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DATA EVALUATION REPORT

STUDY TYPE: Acute oral LD_{50} - rats TOX CHEM NO: 454E

MRID NO: 406126-20

TEST MATERIAL: N-Ethyl Perfluorooctanesulfonamide

SYNONYMS: GX-071

STUDY NUMBER: Project No.: 86G-0001

SPONSOR: Griffin Corporation Valdosta, GA

TESTING FACILITY: Toxikon Corporation

TITLE OF REPORT: Acute Oral LD_{50} Toxicity Study GX-071

AUTHORS: R.A. Adams, Ph. D., D.A.B.T.

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CONCLUSIONS: Only one animal (high-dose female) died during this study. No LD_{50} was calculated. Under the conditions of this study, the LD_{50} for GX-071 appears to be in excess of 6.0 g/kg.

CLASSIFICATION: Core supplementary, pending receipt of body-weight data.

A. MATERIALS:

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

2. Test Animals:
   Species: rats, both sexes
   Strain: Sprague-Dawley
   Age: 8-12 weeks old
   Weight: 215-226 grams
   Source: Charles River Breeding Laboratories, Wilmington, Del.

Study Design: Five (fasted) rats per sex per group were administered 1.5, 3.0, or 6.0 grams of test material per kg in a 10% gelatin suspension. It is stated that the dose was given in 4-5 mls of the suspension (flavored with a few drops of anise flavoring), which was allowed to harden, and that all animals were dosed on the same day within a 2-3 hour period. The control was administered 4-5 mls of the gelatin; it is not stated whether the control also received anise flavoring. The

animals were observed for 14 days following dosing; body weights were measured and days 7 and 14 following dosing, and a gross necropsy was performed on all animals at termination.

Results: It is stated that the data indicate a treatment-related (females - dose-related) inhibition in weight gain, with an absolute weight loss noted among the high-dose females. The body-weight effects were said to be accompanied by a treatment-related thinning of the fur. There was one (female) death, which was attributed to an apparent impairment in food consumption. No LD_{50} was calculated, but it was suggested that when GX-071 is administered as in this study, the LD_{50} would be in excess of 6.0 grams/kg. It is to be noted that the Appendix referred to in the RESULTS section was not included in the final report. Additionally, on page 11, the dose is incorrectly listed as mg/kg in stead of gm/kg.

Conclusion: This study is classified as supplementary, pending receipt of the body weight data.

Discussion: It is noted that the study results obtained here are in sharp contrast to a study (MRID # 406126-07), in which there was 100% death at 5 g/kg. The vehicle used in these studies differed, suggesting that availability of GX-071 for absorption may depend on the vehicle used. The current study utilized a 10% gelatin suspension; MRID # 406126007 utilized soybean oil. In a third study (MRID # 406126-06), in which a dose of 6 g/kg was tested (vehicle-soybean oil), 4 out of 5 males and 1 of 5 females died. The differences between the two studies testing 6 g/kg were the number of portions the dose was divided into (Study-20 had one portion; Study-06 had three) and the vehicle (gelatin and soybean suspensions, respectively). A fourth study (MRID # 406126-04) also used a 5 g/kg dose, and two males and four females died within 48 hours of dosing. The vehicle was corn oil and the dose was divided into two portions.