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CODING FORM FOR GLOBAL INDEXING

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CIBA-GEIGY Limited  
Basle, Switzerland

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Exp. Toxicology Sisseln  
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JUN 23 1980

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CAS 5026-74-4

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REPORT ON

SKIN IRRITATION IN THE RABBIT AFTER SINGLE APPLICATION OF

TK 12759

EPOXY 0510

Project No.: 800658  
Sponsor: Plastics and Additives Division  
Test material received: March 28, 1980

Additional identification: Physical appearance: yellow liquid  
Batch No.: T-60011

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

The experiment started: May 19, 1980  
The experiment ended: May 26, 1980

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JAN 31 1983

Study director:   
L. Ullmann

Approved by:   
Dr. med. vet. W. Gfeller

Reported: June 2, 1980/wu

Archives: Sisseln WST 452

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1. Summary and Conclusion

Under the conditions of the present experiment TK 12759 was found to cause a marked irritation when applied to intact and abraded rabbit skin.

The calculated primary irritation index was 4.1.

2. Method

Concentration: CONC.

The procedure used is described in the Proposed Guidelines of the United States Environmental Agency (EPA) § 163.81-5 "Primary dermal irritation study", Federal Register, Vol. 43, No. 163, August 22, 1978.

The test was performed on 6 male adult New Zealand White rabbits bred and raised on the premises weighing 2 to 3 kgs. They were housed individually in metal cages numbered by ear tags, were kept at a constant room temperature of  $22 \pm 2^{\circ}\text{C}$ , at a relative humidity of  $55 \pm 10\%$  and on a 10 hours light cycle day. The animals received ad libitum standard rabbit food - NAFAG, No. 814, Gossau SG - and water. Prior to treatment they were adapted to our laboratories for a minimum of 4 days.

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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 "Schröpf schnäpper", Aesculap, Switzerland. Gauze patches of 2.5 x 2.5 cm laden with 0.5 ml of the test material were applied to the prepared abraded and intact 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 a 24 hour application.

The skin reaction was appraised upon removal and during an 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
	<hr/>
Total possible erythema score	4

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**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>
<b>Total possible edema score</b>	<b>4</b>

**3. Results**

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

TK 12759 was found to cause a marked irritation when applied to intact and abraded rabbit skin.

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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 as for the abraded skin were summed up and divided by 4. (FHSLA § 191.11)

Time after exposure hours	MEAN REACTION SCORE			
	e r y t h e m a		e d e m a	
	intact skin	abraded skin	intact skin	abraded skin
24	2	2	1.8	2.5
72	2	2	1.8	2.2
total	4	+ 4	+ 3.6	+ 4.7 = 16.3

primary irritation index =  $16.3 : 4 = 4.1$

Assessment of irritation

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

EVALUATION OF THE SKIN REACTIONS - TABLE 2

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a = intact skin  
b = abraded skin

After 24 hours

Sex		♂			♀		
Animal No.		350	351	352	353	354	355
Erythema	a	2	2	2	2	2	2
	b	2	2	2	2	2	2
Edema	a	2	2	2	2	2	1
	b	2	3	2	3	3	2
Total	a	4	4	4	4	4	3
	b	4	5	4	5	5	4
Mean	a	4			3.7		
	b	4.3			4.2		
Group mean	a	3.8					
	b	4.5					

After 48 hours

	♂			♀		
Animal No.	350	351	352	353	354	355
Erythema	2	2	2	2	2	2
Erythema	2	2	2	2	2	2
Erythema	2	2	2	2	2	1
Erythema	3	2	2	2	2	2
Erythema	4	4	4	4	4	3
Erythema	5	4	4	4	4	4
Mean	4			3.7		
Mean	4.3			4		
Group mean	3.8					
Group mean	4.2					

After 72 hours

	♂			♀		
Animal No.	350	351	352	353	354	355
Erythema	2	2	2	2	2	2
Erythema	2	2	2	2	2	2
Erythema	2	2	2	2	2	1
Erythema	3	2	2	2	2	2
Erythema	4	4	4	4	4	3
Erythema	5	4	4	4	4	4
Mean	4			3.7		
Mean	4.3			4		
Group mean	3.8					
Group mean	4.2					

After 4 days

Sex		♂			♀		
Animal No.		350	351	352	353	354	355
Erythema	a	2	2	2	2	2	2
	b	2	2	2	2	2	2
Edema	a	2	2	2	2	2	1
	b	2	2	2	2	2	1
Total	a	4	4	4	4	4	3
	b	4	4	4	4	4	3
Mean	a	4			3.7		
	b	4			3.7		
Group mean	a	3.8					
	b	3.8					

After 7 days

	♂			♀		
Animal No.	350	351	352	353	354	355
Erythema	2	2	2	2	2	2
Erythema	2	2	2	2	2	2
Erythema	1	1	1	1	1	1
Erythema	1	1	1	1	1	1
Erythema	3	3	3	3	3	3
Erythema	3	3	3	3	3	3
Mean	3			3		
Mean	3			3		
Group mean	3					
Group mean	3					

After 10 days

	♂			♀		
Animal No.	350	351	352	353	354	355
Erythema						
Erythema						
Erythema						
Erythema						
Erythema						
Erythema						
Mean						
Mean						
Group mean						
Group mean						

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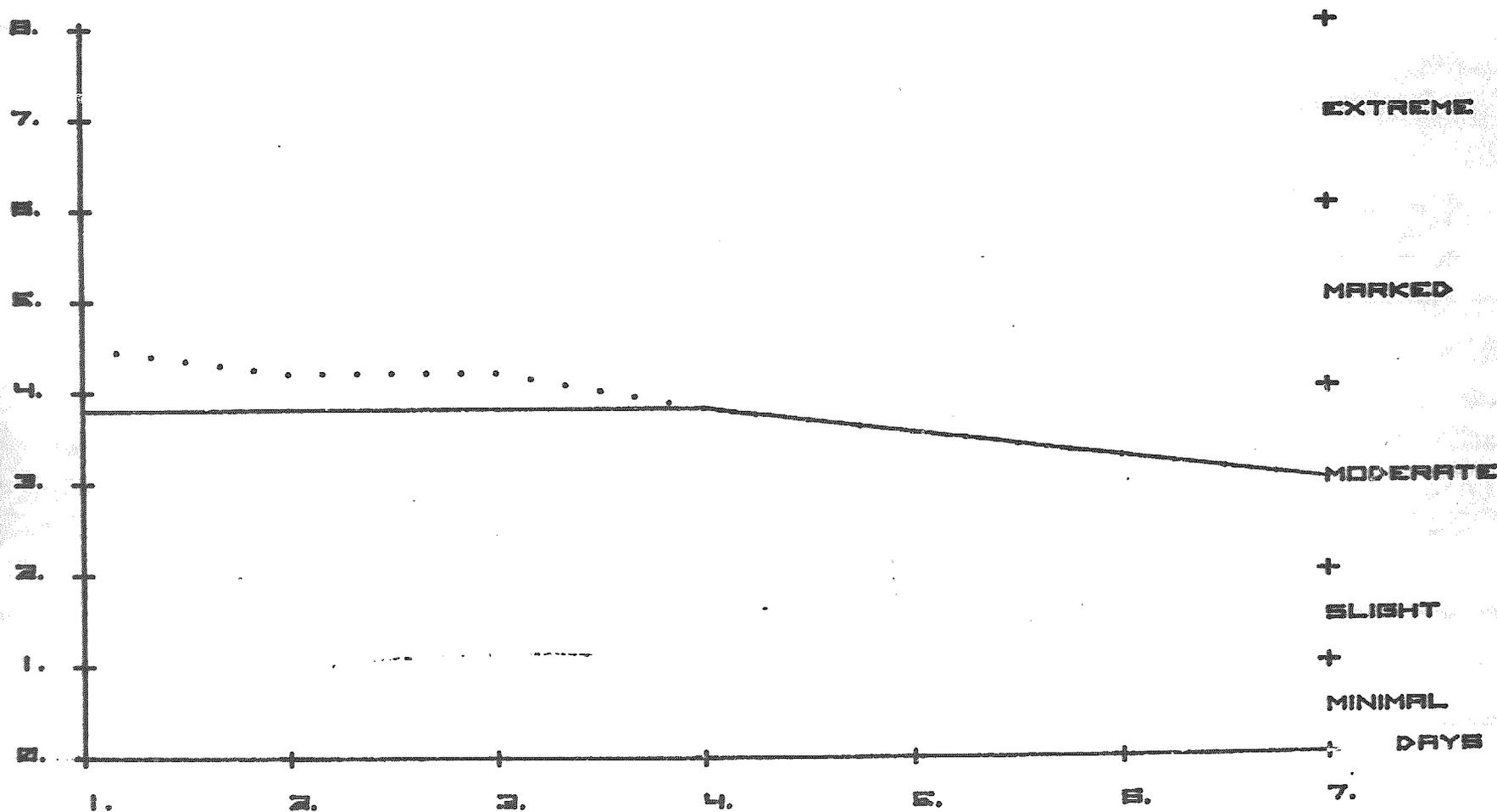
EXP. 82558

TK 12759

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SKIN IRRITATION IN RABBITS  
MEAN REACTION SCORE OF 6 ANIMALS  
3 MALES AND 3 FEMALES

SCORE



- INTACT SKIN    ... ABRADED SKIN

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