1/24/2001



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**DATA EVALUATION REPORT**

| | | | |
|---|---|---|---|
| STUDY TYPE: | Acute Oral Toxicity/Rat<br>OPPTS 870.1100 [§ 81-1] | | |
| DP BARCODE: | D270915 | SUBMISSION CODE: | S576708 |
| P.C. CODE: | 000101 | Case: | 062360 |
| TEST MATERIAL: | Glycolic Acid [70% a.i.] | | |
| SYNONYMS: | Hydroxyethanoic Acid 70% solution; Acetic acid, Hydroxy-70% solution | | |
| CITATION: | Finlay, C. Glycolic Acid 70% Solution: Acute Oral Toxicity in Male and Female Rats; E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine, Newark, DE 19714-0050. Laboratory Project ID: No. 1614, Nov. 2, 1998; MRID 449753-01; Unpublished. | | |
| SPONSOR: | E.I. du Pont de Nemours and Company, Wilmington, DE | | |

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 449753-01), a formulation containing, Glycolic Acid [70% a.i.] was administered undiluted, at 4 dose levels of 0, 1000, 2000 or 3000 mg/kg to each of 5 Sprague-Dawley rats/sex. Observations during the 15 day test period included daily mortality checks, daily body weight determinations and observations for clinical signs of toxicity (except on weekends and holidays). All rats found dead or sacrificed by design were necropsied to detect grossly observable evidence of organ or tissue damage or dysfunction.

Deaths occurred up to 4 days after dosing. Mortality occurred in 0/10 [0 mg/kg], 0/10 [1000], 6/10 [2000] and 9/10 [3000] rats of both sexes. Five (5) males at 3000 mg/kg, 1 female at 2000 mg/kg and 4 females at 3000 mg/kg showed black stomach discoloration.

**In both sexes combined, the calculated $LD_{50}$ was 1,938 mg/kg (Toxicity Category III, 500 thru 5000 mg/kg).**

This acute oral toxicity study in rats is **Acceptable** and satisfies the guideline requirement [§ 81-1] for an Acute Oral Toxicity Study.

COMPLIANCE

Statements of Quality Assurance, Good Laboratory Practice compliance and No Data Confidentiality Claims were signed and dated.

## I. MATERIALS

### A. Test Material

| | |
|---|---|
| Test Compound: | Glycolic Acid |
| Purity: | 70.58% a.i. |
| Lot: | Haskell No. 23274 |
| Synonym: | Hydroxyethanoic acid 70% solution; Acetic acid, Hydroxy-70% solution |
| Description: | Pale-yellow Liquid |
| Storage: | NA |
| Stability: | The test substance appeared to be stable under the conditions of the study. |

### B. Test Animals

| | |
|---|---|
| Species: | Rat |
| Strain: | Sprague-Dawley [Crl:CD(SD)IGS BR] |
| Source: | Charles River Laboratories, Inc., Raleigh, NC |
| Groups: | Four (4) group of 5 ♂ and 5 ♀. |
| Feed: | Purina Rodent LabDiet® 5002, *ad-libitum* |
| Water: | *ad-libitum* |
| Weight: | ♂: 224 to 230 gm [57 to 58 days old]; ♀: 207 to 213 gm [78 or 79 days old], at study start |
| Acclimatization: | 6 days |
| Housing: | NA |
| Environmental: | Temperature: 23° ±1° C<br>Relative humidity 50%±10%<br>Photoperiod: 12 hour light/dark cycle |

## II. METHODS

In life dates: start: 8/16/98, end: 9/09/98

**A. Compound Administration**

Ten (5 males and 5 females) healthy, fasted rats [18 hours] were each dosed by oral intubation with a single, oral dose of the test substance at 0, 1,000, 2,000, or 3,000 mg/kg and observed for 15 days. The test material was not diluted. The test substance was stirred prior to and throughout the dosing procedure.

**B. Observations**

Observations during the 15 day test period included daily mortality checks, daily body weight determinations and observations for clinical signs of toxicity (except on weekends and holidays). All rats found dead or sacrificed by design were necropsied to detect grossly observable evidence of organ or tissue damage or dysfunction.

Individual dose volumes were calculated using fasted body weight obtained prior to dosing and were based on the test substance density of 1.25 gm/ml. Doses were adjusted for purity.

The LD50 value for male and female was calculated from the mortality data using the method of Finney.

**C. Necropsy**

Rats were euthanized via $CO_2$ followed by exsanguination and then necropsied for gross pathology on day 15. Abnormalities were recorded.

**III. RESULTS**

**A. Mortality (Table 1)**

**0 mg/kg** - ♂/♀: no deaths

**1,000 mg/kg** - ♂/♀: no deaths

**2,000 mg/kg** - ♂: 2 animals found dead on day 3; ♀:1 animal found dead on day 1, 3 animals found dead on day 2

**3,000 mg/kg** - ♂: 3 animals found dead on day 3, one animal each, found dead on days 3 and 4; ♀: 4 animals found dead on day 2.

| Dose levels (mg/kg) | Table 1. Mortality* | | |
|---|---|---|---|
| | Males | Females | Total |
| 0 | 0/5 | 0/5 | 0/10 |
| 1,000 | 0/5 | 0/5 | 0/10 |
| 2,000 | 2/5 | 4/5 | 6/10 |
| 3,000 | 5/5 | 4/5 | 9/10 |

*Mortality/total number of animals

**B. Observations**

Test substance related clinical signs often included lethargy, lung noise, red or clear ocular discharge and prostrate posture. Other test substance related clinical signs included hunched posture, red-stained chin, clear oral discharge, bloating, pallor, lack of eating and moribundity.

**C. Gross Pathology**

Five (5) males at 3000 mg/kg, 1 female at 2000 mg/kg and 4 females at 3000 mg/kg showed black stomach discoloration which appeared to be test substance related. This discoloration, about 1 mm thick, could easily be removed by scraping. Most of the rats with black discoloration also had stomachs distended with black fluid.

One female at 2000 mg/kg also showed brown lung discoloration. The authors speculate that this lesion might have been caused by a gavage accident.

**IV. CONCLUSIONS**

In both sexes combined, the $LD_{50}$ was 1,938 mg/kg (Toxicity Category III).