

8EHQ-0902-15200



SILICONES ENVIRONMENTAL, HEALTH AND SAFETY COUNCIL of North America

September 19, 2002

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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

Contain NO CBI

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

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 (40 FR 11110; 16 March 1978) and other Agency guidance, the Silicones Environmental, Health and Safety Council (SEHSC), on behalf of its member companies and Silbond Corporation<sup>1</sup>, submits information concerning a range-finding study with ethyl silicate (CAS No. 78-10-4). Neither SEHSC, any member company, nor Silbond Corporation has made a determination 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 represent over 95 percent of silicone chemical manufacturing capacity in North America and include: Clariant LSM (Florida), Inc.; Degussa Corporation; Dow Corning Corporation; General Electric Silicones; OSi Specialties, a Crompton business; Rhodia Inc.; Shin-Etsu Silicones of America; and Wacker Silicones, A Division of Wacker Chemical Corporation.

**Chemical Substances**

78-10-4 Ethyl silicate

**Ongoing Study**

Tetraethyl Orthosilicate: 7-Day Range-Finding Toxicity Study by Oral Route (Gavage) in Rats. CIT Study Number 24111 TSR.



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<sup>1</sup> Silbond Corporation is not a member of the Silicones Environmental, Health and Safety Council. However, Silbond is a co-sponsor of the study described herein.

## **Summary**

Preliminary results from a 7-day range-finding toxicity study conducted with tetraethyl orthosilicate (ethyl silicate, > 99% purity) in Sprague-Dawley rats show the following test article-related effects in male and female animals:

- A dose-related decrease in body weight gain and food consumption (more marked in males than females).
- The principal target organs at all dose-levels appear to be the kidneys (increase in size and macroscopic findings) and the heart (decrease in size).
- Changes in the size of the prostate, seminal vesicles, uterus, ovaries, lymph nodes, spleen and lungs could not be ruled out as treatment-related effects.

## **Details**

### **Study Design**

In a non-GLP 7-day range-finding toxicity study conducted with ethyl silicate (> 99% purity), male and female Sprague-Dawley rats were exposed by the oral route (gavage) to 0 (Group 1), 200 (Group 2), 600 (group 3), or 1000 (Group 4) mg/kg/day of ethyl silicate for seven days. There were three animals per sex per dose group. Clinical signs, body weights, and food consumption were recorded during the study. All rats were sacrificed for assessment of toxicity at the end of the 7-day dosing period. Selected organs were weighed and a macroscopic examination was conducted.

### **Preliminary Results**

One Group 3 male and two Group 4 male rats did not survive the treatment period.

The main clinical signs observed in the surviving animals during the treatment period were, respectively, for Group 4 males and females: salivation (2/6, 3/6) and emaciated appearance (1/6, 2/6). For Groups 2 and 3, salivation was recorded in one male of each group. When compared to controls, a dose-related decrease in mean body weight gain was observed in treated males (all groups). The body weight of Group 4 females was slightly decreased. When compared to controls, a dose-related decrease in mean food consumption was noted in treated males and females (all groups). The decrease in food consumption was more marked in treated males than in treated females.

Changes in organ weights in the surviving animals were observed at necropsy. Individual absolute and relative weights of kidneys were higher than the highest control in:

- 1/3 males (Group 2);
- 2/2 males and 2/3 females (Group 3);
- The male and 2/3 females (Group 4).

These differences, which appear to be dose-related, were considered to be of toxicological significance.

Individual absolute and relative weights of heart were lower than the lowest control in:

- 1/3 males (Group 2);
- 2/2 males and 1/3 females (Group 3);

- The male and 2/3 females (Group 4).

Although these changes were minor, the differences in heart weights might be an effect of the test-article.

Other differences were observed in the mean weights of other organs in the surviving animals; however, these differences were not dose-related or were minor and/or without the same trend in both sexes. Moreover, the individual values of organ weights in the treated groups were for the most part in the range of the control group. The differences of these mean weights were thus considered to be of no toxicological importance.

The necropsy findings (including the three male animals that did not survive the treatment period) that were considered to be treatment-related were noted for the kidneys in 12 treated animals, as follows:

- Enlargement of the kidneys in 1/3 males and 2/3 females (Group 3) and in all males and 2/3 females (Group 4);
- Paleness or irregular color of the kidneys in 1/3 males (Group 2), in all Group 3 animals, and in all males and 2/3 females of Group 4.

These findings were considered to be of toxicological significance.

A direct or indirect relationship to the treatment could not be ruled out for additional findings (including the three male animals that did not survive the treatment period):

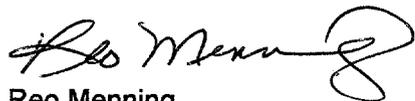
- Reduction in the size of the prostate and/or seminal vesicles in 1/3 males (Group 2), in 1/3 males (Group 3), and in all males of Group 4;
- Reduction in the size of the uterus and/or ovaries in 1/3 females of Group 3 and in 1/3 females of Group 4;
- Enlargement of renal lymph nodes and/or spleen in 1/3 females of Group 3 and in 1/3 females of Group 4;
- Dilatation and/or reddish color or foci of the lungs in 1/3 males of Group 3 and in 1/3 males of Group 4 (these two males were prematurely killed or found dead).

No other necropsy findings were observed.

### 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](mailto:rmanning@sehsc.com), or at the address provided herein.

Sincerely,



Reo Menning  
Executive Director