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Submitting Organization
EXXON CHEMICAL CO

Contractor

Document Title
INITIAL SUBMISSION: LETTER FROM EXXON CHEMICAL CO TO USEPA REPORTING PRELIMINARY RESULTS IN REPRODUCTIVE TOXICITY STUDY OF HEXANOIC ACID, 3,5,5-TRIMETHYL- W/ATTCHMTS, DATED 5/22/98

Chemical Category
HEXANOIC ACID, 3,5,5-TRIMETHYL-

8EHQ-0598-14185

EXXON CHEMICAL COMPANY

EXXON CHEMICAL

Safety and Environmental Affairs Department
David J. Johnson
MANAGER, SAFETY PROGRAMS

8EHQ-98-14185

May 22, 1998

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U. S. Environmental Protection Agency
401 M Street, S. W.
Washington, D. C. 20460-0001

Contains No CBI

Re: Notification of Substantial Risk Under TSCA Section 8(e)

Dear Sir or Madam:

Under the provisions of Section 8(e) of the Toxic Substances Control Act, Exxon Chemical Company is submitting the following preliminary information describing the reproductive toxicity of a substance described as Hexanoic acid, 3,5,5-trimethyl- (CAS Registry Number 3302-10-1). This substance is currently being imported for commercial purposes as defined by TSCA.

Although the toxicity observed in this study is of low concern, we feel that these preliminary results do warrant reporting under the substantial risk reporting requirements of TSCA §8(e). We consider these results to be of low concern because the observed effects in offspring were present only in conjunction with maternal toxicity at the highest dose levels tested. Further, based on our knowledge of how this chemical is used, we believe it is unlikely that this chemical could be used in any way that could lead to actual exposures approaching the dose levels at which effects were observed. The chemical has only limited use as an industrial chemical, with no consumer or other downstream uses. In an industrial setting, potential exposure can be controlled with appropriate personal protective equipment.

The data reported in this submission is from a one-generation reproductive toxicity study in rats. The preliminary results are described below and documented in the attached tables.

Preliminary Reproductive Toxicity Results

In this study, male and female CD rats were administered dietary preparations containing 0, 0.06, 0.12, 0.25 or 0.5% by weight of the test substance (approximately 0, 50, 100, 200 or 400 mg/kg/day) for at least ten weeks prior to mating, during the mating phase, and throughout gestation and lactation in the females. Offspring received the test compound at the same dietary percentages from weaning until study termination (approximately postnatal day 45).

No parental or pup effects were observed at dose levels of 0.12% or less in the diet. Dose-related maternal and pup effects were observed only at dose levels of 0.25% and 0.5%. At the 0.25% dose level, maternal food consumption was decreased, maternal liver weights were increased and pup body weights were decreased. At the 0.5% dose level, maternal food consumption and body weights were decreased and maternal liver weights were increased. Offspring effects were decreased litter size, increased stillbirths, decreased bodyweights and decreased survival during the early postnatal period.

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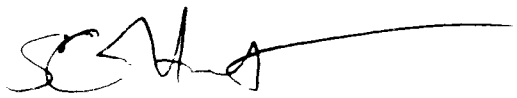
However, because maternal and pup effects occurred at the same doses, there was no evidence of a selective developmental effect. No effects were observed on fertility in the parental animals, and no external malformations were observed in the offspring at any dose level.

A summary of statistically significant findings is provided on Table 1 with detailed data provided on the following attached tables. Please note that the tables should be considered as draft data since they have not yet passed through a quality assurance review. A copy of the final report from this study will be forwarded to you as soon as it is available.

If you have any questions or need additional information, please feel free to contact me on (281) 870-6874.

Sincerely yours,



Steven G. Hentges

SGH/jad
Attachment