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DATA EVALUATION REPORT

STUDY TYPE: Delayed Contact Hypersensitivity Guinea Pigs

TOX CHEM NO: 454E

MRID NO: 406126-11

TEST MATERIAL: N-Ethyl Perfluorooctanesulfonamide

SYNONYMS: GX-071

STUDY NUMBER: SLS 3159.3

SPONSOR: Griffin Corporation

TESTING FACILITY: Springborn Life Sciences, Inc.-Toxicology and Human Safety Division

TITLE OF REPORT: Delayed Contact Hypersensitivity Study in Guinea Pigs with GX-071

AUTHORS: Joseph C. Siglin, B.A.

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CONCLUSIONS: This study is inadequate for use in the assessment of the potential of GX-071 to elicit a delayed contact hypersensitivity response in guinea pigs. No positive control was utilized.

CLASSIFICATION: Core supplementary.

A. MATERIALS:

1. Test Compound: GX-071
   Description: not provided
   Batch #: Lot # 10; SIB ID S86.005.3159
   Purity: not specified

2. Test Animals:
   Species: guinea pigs
   Strain: Hsd:(HA)BR Hartley derived albino
   Age: young adult
   Weight: 300-500 g
   Source: Harlan Sprague Dawley, Inc.

Study Design: There were two phases to this study: an induction phase and a challenge phase, as well as an irritation screen. Body weights were recorded one day prior to each phase/screen and at termination.

Irritation Screen: GX-071 was tested for irritation potential to determine the appropriate concentrations to use in the sensitation study. Closed patches at various concentrations of GX-071 were applied to the animals (one patch per level, four levels per animal) as follows:

1- 0.4 ml of either a 75, 50, or 25% concentration of GX-071 in acetone was placed on a Webril patch or 0.3 grams of test material as supplied was placed in a Hilltop chamber.

2- the animal was placed in a restrainer and the patch(es) applied to the clipped surface of skin.

3- The patch(es) were occluded with a rubber dental dam pulled taut and fastened to the bottom of the restrainer with clips.

About 6 hours after dosing, the dental dam and patches were removed and the animals were returned to their cages. Twenty hours after patch removal, the exposure sites were depilated with a depilatory, which was subsequently washed off and the animals dried and returned to their cages.

After a minimum of two hours after dipilatation, the sites were graded on a scale of 0 to 3 (0=no reaction; ± slight patchy erythema; 1= slight, but confluent or moderate, patchy erythema; 2=moderate erythema; 3=severe erythema with or without edema). An additional grading was performed 24 hours later.

a) induction phase - dermal application of 0.3 g od GX-071 (as supplied) was applied to each animal's back, under the Hill Top Chamber (patch) , as described above. Approximately 6 hours after dosing, the dental dam and patch were removed and the animals were returned to their cages. This procedure was repeated once a week for 3 consecutive weeks, for a total of three 6-hour treatments with test material. After the third induction exposure, the animals were rested for 12-16 days before the primary challenge. No vehicle control was utilized. The protocol stated that the positive control would be dissolved in ethanol for induction and acetone for challenge. The positive control animals were to be induced with three treatments of 0.3% dinitrochlorobenzene (DNCB) and challenged with 0.2 and 0.02% DNCB.

b) challenge phase - animals previously exposed during the induction phase, as well as the previously untreated controls were challenged to the test material after the rest phase. They were treated as described in the irritation screen by applying the 0.3 g aliquot

of test material to an unexposed test site. Approximately 20 hours after patch removal, the exposure sites were debilitated as described previously. After a minimum of two hours after depilitation, the test sites were graded as described previously. All animals were discarded at study termination.

Results: Following a range-finding study in which 100%, 75% and 50% concentrations produced no dermal irritation, the test material was used as received. It was reported that the test material produced no dermal irritation during the induction phase, although no data were provided. Two control animals had slight patchy erythema at 24 hours after the challenge phase. There were no responders reported in the group treated with 100% GX-071 and challenged with 100% GX-071. Although the protocol and MATERIAL AND METHODS section describe the positive control, no mention is made of the results, and no raw data on the positive control were provided.

Comment: This report consists of:

1- the protocol
2- a MATERIAL AND METHODS section
3- raw data sheets
4- a one-page summary giving the PURPOSE, RESULTS (Table), and a CONCLUSION.

Conclusion: This study is inadequate in that there was no positive control utilized to demonstrate that a sensitizer could be identified under the conditions of the study. This study is classified as supplementary.