Reviewed by: Linda L. Taylor, Ph.D. Linda Lee Taylor 8/8/88
Section III, Tox. Branch (TS-769C)
Secondary Reviewer: Marcia van Gemert, Ph.D. M van Gemert 8/9/88
Head, Section III, Tox. Branch (TS-769C)

DATA EVALUATION REPORT

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

MRID NUMBER: 406126-07

TEST MATERIAL: N-Ethyl Perfluorooctanesulfonamide

SYNONYMS: GX-071

STUDY NUMBER: Project No.: UGA 003

SPONSOR: Griffin Corporation Valdosta, GA

TESTING FACILITY: Department of Pathology College of Veterinary Medicine
The University of Medicine University - Georgia

TITLE OF REPORT: Acute Oral Limit Toxicity Test In Rats GX-071 (LOT 4)

AUTHORS: Willie L. Chapman, D.V.M., Ph. D.

REPORT ISSUED: November 20, 1985; amended April 20, 1988

CONCLUSION: All animals died within 10 days of GX-071 administration at a dose level of 5 grams/kg.

CLASSIFICATION: Core minimum.

A. MATERIALS:

1. Test Compound: GX-071
   Description: not specified
   Batch #: BN 8406191; Lot 4
   Purity: 99+%

2. Test Animals:
   Species: rats, both sexes
   Strain: Sprague-Dawley
   Age: 46-68 days old
   Weight: males-205grams; females-189 grams
   Source: Harlan Sprague Dawley, Inc., Indianapolis, IN

Study Design: Five (fasted) rats per sex were given single (5000 mg/kg) doses of test material by intragastric intubation (suspended in soybean oil) in two divided portions given two hours apart. Animals were weighed prior to dosing and at 7 days after treatment. Twice-daily observations were made for 10 days following dosing. No pathological examinations were performed.

Results: According to the study text, abnormal clinical signs observed in the treated animals included weight loss, emaciation, inappetance, ruffled hair coat, depression, and convulsions. All treated animals were dead within 7-10 days following dosing. Fifty percent were dead within 24 hours (3 males, 2 females) and 80% (4/sex) within 48 hours. On days 4 and 5 after dosing, one animal per sex displayed ruffled hair coats, hunched posture, and convulsed when provoked by auditory stimuli.

Conclusion: All animals administered 5000 mg/kg died within 10 days of test material administration. No LD_{50} was attained. The study is classified as core minimum.

Discussion: In a similar study in which a dose of 5000 mg/kg was tested (MRID # 406126-04), two males and four females died within 48 hours. The vehicle in this latter study was corn oil (dose divided into 2 portions, four hours apart), in contrast to soybean oil used in the current study. Two other studies in which doses of 6000 mg/kg were tested (MRID #s 406126-06 and 406126-20) also had dissimilar results. In MRID # 406126-06, four males and one female died (out of 5/sex). The vehicle was soybean oil and the dose was divided into 3 portions. In MRID # 406126-20, only one female died. The test substance was administered in a gelatin suspension (one portion).