

OFFICE OF TOXIC SUBSTANCES
CODING FORM FOR GLOBAL INDEXING

REV. 7/27/82

Microfiche No. (7) •		OTS 0206476		1		No. of Pages		2	
Doc I.D.		878214017		3		Old Doc I.D.		8DS	
Case No. (2)		OTS 84003A						5	
Date Produced (6)		092375		6		Date Rec'd (6)		7	
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Check One: <input type="checkbox"/> Publication <input type="checkbox"/> Internally Generated <input checked="" type="checkbox"/> Externally Generated									
Pub/Journal Name									

Author(s)									

Organ. Name									
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D & B NO. (11)									

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Doc Title									
SKIN IRRITATION IN THE RABBIT AFTER									
SINGLE APPLICATION OF TK 10412									
23									
Chemical Name (300 per name)									
GLYCIDOL & ITS DERIVATIVES									
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CAS No. (10)									
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CIBA-GEIGY Limited
Basle, Switzerland

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CAS 17557-23-2

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September 23, 1975/wu

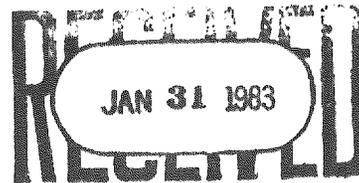
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SKIN IRRITATION IN THE RABBIT AFTER SINGLE APPLICATION OF

TK 10412

Batch No.: Op. 603062

Project No.: Siss 4921



1. Summary and Conclusion

The primary irritation index, a measure of the acute irritation to the rabbit skin was 2.3. This indicates that the substance is a moderate irritant to the rabbit skin.

THIS DOCUMENT HAS BEEN DECLASSIFIED
PER LETTER FROM CIBA-GEIGY DATED
MARCH 1, 1984. (SEE LAST SIX FRAMES
OF FICHE (FICHE SET)).

2. Method

The procedure used was the patch test technique described in the "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" (1959), the US Association of Food and Drug Officials (AFDO).

The test was performed on 3 male and 3 female rabbits of the Russian breed weighing 1.5 to 2 kg. They were housed individually in metal cages, were kept at a constant room temperature of $18 \pm 1^{\circ}$ C, at a relative humidity of 55 ± 5 % and on a 14 hours light cycle day. The animals received ad libitum standard rabbit food - NAFAG, Gossau SG - and water. Prior to treatment they were adapted to our laboratories for a minimum of 8 days.

Two days 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 the left side was slightly scarified. For treatment gauze patches of 2.5 x 2.5 cm soaked with the test substance were applied to the prepared abraded and non abraded 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 a 24 hour exposure.

The skin irritation was scored immediately and 48 hours after removal of the dressings (24 and 72 hours after initiation of treatment). Skin irritation was scored in accordance with the irritation score from table 1.

The severity of skin irritation was rated as follows: A mean value of less than 2 indicated mild, from 2 to 5 moderate and above 6 severe skin irritation.

Score for skin irritation in rabbits (Table 1)

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)	<u>4</u>
Maximum 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 approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	<u>4</u>
Maximum possible edema score	4

3. Results - Table 2

The primary irritation index is the mean value of the sum of the scores for erythema and edema from all 6 rabbits 24 and 72 hours after initiation of treatment. The maximum possible score is 8.

The primary skin irritation index in this experiment was established to be 2.3.


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Skin irritation in individual rabbits - Table 2

Animal No. Sex	Skin Reaction	24 hrs after application		72 hrs after application	
		intact skin	scarified skin	intact skin	scarified skin
1 ♂	Erythema	2	2	1	2
	Edema	1	1	0	1
2 ♂	Erythema	0	3	0	3
	Edema	0	2	0	1
3 ♂	Erythema	2	2	2	2
	Edema	1	3	0	1
4 ♀	Erythema	0	1	0	0
	Edema	0	0	0	0
5 ♀	Erythema	0	3	0	4
	Edema	0	4	0	3
6 ♀	Erythema	0	3	0	1
	Edema	0	2	0	0

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