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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

Dear 8(e) Coordinator:

Contains No CBI

Glycolic Acid
CAS No. 79-14-1

In our letter of March 29, 1995, we informed the Agency of the results of a pilot rat developmental toxicity study with 70% technical grade glycolic acid. This letter is to inform you of the preliminary results of a recently completed rat developmental toxicity study conducted with Glypure® 99 high purity glycolic acid - crystalline.

The study results described in this letter are qualitatively and quantitatively similar to the results obtained in the pilot developmental toxicity study, which were reported to the Agency.

Solutions of the test material in deionized water were administered by gavage to groups of 25 rats on days 7-21 of gestation (copulation plug detection was designated as day 1) at daily dose levels of 0, 75, 170, 300, or 600 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.

Developmental toxicity was observed at 300 and 600 mg/kg. At 300 mg/kg, there were slight, but non-statistically significant, increases in the incidences of two malformations: fused ribs and fused vertebra. At 600 mg/kg, these two malformations were significantly increased. In addition, the following malformations and variations were also significantly increased: absent ribs, abnormally fused and cleft sternebra, hemi-vertebra, misaligned and incompletely ossified sternebra, and incompletely ossified vertebra. Mean fetal weight was significantly reduced at 600 mg/kg.

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Maternal toxicity was also observed at 300 and 600 mg/kg. At 300 mg/kg, lung noise (wheezing/rattling persisting into the afternoon and occasionally into the next day) was slightly increased (2/25 affected). At 600 mg/kg, lung noise was markedly increased (8/25 affected). Other adverse clinical observations were significantly increased at 600 mg/kg and included abnormal gait (staggering), lethargy, and irregular respiration. In addition, mean maternal body weight, weight change, and food consumption were significantly reduced at 600 mg/kg.

There was no evidence of either maternal or developmental toxicity at 75 or 150 mg/kg, and thus, the no-observed-effect level was 150 mg/kg. Therefore, under the conditions of this study, glycolic acid was not uniquely toxic to the rat conceptus and should not be considered a developmental toxin.

We also conclude that our internal existing safe exposure limit (Acceptable Exposure Limit) of 10 mg/m^3 (3 ppm), 8- and 12-hr TWA, remains valid and that additional exposure controls are unwarranted.

EPA is being notified of these results in conformance with the Agency's June, 1991 guidance regarding the reportability of such data under TSCA section 8 (e).

Sincerely,

A. Michael Kaplan for CFR

Charles F. Reinhardt, M.D.
Director

CFR/SMM:dj
Phone: (302) 366-5285

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