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Via Certified Mail

March 12, 2009

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
Attn: Section 8(e)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001



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

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances and Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, the Silicones Environmental, Health and Safety Council (SEHSC)¹ submits, on behalf of its member companies, information concerning an ongoing study with Dimethoxydimethylsilane (CAS No. 1112-39-6). Neither SEHSC, nor any member company, has made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings

Chemical Substances

1112-39-6 Dimethoxydimethylsilane



Ongoing Study

Combined Repeated Dose Toxicity Study with the Reproductive/Developmental Toxicity Screening Test for Dimethoxydimethylsilane in Sprague-Dawley Rats via Oral Gavage.

¹ SEHSC is a not-for-profit trade association whose mission is to promote the safe use of silicones through product stewardship and environmental, health, and safety research. The Council is comprised of North American silicone chemical producers and importers.

Contains No CBI **CONTAINS NO CBI**

Summary

Results from a repeated-dose, subchronic toxicity study with reproductive/developmental screening endpoints conducted with dimethoxydimethylsilane in Sprague-Dawley rats show a statistically significant reduction in litter size at the high dose of 1000 mg/kg/day compared to controls. Differences were noted in other reproductive parameters between the high dose group and control group for the percentage of post-implantation loss, days of gestation, the number of viable pups at day 4, final average pup weight, and the percent of postnatal loss. There were no structural abnormalities observed for pups in any dose group. Maternal body weight change for the third week of gestation was reduced for high dose dams compared to controls, which is likely related to the reduction in the number of pups/litter. There were no statistically significant body weight changes or food consumption differences in the toxicology female group. The only statistically significant changes in female organ weights and ratios were liver (increased at 250 and 1000 mg/kg/day) and spleen (decreased at 1000 mg/kg/day only).

Details

Study Design

In a combined repeated-dose subchronic toxicity study with reproductive/developmental screening endpoints conducted with dimethoxydimethylsilane, male and female Sprague-Dawley rats were exposed by oral gavage to doses of 0, 50, 250 or 1000 mg/kg bw/d for 28 to 42 consecutive days. The study animals were divided into three groups. Group 1 (male toxicity group) consisted of 10 male rats per exposure concentration. Rats in this group were exposed for 29 consecutive days and then euthanized the next day for assessment of toxicity. Group 2 (female toxicity group) consisted of 10 female rats per dose group. Rats in this group were exposed for 28 consecutive days and then euthanized the next day for assessment of toxicity. Group 3 (female reproductive toxicity group) consisted of 10 female rats per dose group. Rats in this group were exposed for a two-week pre-mating phase, a 1 – 14-day mating phase, and through day 3 postpartum. Beginning on study day 14, males from group 1 were paired with reproductive group females from the same dose group after dosing each day. Pairing ended when there was positive evidence of copulation. This study design is based on the USEPA OPPTS 870.3650 and OECD 422 test guidelines that include a neurotoxicity screening assessment.

Preliminary Results

There were no maternal deaths. There were no statistically significant differences across treatment groups for corpora lutea counts and the total implants. However, there were statistically significant differences between controls and the high dose (1000 mg/kg/day) dams for post-implantation losses, gestation length, total pups and total live pups. The number of viable pups on day 4 and the ratio of the number of viable pups to the total litter size were significantly decreased in the 1000 mg/kg/day group relative to the control group. The initial litter weight and average pup weights were significantly increased for pups in the 250 mg/kg/day group relative to controls, after adjusting for litter size, but no other significant differences were noted for Day 0 weights among the other treatment groups. The postnatal Day 4 litter weight and average pup weights, however, were significantly decreased in the 1000 mg/kg/day group when compared with control animals. The percentage of postnatal loss was

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significantly different in the 1000 mg/kg/day group, having a significantly higher loss than did the dams in the control group. There were no structural abnormalities observed for pups in any dose group.

Maternal body weight change for the third week of gestation was reduced for high dose dams compared to controls, which is likely related to the reduction in the number of pups/litter.

There were no statistically significant body weight changes or food consumption differences in the toxicology female group. The only statistically significant changes in female organ weights and ratios were liver (increased at 250 and 1000 mg/kg/day) and spleen (decreased at 1000 mg/kg/day only). No statistically significant findings were noted for the female toxicology group with motor activity and the functional observational battery.

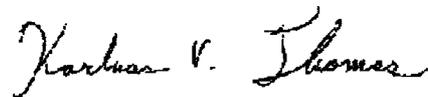
Tissue sectioning and histopathology results for the control and high dose toxicity female and male groups are not yet available.

Action

SEHSC will provide U.S. EPA with a copy of the final report for this study when it is available.

If you have any questions concerning this submission, please contact me at (703) 788-6570, kthomas@sehsc.com, or at the address provided herein.

Sincerely,



Karluss Thomas
Executive Director