

8EHQ-0570-13401

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DuPont Central Research and Development



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March 29, 1995

ORIGINAL

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Document Processing Center (TS-790)
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460



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Dear 8(e) Coordinator:

70% Technical Grade Glycolic Acid

This letter is to inform you of the preliminary results of a recently completed pilot rat developmental toxicity study conducted on the subject mixture. The mixture is comprised of 70% glycolic acid (CAS No. 79-14-1), 1.1% methoxyacetic acid (CAS No. 625-45-6), 0.8% diglycolic acid (CAS No. 110-99-6), 3000 ppm formic acid (CAS No. 64-18-6) and 560 ppm formaldehyde (CAS No. 50-00-0).

Solutions of the test material in distilled water were administered by gavage to groups of 8 rats on days 7-21 of gestation (copulation plug detection was designated as day 1) at daily dose levels of 0, 125, 250, 500, or 1000 mg/kg of body weight. Surviving females were sacrificed on day 22 of gestation and the live fetuses examined for external, visceral and skeletal alterations.

Maternal toxicity was detected at 500 and 1000 mg/kg. At 500 mg/kg, there were significant increases in the clinical observations of wet chin and lung noise. Maternal weight gains were significantly reduced over Days 21-22G. At 1000 mg/kg, one of eight dams died prematurely. Among the survivors, maternal weight changes were reduced at several intervals during the course of the dosing period and when averaged over the dosing period (Days 7-22G). Maternal food consumption was similarly affected. Adverse clinical observations were significantly increased at 1000 mg/kg and included abnormal gait, lung noise, salivation, stained and wet fur.

Developmental toxicity was detected at 500 and 1000 mg/kg. At 500 mg/kg, mean fetal weight was reduced and the incidence of retarded sternal ossification was increased. At 1000 mg/kg, developmental toxicity was manifest as reduced mean fetal body weight and increased fetal resorptions. In addition, there were increases in fetal malformations and variations at 1000 mg/kg. All these changes were statistically significant.

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There was no evidence of either maternal or developmental toxicity at 250 or 125 mg/kg/day.

Under the experimental conditions employed and based upon EPA's June, 1991 guidance regarding the reportability of such data under TSCA Section 8(e), the Agency is being notified of these results.

Considering the outcome of this pilot study, we are in the process of planning a definitive developmental toxicity study in rats.

Sincerely,

Charles F. Reinhardt

Charles F. Reinhardt, M.D.
Director

CFR/SMM:dj
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