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Parametrix

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MR 272304

January 19, 2004
PMX# 555-3451-003



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Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
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Subject: TSCA 8(e) Submission

Dear Sir/Madam:

Parametrix, Inc. is submitting preliminary results from an oral reproduction/developmental toxicity screening study in rats to the United States Environmental Protection Agency (USEPA) pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The study provides information on dichlorodioctylstannane CAS# 3542-36-7.

Parametrix, Inc. is making this submission on behalf of the Organotin Environmental Programme (ORTEP) Association member companies producing dichlorodioctylstannane in the United States. The managing parties of this international consortium assert on behalf of the sponsoring companies that this notice does not involve effects in humans. It does not contain confidential business information [CBI] under TSCA.

Information below is based on the audited draft report of a 90-day oral study in rats conducted in accordance with OECD guideline 408 with the addition of a satellite group for a reprotoxicity screen as outlined in OECD guideline 421. The test substance is not a material of commerce. It was prepared to accommodate testing of dichlorodioctylstannane (CAS# 3542-36-7) in the High Production Volume (HPV) program. The material contained approximately 94% dichlorodioctylstannane, about 2% trichlorooctylstannane (CAS# 3091-25-6), and the remainder other octyltin compounds.

Groups of 10 male and 10 female rats were administered test substance mixed in feed at 0, 10, 100, 300 mg/kg of diet. During the 90 day study, test substance intake of the male animals averaged 0.7, 6.5 and 19.3 mg/kg body weight/day and in females were 0.7, 6.8, and 19.8 mg/kg body weight/day for the low, mid, and high dose, respectively.

Mean terminal body weight was statistically significantly decreased in the high dose females, as were interim bodyweights in high dose males and females throughout the study. Of the reported organ



weights, which were statistically significantly different from control, only the decreased thymus weight (all doses) had associated histopathological findings (lymphoid depletion in the thymus at the mid and high doses). Increased urinary crystals in high dose females, and several small but statistically significant changes in clinical chemistry and hematology parameters were also noted.

Because the decreased thymus weight was dose related, the lowest observed adverse effect level (LOAEL) in this study is the low dose, 10 ppm.

In the satellite group to screen for reprotoxicity, test substance was administered to females 2 weeks prior to mating with main group males. Test substance intake in females during gestation ranged from 0.5 - 0.7, 4.2 - 6.2, and 8.4 - 17mg/kg body weight/day for the low, mid, and high dose, respectively. At the high dose, mean body weight and body weight change of females was decreased relative to controls. In the high and mid doses, reduced gestation, live birth, and pup viability indices, increased post-implantation loss, and increased incidence of runts were observed. Overt lymphoid depletion of thymus was reported in dams at all dose levels.

The no observed adverse effect level (NOAEL) for reproductive and developmental effects and the lowest observed adverse effect level (LOAEL) for the maternal animals in this study were the low dose group of 10 ppm in diet (m: 0.7, f: 0.5 - 0.7 mg/kg/day).

Further questions regarding this submission may be directed to me at (425) 822-8880. Final reports are available to the Office of Pollution Prevention and Toxics upon request.

Best regards,
PARAMETRIX, INC.



Terry Phipps
ORTEP Association
High Production Volume Technical Coordinator

cc: Managing Parties:
ATOFINA Chemicals, Inc.
Crompton Corporation
Rohm and Haas Company