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Exp. Toxicology Sisseln  
GU 2.1

CAS 2425-79-8

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REPORT ON 878213979

SKIN IRRITATION IN THE RABBIT AFTER SINGLE APPLICATION OF

TK 10352/d

DY 026 (dest.)

Project No.: 810915  
Sponsor: Plastics and Additives Division

Test material received: July 13, 1981

Additional identification: Physical appearance: liquid

Batch No.: Mo 818

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

RECEIVED  
JAN 31 1983

The experiment started: October 19, 1981

The experiment ended: November 2, 1981

Study director: *W. Kobel*  
Dr. med. vet. W. Kobel

Reported: November 18, 1981/va

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Archives: Sisseln WST 454

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1. Summary and Conclusion

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

The calculated primary irritation index was 4.3.

2. Method

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 3 male and 3 female adult New Zealand White rabbits bred and raised at Kleintierfarm Madörin AG, CH-4414 Füllinsdorf 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 12 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 "Schröpfeschnäpper", Aesculap, Switzerland. Gauze patches of 2.5 x2.5 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 14 days on the basis of the following evaluation scheme.

Score for skin irritation in rabbits

Zrythema 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
<b>Total possible erythema score</b>	<b>4</b>

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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 19352/d was found to cause a marked irritation when applied to intact and abraded rabbit skin.

Until after 7 days ischaemic areas were observed on 7/12 application sites.

After 10 and 14 days crusts had developed on several application sites.

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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. (PHSLA § 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	2.5	1.3	2.3
72	2.2	2.5	1.7	2.5
total	4.4	+ 5.0	+ 3.0	+ 4.8 = 17.2

primary irritation index =  $17.2 : 4 = 4.3$

Assessment of irritation

- 0
- 0.1-1.0 = minimal
- 1.1-2.0 = slight
- 2.1-4.0 = moderate
- 4.1-6.0 = marked
- 6.1-8.0 = extreme

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## EVALUATION OF THE SKIN REACTIONS - TABLE 2

a = intact skin  
b = abraded skin

After 24 hours

Sex		♂			♀		
Animal No.		109	110	111	112	113	114
Erythema	a	1	2	3	2	1	4
	b	1	2	3	3	2	4
Edema	a	1	1	2	1	1	2
	b	1	2	3	3	2	3
Total	a	2	3	5	3	2	6
	b	2	4	6	6	4	7
Mean	a	3.3			3.7		
	b	4			5.7		
Group mean	a	3.5			3.8		
	b	4.8			5.7		

After 48 hours

Sex		♂			♀		
Animal No.		109	110	111	112	113	114
Erythema	a	1	3	3	2	1	4
	b	1	3	3	3	1	4
Edema	a	1	2	3	1	2	3
	b	1	3	3	3	2	3
Total	a	2	5	6	3	3	7
	b	2	6	6	6	3	7
Mean	a	4.3			4.3		
	b	4.7			5.3		
Group mean	a	4.3			4.3		
	b	5			5.3		

After 72 hours

Sex		♂			♀		
Animal No.		109	110	111	112	113	114
Erythema	a	1	3	3	2	0	4
	b	1	3	3	3	1	4
Edema	a	1	2	3	1	1	2
	b	1	3	3	3	2	3
Total	a	2	5	6	3	1	6
	b	2	6	6	6	3	7
Mean	a	4.3			3.3		
	b	4.7			5.3		
Group mean	a	3.8			3.8		
	b	5			5.3		

After 4 days

Sex		♂			♀		
Animal No.		109	110	111	112	113	114
Erythema	a	1	3	3	2	1	4
	b	1	3	3	3	2	4
Edema	a	1	2	2	2	0	2
	b	1	2	2	3	2	3
Total	a	2	5	5	4	1	6
	b	2	5	5	6	4	7
Mean	a	4			3.7		
	b	4			5.7		
Group mean	a	3.8			3.8		
	b	4.8			5.7		

After 7 days

Sex		♂			♀		
Animal No.		109	110	111	112	113	114
Erythema	a	1	3	3	2	1	4
	b	1	2	3	3	2	4
Edema	a	1	2	2	2	0	2
	b	1	2	2	3	1	4
Total	a	2	5	5	4	1	6
	b	2	5	5	6	3	8
Mean	a	4			3.7		
	b	4			5.7		
Group mean	a	3.8			3.8		
	b	4.8			5.7		

After 10 days

Sex		♂			♀		
Animal No.		109	110	111	112	113	114
Erythema	a	1	1	X	2	2	X
	b	1	3	X	3	3	X
Edema	a	1	1	X	2	2	X
	b	1	3	X	3	3	X
Total	a	2	2		4	4	
	b	2	6		6	6	
Mean	a						
	b						
Group mean	a						
	b						

X strong crust formation

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EVALUATION OF THE SKIN REACTIONS TABLE 2

a = intact skin  
b = abraded skin

After 14 days

Sex		♂			♀		
Animal No.		109	110	111	112	113	114
Erythema	a	2	2	2	X	X	X
	b	2	2	2	X	X	X
Edema	a	2	1	1	X	X	X
	b	2	1	2	X	X	X
Total	a	4	3	3			
	b	4	3	4			
Mean	a	3.7					
	b	3.7					
Group mean	a						
	b						

After

Sex		♂			♀		
Animal No.							
Erythema	a						
	b						
Edema	a						
	b						
Total	a						
	b						
Mean	a						
	b						
Group mean	a						
	b						

After

Sex		♂			♀		
Animal No.							
Erythema	a						
	b						
Edema	a						
	b						
Total	a						
	b						
Mean	a						
	b						
Group mean	a						
	b						

After

Sex		♂			♀		
Animal No.							
Erythema	a						
	b						
Edema	a						
	b						
Total	a						
	b						
Mean	a						
	b						
Group mean	a						
	b						

After

Sex		♂			♀		
Animal No.							
Erythema	a						
	b						
Edema	a						
	b						
Total	a						
	b						
Mean	a						
	b						
Group mean	a						
	b						

After

Sex		♂			♀		
Animal No.							
Erythema	a						
	b						
Edema	a						
	b						
Total	a						
	b						
Mean	a						
	b						
Group mean	a						
	b						

\* Strong crust formation

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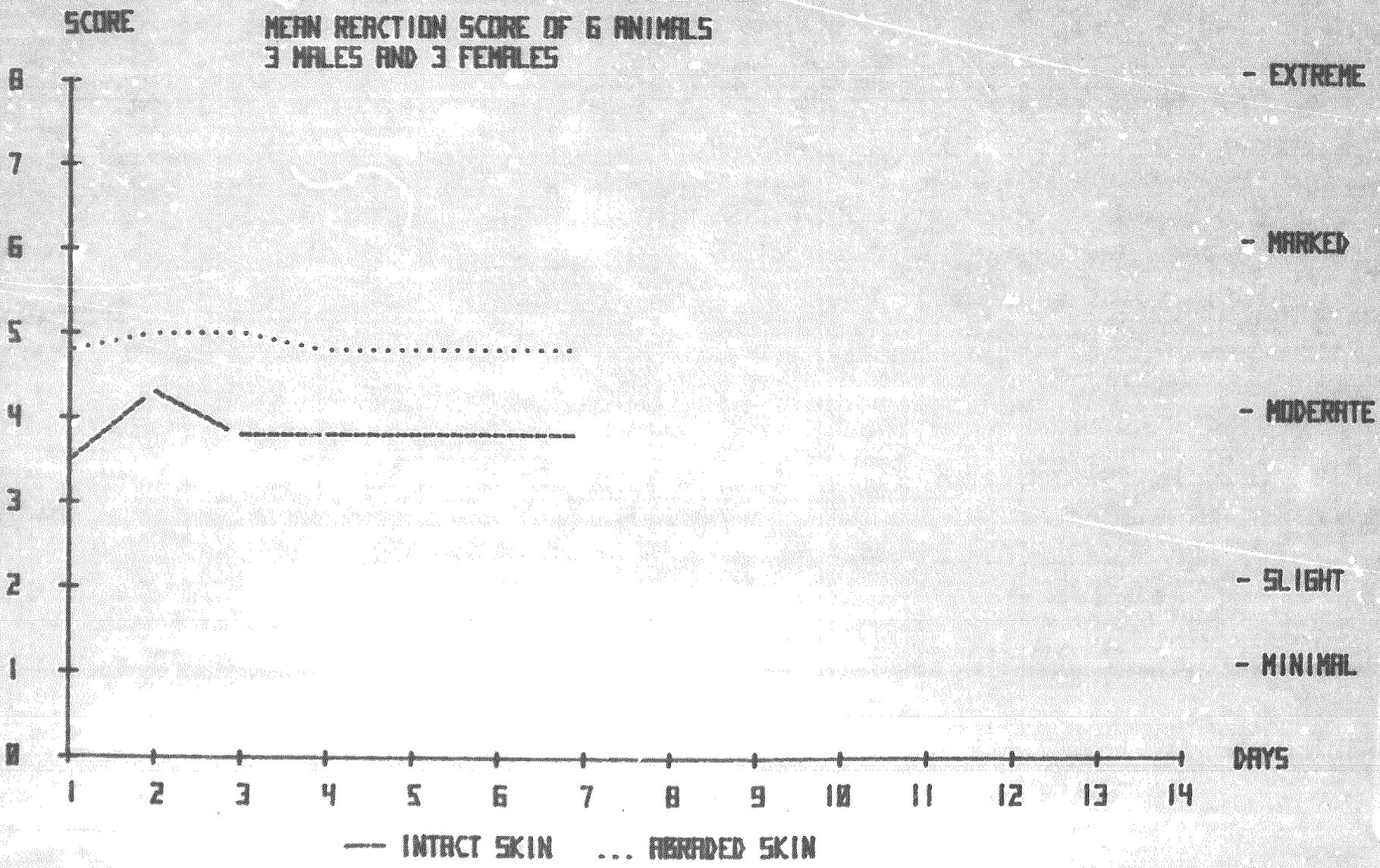
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EXP.: 818915

TK-10352/D

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

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