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DATA EVALUATION REPORT

STUDY TYPE: Primary Dermal Irritation - rabbits TOX CHEM NO: 454E

ACCESSION NUMBER: MRID NO: 406126-10

TEST MATERIAL N-Ethyl Perflourooctanesulfonamide

SYNONYMS: GX-071

STUDY NUMBER: PROJECT NO.:85G-0031

SPONSOR: Griffin corporation

TESTING FACILITY: Toxikon Corporation

TITLE OF REPORT: Primary Dermal Irritation Study Of GX-071 In Rabbits

AUTHORS: Richard Adams , Ph. D.

REPORT ISSUED: September 26, 1985; amended March 21, 1988

CONCLUSIONS: GX-071 was reported to be a potential mild skin irritant, based on a Primary Dermal Irritation Score of 0.13.

CLASSIFICATION: Core minimum

A. MATERIALS:

1. Test Compound: GX-071
   Description: white needle crystals
   Batch # not specified
   Purity: 99+%

2. Test Animals:
   Species: male and female rabbits
   Strain: New Zealand White
   Age: young adult (6-9 months)
   Weight: 2.5-3.9 kilograms
   Source: Peter Mazzoleni, Taunton, MA

Study Design: The application sites were prepared by clipping the skin of the trunk free of hair (time period before test substance application was not stated). There were two application sites per animal. The test substance (0.5 grams of solid) was introduced under gauze patches that were applied to the skin and secured with adhesive tape. The animals were immobilized (method not specified). The entire trunk of the animal was then wrapped with an impervious, nonreactive rubberized elastic band material. Exposure was for 4 hours. Following exposure, the wrapping was removed and the skin was wiped to remove any test substance remaining. Animals were observed for signs of erythema and edema at 4, 24, 48, and 72 hours after exposure. Body weights were recorded prior to study initiation and at the end of the observation period. Observations were scored according to the "Draize Scale for Scoring Skin Reactions" (FDA, 1965).

Results: None of the animals displayed clinical signs that could be attributed to the test substance. All animals either maintained their body weight or gain weight during the study. Very slight erythema (value=1) was reported in 3 of 6 test animals, with no evidence of edema at the four-hour observation period. No other effects were noted at any other time point. The final Primary Dermal Irritation Score for GX-071 was reported as 0.13, and was considered to have the potential of a mild irritant.

Conclusion: GX-071 was reported as a potential mild irritant.