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FYI - 0399 - 1355



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MR 19740

March 2, 1999

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Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460



FYI-99-001355



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Attn: 8(e) Coordinator

SUBJECT: POSSIBLE REPRODUCTIVE EFFECTS NOTED IN AN INTERIM REPORT FROM A TWO-GENERATION DRINKING WATER STUDY WITH PHENOL

The following information is submitted on a FYI basis as information that the Agency may find useful.

The study is being conducted as part of an Enforceable Consent Agreement between US phenol manufacturers, as represented by the CMA Phenol Panel, and the US EPA. A draft report of the study has just been received, and the final report will be submitted to EPA in June 1999.

Rats were dosed with drinking water containing 0, 200, 1000, or 5000 ppm of phenol for 10 weeks prior to and during mating for two generations, the parental [P1] and F1 generations. The F2 generation was not maintained on phenol-containing drinking water, and was sacrificed at weaning [day 21]. At the 5000 ppm concentration in both sexes and in both P1 and F1 generations, there was decreased water intake with corollary decreased food intake and body weight gain; this is believed to be due to flavor aversion. Litter survival and offspring body weight were reduced in the 5000 group in both F1 and F2 generations; for survival this effect was more pronounced in the F2 generation. Delays in vaginal opening and preputial separation in the F1 generation were associated with decreased body weight gain. Mating performance and fertility were not affected. Vaginal cytology/cyclicality and male reproductive functions [epididymal/testes sperm counts, motility and morphology] were unaffected by treatment. No adverse treatment-related effects were observed microscopically in the testes, ovaries, uterus, prostate or any other tissues examined. Several absolute organ weight and relative organ weight changes at the 5000 ppm concentration were related to decreased body weight gain. A statistically significant decrease in the absolute weight of the prostate at all three concentrations, and of relative prostate weight at the 1000 ppm concentration, was reported in the F1 generation. A statistically significant decrease in absolute and relative uterus weight was reported at all three treatment concentrations in the F1 generation, but the magnitude of the decrease in relative weights was not dose-dependent.

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Decreased rat litter weights and pup survivability from maternal exposure to phenol has been previously reported at 7000 and 8000 ppm phenol in the drinking water, but this effect is now shown at a lower concentration [5000 ppm]. These effects are believed to be secondary to flavor aversion of phenol-containing drinking water. It is unclear if the decreased prostate and uterus weights are treatment-related. However, considering the lack of an apparent dose-dependent effect, and in the absence of any functional reproductive effect, and in the absence of any histological changes in these reproductive organs, these effects are not believed to indicate an adverse health effect.

This report is filed to provide information EPA may find useful. In no way is it intended as a waiver of any rights or privileges belonging to Shell Chemical Company as the reporting corporation, its agents or employees. The reporting corporation, its agents and employees, reserve the right to object to this report's use or admissibility in any subsequent judicial or administrative proceeding against the corporation, its agents or employees.

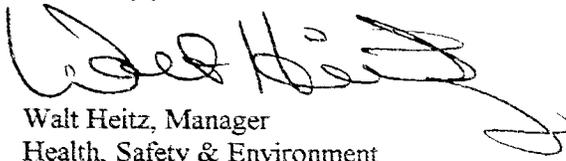
This report has been compiled based on information available as of the date of filing. The corporation, its agents and employees reserve the right to supplement the data contained in this report, and to revise and amend any conclusions drawn therefrom.

This report contains no Confidential Business Information.

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