

Report Title: Primary Skin Irritation Study in Rabbits

Test Type: Skin Irritation

Conducting Laboratory and Location: International Research and Development Corporation

Test Substance(s): T-7119 – 2% Octopirox in shampoo at pH 7.5

Species: Rabbit

of Animals: 2 male, 1 female

Test Conditions: 2 male and 1 female New Zealand White rabbits exposed to two patches on the back with 0.4 ml applied as a 10% (w/w) solution in distilled water for 24 hr. One patch was applied to intact skin and the other to abraded skin. Test sites were graded at 24 and 72 hr.

Results: Moderately irritating to the skin

Study #: 191-080; see related studies 191-081 and 191-082

Report Date: 10/25/77

Accession #: 21613

Primary Skin Irritation Study in Rabbits

SPONSOR: Procter and Gamble Company

TEST MATERIAL: T-7119

STUDY NUMBER: 191-080

DATE: October 25, 1977

PROCEDURE: Animals

Three New Zealand White Rabbits (obtained from Kuiper's Rabbit Ranch, Gary, Indiana), 2 males and 1 female, weighing from 2495 to 3500 grams, were used in this study. The rabbits were maintained in accordance with the recommendations contained in H.E.W. Publication No. 74-23 (N.I.H.) entitled "Guide for the Care and Use of Laboratory Animals" and were conditioned for a minimum of 26 days prior to study initiation.

Administration

0.4 milliliter of the test material was applied, as a 10% (w/w) solution in distilled water, to each of two 38 x 38 mm Parke-Davis Readi-Bandages with a 20 x 20 mm felt pad which were then placed on the two sites on the backs of each of the rabbits. One of the sites was abraded while the other remained intact. The patches were secured in place with several wrappings of 75 mm Elastoplast tape and collars were placed on each animal. Following the 24 hour application period, the collars and patches were removed and any test material remaining on the sites was removed with a damp cloth.

Observations

-for irritation of the skin at 24 and 72 hours. (The observations at 24 hours were made 30 minutes following removal of the patches.) (See attached protocol for specific experimental design used.)

RESULTS:

Effects of the test material determined at indicated intervals and scored according to the attached grading system. Grade of effect with time is shown in the table on the following page. Individual rabbit scores are presented in Table 1.

Primary Skin Irritation (cont.)

RESULTS
(cont.):

Number of Animals Exhibiting Signs with Scoring "Value"

Observations	Value	Intact Skin		Abraded Skin	
		Hours		Hours	
		24	72	24	72
Erythema,	0				
Eschar	1		1/3		
Formation	2	3/3	1/3	3/3	2/3
	3		1/3		1/3
	4				
Edema	0				
Formation	1	1/3		1/3	
	2	2/3	3/3	2/3	3/3
	3				
	4				

Primary Irritation Score (Index): 4.1

	<u>Value</u>
<u>Erythema and Eschar Formation:</u>	
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
<u>Edema Formation:</u>	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raising approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm extending beyond the area of exposure)	4

T-7119:

Individual Rabbit Scores and Score Calculation

TABLE 1.

Intact Skin									
Animal No./Sex	Erythema					Edema			
	Observation Period (Hours)					Observation Period (Hours)			
	24	72				24	72		
29489, Male	2.0	2.5				2.0	2.0		
29588, Female	2.0	3.0				1.5	2.0		
29589, Male	2.0	1.5				2.0	2.0		
Total	6.0	7.0				5.5	6.0		
Average (Value)	2.0	2.3				1.8	2.0		

Abraded Skin									
Animal No./Sex	Erythema					Edema			
	Observation Period (Hours)					Observation Period (Hours)			
	24	72				24	72		
29489, Male	2.0	2.5				2.0	2.0		
29588, Female	2.0	3.0				1.5	2.0		
29589, Male	2.0	2.0				2.0	2.0		
Total	6.0	7.5				5.5	6.0		
Average (Value)	2.0	2.5				1.8	2.0		

Calculation for Primary Skin Irritation Score (Score = sum of the values (averages) divided by the number of observation periods used in evaluating the Primary Irritation Score times 2

$16.4 \div 4 = 4.1$

Primary Skin Irritation (cont.)

CONCLUSION: Based upon the results obtained, T-7119 would not be considered a primary skin irritant. The test material would be further classified, based upon the Primary Irritation Index, as being moderately irritating to the skin.



Wilson P. Dean, B.A.
Director of Acute Toxicology
and Special Studies

Approved by: D. Clifford Jessup, Ph.D.
Associate Director of Research

