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DATA EVALUATION REPORT

Study Type: Dermal Sensitization - Guinea Pig (81-6) Tox. Chem. No.: 9098

MRID Number: 415455-01

Test Material: Firebrake ZB Zinc Borate 2335

Study Number(s): 90-4038-21

Sponsor: US Borax Research
412 Crescent Way
Anaheim, CA 92801

Testing Facility: Hill Top Biolabs, Inc.
Main and Mill Streets
Miamiville, OH 45147

Title of Report: Delayed Contact Hypersensitivity Study in Guinea Pigs

Author(s): James J. Kreuzmann

Report Issued: April 18, 1990

Conclusions: Under the conditions of this study, Firebrake ZB Zinc Borate 2335 is not a dermal sensitizer.

Classification of Data: Core - Supplementary
(Deficient in that concurrent positive or negative control data were not provided.)

This study does not satisfy the guideline requirements (81-6) for a "Dermal Sensitization Study in Guinea Pigs".

A. MATERIALS AND METHODS and RESULTS

This study was conducted in Hartley albino guinea pigs weighing from 381 to 538 g. Half male and half female animals were used for each phase of the study. The three phases were irritation, induction and challenge. Food and water were available ad libitum through out the study.

1. Irritation

The irritation phase of the study was conducted to determine the appropriate treatment level for the subsequent two phases.

The fur was clipped from the backs of the four male and four female test animals on the day prior to application of the test material. Patches on which the test material was placed were applied to the shaved backs and occluded with a rubber dental dam. The patches were left in place for six hours, during which time the guinea pigs were kept in restrainers. Concentrations used for this study were 75, 50, 25, 10, 5, 2.5, 1 and 0.5% w/v in distilled water. Excess material was removed from the test sites when the patches were removed. Animals were depilated and scored for irritation at 24 and 48 hours after treatment. Sites were scored as follows: 0 = no reaction; \pm = slightly patchy erythema; 1 = slight but confluent, or moderate patchy erythema; 2 = moderate erythema; 3 = severe erythema with or without edema.

No score greater than a \pm was reported at any concentration in the primary irritation assay. On this basis, the 75% concentration was selected for the remaining phases.

2. Induction

During this portion of the study, ten male and ten female guinea pigs were prepared and patched as described in the "Irritation" section above with the exception that the only concentration applied was 75% w/v in distilled water and the application was made for six hours once each week for three weeks to the left shoulder of each animal.

3. Challenge

Approximately two weeks after the final induction treatment, the 20 induced guinea pigs and five male and five female naive guinea pigs were patched with the test material at 75% w/v in distilled water as described in the "Irritation" section. The newly patched sites were observed at 24 and 48 hours after treatment and scored for erythema and edema.

The results are presented in the table below. No score greater than a \pm was reported for any animal. In addition, the incidence of \pm scores was comparable for induced and naive guinea pigs, indicating that no sensitization was occurring.

INCIDENCE OF RESPONSES TO 75% FIREBRAKE ZB

GROUP	24-HOUR					48-HOUR				
	0	+	1	2	3	0	+	1	2	3
Test	13	7	0	0	0	15	5	0	0	0
Naive	4	6	0	0	0	3	7	0	0	0

B. DISCUSSION

Based upon the data provided by the registrant, no evidence of dermal sensitization was reported. Primary irritation due to the test material at concentrations up to 75% w/v in distilled water was equivocal.

The study report does not contain positive or negative control data run concurrent with the study. Historical data for positive controls were provided but these are of little value. In the absence of confirmation that the test system was responsive, i.e., positive control data, this study can not be considered to adequately evaluate the sensitization potential of the test material.