schroepfschnaepper", Aesculap, Switzerland. Gauze patches of 2.5 x 2.5 cm soaked with 0.5 ml of the test material were applied to the prepared abraded and intact skin.

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The patches were covered with an impermeable material and were fastened to the body of the rabbit with adhesive tape. The dressings were removed after 24 hours.

The skin reaction was assessed upon removal and during a subsequent observation period of 7 days on the basis of the following evaluation scheme.

SCORE FOR SKIN IRRITATION IN RABBITS

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
Total possible erythema score	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 more than 1 mm).....	3
Severe edema (raised more than 1 mm and extending beyond area of exposure).....	4
Total possible edema score	4

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4.4 Procedure

Starting date of the experiment

09.08.82

End date of the experiment

16.08.82

5. RESULTS

The results of the primary skin irritation test are reported in tables 1 and 2 .

(b) (4) was found to cause a minimal irritation when applied to intact and abraded rabbit skin.

6. ARCHIVES

Final Report

WST 454

Copy of the Final report

WST 452

Raw Data

WST 454

7. DISTRIBUTION

Sponsor

Archives

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CALCULATION OF THE PRIMARY SKIN IRRITATION INDEX (TABLE 1)

The scores read after 24 and 72 hours for erythema and edema for the intact as well for the abraded skin were summed up and divided by 4 (FHSLA paragraph 191.11)

MEAN REACTION SCORE				
TIME AFTER EXPOSURE HOURS	ERYTHEMA		EDEMA	
	INTACT SKIN	ABRADED SKIN	INTACT SKIN	ABRADED SKIN
24	1.0	0.5	0.3	0.2
72	0.2	0.0	0.0	0.0
TOTAL	1.0 + 0.5	+ 0.3	+ 0.2	= 2.0

PRIMARY IRRITATION INDEX = 2.0 : 4 = 0.5

ASSESSMENT OF IRRITATION

- no irritation..... 0
- minimal..... 0.1-1.0
- slight..... 1.1-2.0
- moderate..... 2.1-4.0
- marked..... 4.1-6.0
- extreme..... 6.1-8.0

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EVALUATION OF THE SKIN REACTIONS

a = intact skin
 b = abraded skin

Test Nr.: 821170
 Substance: TE 0665

Study conducted from 8.1.71 to 16.1.71

		After 24 hours						After 48 hours						After 72 hours					
Sex		♂			♀			♂			♀			♂			♀		
Animal No.		34	35	36	37	38	39	34	35	36	37	38	39	34	35	36	37	38	39
Erythema	a	1	1	1	1	1	1	0	0	1	1	0	0	1	0	0	0	0	0
	b	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Edema	a	0	0	0	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0
	b	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	a	1	1	1	2	1	2	0	0	1	2	0	0	1	0	0	0	0	0
	b	1	1	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mean	a	1			1.7			0			0.7			0.3			0		
	b	0.7			0.7			0			0			0			0		
Group mean	a	1.3						0.3						0.2					
	b	0.7						0						0					

		After 4 days						After 7 days						After 10 days					
Sex		♂			♀			♂			♀			♂			♀		
Animal No.		34	35	36	37	38	39	34	35	36	37	38	39	34	35	36	37	38	39
Erythema	a	0	0	0	0	0	0	0	0	0	0	0	0						
	b	0	0	0	0	0	0	0	0	0	0	0	0						
Edema	a	0	0	0	0	0	0	0	0	0	0	0	0						
	b	0	0	0	0	0	0	0	0	0	0	0	0						
Total	a	0	0	0	0	0	0	0	0	0	0	0	0						
	b	0	0	0	0	0	0	0	0	0	0	0	0						
Mean	a	0			0			0			0								
	b	0			0			0			0								
Group mean	a	0						0											
	b	0						0											

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