MR # 306484

PUBLIC COPY

August 15, 2007

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, D.C. 20460

Company Sanitized

8EHQ-06-16486

Dear 8(e) Coordinator:

8EHQ-06-16486
Hydrofluorocarbon

This letter is to inform you of the results of a recently conducted developmental toxicity study in rats with the R&D test substance referenced above.

Groups of 25 time-mated pregnant female Crl:CD®(SD) rats were exposed via whole body inhalation exposures to the test substance at atmospheric concentrations of 500, 1,000, or 5,000 ppm for 6 hours per day during gestation days (GD) 6 to 20. Control group females were exposed to conditioned air alone according to the same exposure regimen. During the in-life portion of the study, maternal body weights, food consumption, and clinical signs data were collected. A gross pathology exam was conducted on dams on GD 21; the uterine contents were examined and described (number and status of implantation sites, and fetal assessment – viable, nonviable, location, fetal weight, external alterations). Approximately one-half of the fetuses were subjected to soft tissue examinations (visceral and head); all fetuses were examined for skeletal alterations.

There was no test substance related maternal mortality, nor were there any test substance-related clinical signs of toxicity or gross pathological observations in dams at any exposure concentration. Test substance-related decreases in maternal body weight gain and food consumption were observed at 5,000 ppm. The number of resorptions and live fetuses, fetal weight, and fetal sex ratio were similar across groups. No test substance related fetal external or visceral malformations or variations were observed at any exposure level. The occurrence of bent rib, a skeletal variation, was increased at 1,000 and 5,000 ppm. The occurrence of 7th cervical rib, another skeletal variation, was increased at all concentration levels. No other test substance-related fetal skeletal variations or malformations were observed. Under the conditions of this study, a no-observed-effect level (NOAEL) was not established for developmental toxicity. The NOAEL for maternal toxicity was 1,000 ppm due to reduced bodyweight gains and food consumption at 5,000 ppm.

Under these experimental conditions, the findings described above appear to be reportable, based upon EPA's TSCA Section 8(e) reporting criteria.

Sincerely,

8907000045015