

Parametrix

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September 29, 2003
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Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Avenue, N.W.
Washington, D.C. 20460

Contain NO CBI

Re: 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 dibutylchlorostannane CAS # 683-18-1.

Parametrix, Inc. is making this submission on behalf of the Organotin Environmental Programme (ORTEP) Association member companies producing dibutylchlorostannane 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 421.

Groups of 12 male and 12 female rats were administered test substance mixed in feed at 0, 5, 30, and 200 mg/kg of diet. During the intervals measured, test substance intake of the male animals ranged from 0.3 – 0.4, 1.9 – 2.3, and 10.4 - 13 mg/kg body weight/day while the ranges in females were 0.3 – 0.4, 1.7 – 2.4, and 6.2 – 15.4 mg/kg body weight/day for the low, mid, and high dose, respectively.

Statistically significant decreases in mean body weights and body weight changes were noted in the high dose males and females at various measurement intervals. Body weight change in the mid dose males was also decreased from days 14 to 21.

The high and mid dose female animals exhibited reduced relative and absolute thymus weights accompanied by lymphoid depletion. An increased incidence of ovarian cysts was also reported in high dose females.

Food consumption was also consistently decreased in the high dose males and females, but was not statistically significant at all measurement intervals.

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

- Reduced gestation index
- Increased postimplantation loss
- Lower number of dams with liveborn pups
- Increased number of stillborn pups and dams pregnant with no delivery
- Reduced numbers of pups per litter and of liveborn pups per litter
- Increased postnatal pup mortality
- Decreased number of live pups on postnatal days 1 and 4
- Lower mean pup weights and increased percentage of runts

The no observed adverse effect level (NOAEL) for general toxicity is 5 mg/kg of diet. The NOAEL for reproductive toxicity is 30 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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