

Parametrix

8EHQ-1003-15430

NR 269946

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RE: TSCA 8(e) Submission



Dear Sir/Madam:

Parametrix, Inc. is submitting preliminary results from a combined oral repeated dose toxicity study with reproduction/developmental toxicity screening 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 tetrabutylstannane CAS # 1461-25-2.

Parametrix, Inc. is making this submission on behalf of the Organotin Environmental Programme (ORTEP) Association Member companies producing tetrabutylstannane 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 study conducted in accordance with OECD guideline 422.

Groups of 12 male and 12 female rats were administered test substance mixed in feed at 0, 100, 300, and 2000 mg/kg of diet. During the intervals measured, test substance intake of the male animals ranged from 6 – 7, 17 – 20, and 109 – 130 mg/kg body weight/day while the ranges in females were 5 – 8, 16 – 24, and 100 – 118 mg/kg body weight/day for the low, mid, and high dose, respectively.

Mean body weights and body weight changes were statistically significantly decreased in the high dose males and females at various measurement intervals.

Reduced relative and absolute thymus weights of male animals in the high dose group and relative spleen weight of the high and mid dose group were statistically significant, while reductions in the thymus weights in female high dose animals and male and female mid dose animals did not reach statistical significance. Lymphoid depletion of the thymus in females of the mid and high dose group and paracortical lymphoid depletion in the high dose males and females were also noted.

Food consumption was also consistently decreased in the high dose males and females, and at one time interval in the mid dose females.

Statistically and/or biologically significant reproductive findings in the high dose group included:

- Reduced numbers of pups delivered
- Reduced number of live pup/litter on postnatal days 1 and 4
- Increased postnatal pup mortality
- Increased numbers of runts

The no observed adverse effect level (NOAEL) for general toxicity was 100 mg/kg of diet. The NOAEL for reproductive toxicity was 300 mg/kg of diet in this study.

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 to Managing Parties:

- A TOFINA Chemicals, Inc.
- Crompton Corporation
- Rohm and Haas Company

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