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April, 1982

CAS No. 2425-79-8

REPORT

TK 10352/d

REPETITIVE SKIN IRRITATION IN THE RABBIT AFTER FIVE CONSECUTIVE APPLICATIONS

GU PROJECT NO. 811527

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JAN 31 1983

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TABLE OF CONTENTS

1 INTRODUCTION..... 2

2 SUMMARY AND CONCLUSIONS..... 3

3 PERSONNEL..... 3
Study Director:..... 3
Technical Personnel:..... 3

4 MATERIALS AND METHODS..... 4

4.1 Test Article..... 4
Code No..... 4
Batch No..... 4
Description..... 4
Stability..... 4
Purity..... 4
Test Article Received:..... 4

4.2 Experimental Animals..... 4
Rationale..... 4
Species and strain..... 4
Source..... 4
Initial age..... 4
Initial body weight range..... 5
Number of animals..... 5
Individual identification..... 5
Husbandry..... 5
Diet..... 5

4.3 Design..... 5
Basis..... 5
Application of the substance..... 5

4.4 Procedure..... 8
Starting date of the experiment..... 8
End date of the experiment..... 8

5 Results..... 8
Skin irritation..... 8
Bodyweight..... 9
Symptoms..... 9
Autopsy..... 9

6 Archives..... 10
Final Report..... 10
Copy of the final report..... 10
Raw Data..... 10

CONFIDENTIAL

TABLE OF CONTENTS (cont'd)

7 Distribution..... 10
Sponsor..... 10
Archives..... 10

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1. INTRODUCTION

At the request of the Plastics & Additives Division an subacute study in rabbits was conducted. The purpose was to determine the skin irritating potency of TK 10352/d after five consecutive applications on the rabbit skin.

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

Study Director G. Seifert, T.C.G., Section Head

G. Seifert

.....

date: May 11, 82

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2. SUMMARY AND CONCLUSIONS

Under the conditions of the present experiment TK 10352/d was found to cause extreme irritation when applied to intact and abraded rabbit skin.

The calculated primary irritation index was 7.1.

3. PERSONNEL

Study Director:

G. Seifert, T.C.G., Section Head

Technical Personnel:

S. Winter
E. Schaer
E. Fankhauser

The job descriptions and the summaries of training and professional experience for all personnel participating in this study are filed in the archives of the test facility.

4. MATERIALS AND METHODS

4.1 Test Article

Code No

TK 10352/d

Batch No.

No 818

Description

liquid

Stability

determined by the sponsor

Purity

information not alvailable

Test Article Received:

November 18, 1981

4.2 Experimental Animals

Rationale

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

Species and strain

New Zealand White Rabbits

Source

Kleintierfarm Madoerin AG, CH-4414 Fuellinsdorf

Initial age

14 weeks

Initial body weight range

2-3 kg

Number of animals

6 males/females

Individual identification

ear tags

Husbandry

Animals were housed individually in metal cages.

The animal room was air conditionned: 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 on the method of Draize, described in the "Appraisal of the Safety of Chemicals and Foods, Drugs and Cosmetics" (1959) of the US Association of Food and Drug Officials (AFDO).

Application of the substance

Before treatment the entire back and the flank of the rabbits were shaved with an electric clipper.

Gauze patches of 4 x 5 cm soaked with 0.5 ml of the test material were applied to the skin.

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 after removal 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 percepible)	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

Primary reaction score = score after the first 24 hours = RAW*

Mean reaction score = average score on days 1-5 = RDM*

Final reaction score = score on day 5 of test = RDM*

The severity of skin irritation was rated as follows :

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0	= none
>0 - 1	= minimal
>1 - 2	= slight
>2 - 4	= moderate
>4 - 6	= marked
>6 - 8	= extreme

A new patch was then applied to the same dorsal area, and the procedure was repeated for a total of 5 consecutive days. The fifth dressing was removed 8 hours after the application and the skin reaction was then recorded.

The skin reaction was recorded again on days 8, 9 and 10 (recovery period).

Bodyweights were recorded at -3 days, at initiation and day 3 and 5 of the treatment period and at day 8 and 10 of the observation period.

Toxic symptoms were recorded daily.

4.4 Procedure

Starting date of the experiment

March 15, 1982

End date of the experiment

March 19, 1982

5. RESULTS

Skin irritation

See Table 1

Under the experimental conditions the animals showed:

a primary reaction score of :

6.3

a mean reaction score of:

7.1

a final reaction score of:

8

After treatment with TK 10352/d there was no tendency of recovery during the observation period.

The vehicle treated patches showed no irritation effect on the skin of rabbits.

Bodyweight

See Table 2

The bodyweights were decreased in the rabbits during the treatment period. There was a slight recovery during the observation period.

Symptoms

See Table 3

The rabbits had not fully recovered at the end of the observation period.

All animals were killed and autopsied after the 10 test days.

Autopsy

No substance related gross organ changes were observed, which could be related to substance application.

Observations during test period:

The application sites in all of the animals during the whole test period showed:

- necrosis
- erythemas extended beyond the applications sites
- the substance - hardened skin broke off.

6. **ARCHIVES**

Final Report

WST 454

Copy of the final report

WST 452

Raw Data

WST 454

7. **DISTRIBUTION**

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Archives

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