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May 13, 2004

TSCA Document Control Center (7407)
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

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Re: TSCA Section 8(e) Notification of Substantial Risk: Vinyl-tris(2-methoxyethoxy)silane

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 Statement of Interpretation and Enforcement Policy (68 Fed. Reg. 33129; June 3, 2003) and other Agency guidance, the Silicones Environmental, Health and Safety Council (SEHSC), on behalf of its member companies and Degussa Corporation¹, submits information concerning a range-finding study with vinyl-tris(2-methoxyethoxy)silane (CAS No. 1067-53-4). Neither SEHSC, any member company, nor Degussa Corporation has made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings.

SEHSC is a not-for-profit trade association whose mission is to promote the safe use and stewardship of silicones. The Council is comprised of North American silicone chemical producers and importers. SEHSC's members include: Clariant LSM (Florida), Inc.; Dow Corning Corporation; General Electric Silicones; Rhodia Inc.; Shin-Etsu Silicones of America; and Wacker Silicones, A Division of Wacker Chemical Corporation.

Chemical Substances

1067-53-4 Vinyl-tris(2-methoxyethoxy)silane



Ongoing Study

A 7-day Repeat Oral (Gavage) Dose Range-Finding Study of Vinyl-tris(2-methoxyethoxy)silane in Rats. WIL Research Laboratories Study Number WIL-401004.

¹ Degussa Corporation is not a member of the Silicones Environmental, Health and Safety Council. However, Degussa Corporation is a co-sponsor of the study described herein.

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Summary

Preliminary results from a 7-day range-finding toxicity study conducted with vinyl-tris(2-methoxyethoxy)silane (> 99% purity) in Sprague-Dawley rats show the following test article-related effects in male and female animals:

- The range-finding study has used 100, 300 and 1000 mg/kg/day dose levels of the test article.
- One male rat in 1000 mg/kg/day group was found dead the day prior to scheduled euthanasia (study day 6).
- Dose-related decreases in body weights, body weight gain, and food consumption (more marked in males than females) were observed at 300 and 1000 mg/kg dose levels.
- The principal target organs at 300 and 1000 mg/kg/day dose-levels appear to be the testes, prostate glands and epididymides (marked reduction in weights).
- Testes-to-body weight, epididymides-to-body weight, and seminal vesicle-to-body weight ratios were not altered in a dose-responsive manner.
- Decreases in other organ weights, including kidneys, liver, and seminal vesicles, were also observed at 1000 mg/kg/day in male rats.

Details

Study Design

Four groups of 3 female and 3 male CrI:CD[®](SD)IGS BR rats were administered the test article, vinyl-tris(2-methoxyethoxy)silane, once daily for seven consecutive days by oral gavage. Dose levels were 100, 300, and 1000 mg/kg/day. A concurrent control group was given the vehicle and dehydrated and deacidified corn oil. The dosage volume for all groups was 5 mL/kg.

All animals were observed twice daily for appearance and behavior. Clinical observations, body weights, and food consumption were recorded at appropriate intervals. All rats were sacrificed for assessment of toxicity at the end of the 7-day dosing period. Selected organs from male and female rats were weighed and macroscopic examination was conducted. Data was analyzed using appropriate statistical tests.

Preliminary Results

Toxicity was evident in male rats at 300 and 1000 mg/kg/day. Test article-related clinical findings in the males included brown material around the urogenital or anogenital area, soft stool, and decreased defecation at 1000 mg/kg/day group.

One male rat in the 1000 mg/kg/day group was found dead the day prior to scheduled euthanasia (study day 6). Test article-related reductions ($p < 0.01$) in food consumption (g/animal/day) were noted among males in the 300 (21-29% reduction) and 1000 (67-71% reduction) mg/kg/day groups throughout the dosing period. These reductions in food consumption correlated with significantly decreased body weights ($p < 0.05$) and body weight gains ($p < 0.01$) at 1000 mg/kg/day. The mean body weight of the two surviving males in the 1000 mg/kg/day group was 21% lower than the control group value on study day 7. Non-dose-dependent effects on testes weights (absolute and relative to brain weight or relative to body weight) were observed at the 300 and 1000 mg/kg/day dosage levels

following 7 days of dose administration (26% and 33% reduction versus controls, respectively). Similar effects were noted on other organs of male animals at 1000 mg/kg/day, including organ weight effects on seminal vesicles (27%), prostate (53%), epididymides (24%), liver (29%), and kidneys (10%). Non-significant reductions in organ weights were observed at 300 mg/kg/day for prostate (11%) and epididymides (15%). Organ weight changes therefore appear to be primarily a reflection of general reductions in food consumption and subsequent reductions in body weight and general toxicity.

Test article-related reductions in food consumption (g/animal/day) were noted among females in the 1000 mg/kg/day group (27-38% reduction) throughout the dosing period; the difference was statistically significant ($p < 0.05$) during days 4-7. This corresponded to a non-significant reduction in body weight gain among female rats at the same dose level. No other signs of toxicity were noted in the female rats at the dose levels tested.

Actions

SEHSC will notify EPA of any further relevant information that may be developed concerning this material. SEHSC also will provide EPA with the copy of the final report containing these study results when it is available. If you have any questions concerning this study, please contact me at (703) 904-4322, rmanning@sehsc.com, or at the address provided herein.

Sincerely,



Reo Menning
Executive Director