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DATA EVALUATION REPORT

STUDY TYPE: Single Dose Dermal Toxicity-rabbits TOX CHEM NO: 454E

MRID NO: 406126-08

TEST MATERIAL: N-Ethyl Perfluorooctanesulfonaimid

SYNONYMS: GX-071

STUDY NUMBER: 85G-0032

SPONSOR: Griffin Corporation

TESTING FACILITY: Toxikon Corporation

TITLE OF REPORT: Single Dose Dermal Toxicity Study of GX-071 in Rabbits
Limit Test

AUTHORS: Richard Adams, Ph.D.

REPORT ISSUED: September 18, 1985; amended March 21, 1988

CONCLUSIONS: The single dose dermal LD₅₀ for GX-071 is greater than
2000 mg/kg; Toxicity Category III.

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 and 8 months
Weight: 2.7-3.2 kilograms
Source: Peter Mazzoleni, Taunton, MA

Study Design: The site of application was prepared by clipping the skin of the trunk free of hair. The length of time prior to dosing was not specified. The test material was applied to the skin under gauze patches placed directly on the skin (area of 10% of the body surface) of 10 animals. There were no controls. The animals were

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immobilized with patches secured in place by adhesive tape. The entire trunk was then wrapped with an imperious, nonreactive rubberized elastic band material to keep the test material in contact with the skin for 24 hours. The wrappings were removed after 24 hours, excessive test material removed by wiping off the material remaining on the skin. The animals were observed for signs of erythema and edema and weighed on days 7 and 14 and observed for clinical signs of toxicity (daily) for 14 days. All animals were subjected to a gross necropsy at the end of the study. Note: The criteria for the selection of the animals for testing was not described.

Results: All rabbits survived the 14-day study period. None of the animals were reported to have exhibited any clinical signs that could be attributed to the test material. Four of the 10 rabbits exhibited very slight erythema after the 24-hour exposure period.

The animals either maintained or gained weight during the observation period (males +0.132 kg; females +0.126 kg). Note: The final body weight for the males was incorrectly reported as 3.07 kg; it should read 3.03 kg.

There were no significant lesions reported for any of the animals.

Conclusion: The acute dermal LD₅₀ in rabbits is greater than 2000 mg/kg.