

Microfiche No. (7)	OTS 0206476	1	No. of Pages	2
Doc I.D.	878213986	3	Old Doc I.D.	4 PDS
Case No.(s)	OTS 84003A	5		
Date Produced (6)	081578	6	Date Rec'd (6)	7 013183
			Conf. Code	8 N-
Check One:	<input type="checkbox"/> Publication	<input type="checkbox"/> Internally Generated	<input checked="" type="checkbox"/> Externally Generated	9
Pub/Journal Name				9
Author(s)				10
Organ. Name	CIBA GEIGY CORP			11
Dept/Div	PLASTICS & ADDITIVES DIV			12
P.O. Box	13	Street No./Name	3 SKYLINE DR	
City	15 HAWTHORNE	State	16 NY	18 Zip 10532, Country
MID No. (7)	19	D & B NO. (11)	20	
Contractor				21
Doc Type	R.I. U.P. HEAD S.D. S.U.H.S F.N			22
Doc Title	SKIN IRRITATION IN THE RABBIT AFTER SINGLE APPLICATION OF TK 12405			23
Chemical Name (300 per name)	25		CAS No. (10)	24
GLYCIDOL & ITS DERIVATIVES			999999994	
OXIRANE, [[4-(1,1-DIMETHYLETHYL)PHENOXY]			3101-60-8	
METHYL]-				

ce
8/9/82
VA

Toxicology
GU 2.1

XU 228
CAS. 3101-60-8

CONFIDENTIAL

XU 238
SKIN IRRITATION IN THE RABBIT AFTER SINGLE APPLICATION OF TK 12405

Batch No.: L-188

878213986,

Project No.. 457078 - Siss 6470

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

1. Summary and Conclusion

Under the conditions of the present experiment TK 12405 was found to cause a moderate irritation when applied to intact and abraded rabbit skin.

The calculated primary irritation index was 3.67.

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 Himalayan breed weighing 1.5 to 2 kgs. They were housed individually in metal cages, were kept at a constant room temperature of $22 \pm 1^{\circ}$ C, at a relative humidity of 55 ± 5 % and on a 10 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 4 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 one side was slightly scarified. 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.

**TSCA CONFIDENTIAL
BUSINESS INFORMATION**

RECEIVED
JAN 31 1983
RECEIVED

000002

457078

CONFIDENTIAL

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

457078

CONFIDENTIAL

3. Results - Tables 1 and 2 and figure

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

TK 12405 was found to cause a moderate irritation when applied to intact and abraded rabbit skin.

The pH value of the test material: 6

Dr. med. vet.  K. Sachsse


L. Ullmann

000004

457078

CONFIDENTIAL

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 h	mean reaction score of 6 rabbits			
	erythema		edema	
	intact skin	abraded skin	intact skin	abraded skin
24	2	2	2	2
72	2	2.17	1.17	1.33
total	4	4.17	3.17	3.33 = 14.67

primary irritation index = $14.67 : 4 = \underline{3.67}$

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

a = intact skin
b = abraded skin

CONFIDENTIAL

After 24 hours

Sex		♂				♀	
Animal No.		1	2	3	4	5	6
Erythema	a	2	2	2	2	2	2
	b	2	2	2	2	2	2
Edema	a	2	2	2	2	2	2
	b	2	2	2	2	2	2
Total	a	4	4	4	4	4	4
	b	4	4	4	4	4	4
Mean	a	4				4	
	b	4				4	
Group mean	a	4					
	b	4					

After 48 hours

	♂				♀	
Animal No.	1	2	3	4	5	6
Erythema	2	2	2	2	2	2
	2	2	2	2	2	2
Edema	2	2	2	2	2	2
	2	2	3	2	2	2
Total	4	4	4	4	4	4
	4	4	5	4	4	4
Mean	4				4	
	4.3				4	
Group mean	4					
	4.15					

After 72 hours

	♂				♀	
Animal No.	1	2	3	4	5	6
Erythema	2	2	2	2	2	2
	2	2	2	2	3	2
Edema	1	1	1	1	2	1
	1	1	1	1	3	1
Total	3	3	3	3	4	3
	3	3	3	3	6	3
Mean	3				3.3	
	3				4	
Group mean	3.11					
	3.10					

After 4 days

Sex		♂				♀	
Animal No.		1	2	3	4	5	6
Erythema	a	1	1	2	1	1	1
	b	1	1	2	1	1	1
Edema	a	1	1	1	1	1	1
	b	1	1	1	1	1	1
Total	a	2	2	3	2	2	2
	b	2	2	3	2	2	2
Mean	a	2.3				2	
	b	2.3				2	
Group mean	a	2.15					
	b	2.15					

After 7 days

	♂				♀	
Animal No.	1	2	3	4	5	6
Erythema	1	1	1	1	1	1
	1	1	1	1	1	1
Edema	0	0	0	0	0	0
	0	0	0	0	0	0
Total	1	1	1	1	1	1
	1	1	1	1	1	1
Mean	1				1	
	1				1	
Group mean	1					
	1					

After 10 days

	♂				♀	
Animal No.	1	2	3	4	5	6
Erythema						
Edema						
Total						
Mean						
Group mean						

900060

457078

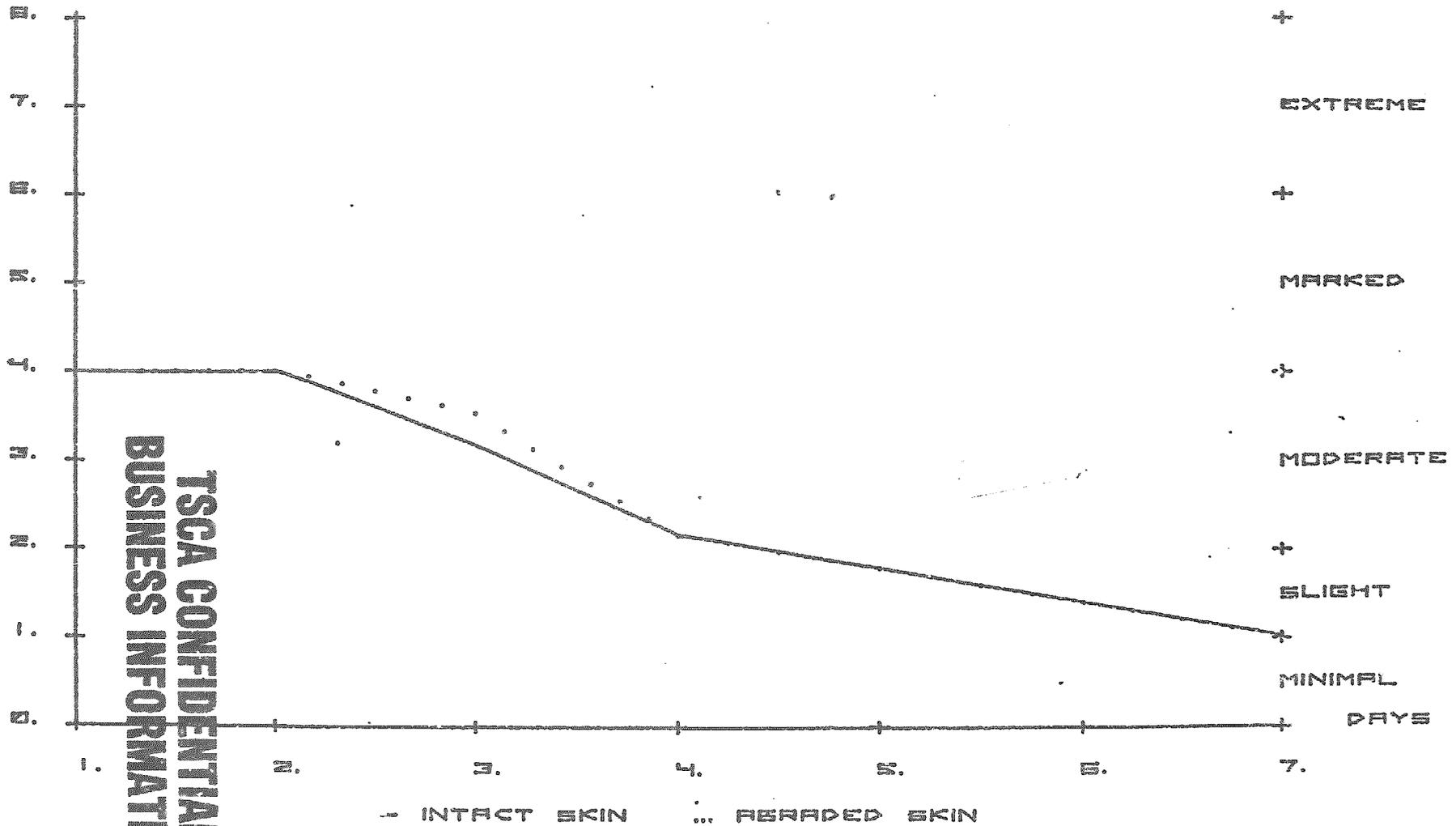
EXP. 4570 B.

TK 12405

CONFIDENTIAL

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

SCORE



TSCA CONFIDENTIAL
BUSINESS INFORMATION

000007