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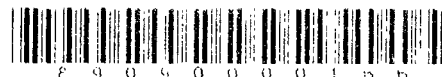
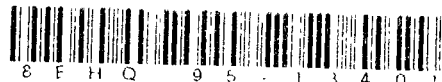
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DuPont Haskell Global Centers
for Health and Environmental Sciences
1090 Elkton Road, P.O. Box 50
Newark, DE 19714-0050

March 3, 2009

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20004



Dear 8(e) Coordinator:

8EHQ-95-13401
70% Technical Grade Glycolic Acid

This letter is to inform you of the preliminary results of a recently conducted developmental toxicity study in rats with the test substance referenced above. The test substance is comprised of 71.3% glycolic acid (CAS no. 79-14-1), 1.0 % methoxyacetic acid (CAS No. 625-45-6), 1.0% diglycolic acid (CAS no. 110-99-6), 0.3% formic acid (CAS No. 64-18-6), and 0.04 ppm formaldehyde (CAS No. 50-00-0) in water.

Groups of 22 time-mated Crl:CD®(SD) rats were administered formulations of the test substance in deionized water by once daily gavage on gestation days (GD) 6-20 at daily dose levels of 0, 100, 300, or 900 mg/kg/day. The dose volume was 10 ml/kg for all groups. Dose formulations were buffered to pH 3 to comply with current animal welfare guidelines. The control group rats were dosed with deionized water only. During the in-life portion of the study, maternal clinical observations, body weights, and food consumption data were collected. On GD 21, all dams were euthanized and a gross external and visceral examination was performed. The uterus of each pregnant female was removed and the uterine contents were examined and described; all fetuses were removed and individually identified, weighed, sexed, and examined for external alterations. Approximately one-half of the fetuses were examined for soft tissue alterations; all fetuses were examined for skeletal alterations.

Developmental toxicity was evident at the highest dose tested (900 mg/kg/day) and consisted of reduced fetal weight and increased fetal malformations and variations. Two litters at 900 mg/kg/day had malformed fetuses. These malformations included absent and fused ribs, hemivertebrae, sternoschisis, gastroschisis, macrophthalmia, and absent stomach, spleen, pancreas, and intestines. In addition, there was an increased incidence of fetal variations which included bipartite ossification of the thoracic and/or lumbar centrum, misaligned sternbrae, and supernumary ribs (short and/or full).

There was no test substance-related maternal toxicity observed at any dose level. There was no evidence of developmental toxicity at 300 mg/kg/day (NOEL) or below.

The results of the current study are consistent with previous studies with the exception of the absence of maternal toxicity at the highest dose. A significant difference in the conduct of this study versus previous studies was the use of a buffered dose solution to comply with current animal welfare guidelines. The NOEL for this study is higher than previously observed (300 mg/kg/d vs. 250 mg/kg/d).

Confidential

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This information is submitted in accordance with current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act or, where it is not clear that reporting criteria have been met, it is submitted as a precautionary measure and because it is information in which EPA may have an interest.

Sincerely,

A handwritten signature in cursive script that reads "A. Michael Kaplan". The signature is written in black ink and includes a long horizontal flourish at the end.

A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs

AMK/JML: clp
(302) 366-5260