

## CODING FORMS FOR SRC INDEXING

Microfiche No.	OTS0574126		
New Doc ID	88010000070	Old Doc ID	8EHQ-0201-14858
Date Produced	01/22/01	Date Received	02/02/01
		TSCA Section	8E
Submitting Organization	SILICONES ENV HLTH & SFTY CNCL		
Contractor	HUNTINGDON LIFE SCIENCES		
Document Title	INITIAL SUBMISSION: LETTER FROM SEHSC NA TO USEPA REPORTING SUMMARY RESULTS OF ACUTE ORAL TOXICITY STUDIES IN RATS OF ETHYLTRIACETOXYSILANE & METHYLTRIACETOXYSILANE, DATED 1/22/01		
Chemical Category	ETHYLTRIACETOXYSILANE; METHYLTRIACETOXYSILANE		

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BEHQ-0201-11858

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SILICONES ENVIRONMENTAL, HEALTH AND SAFETY COUNCIL of North America

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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 20004

Re: TSCA Section 8(e) Notification of Substantial Risk: Ethyltriacetoxysilane: Acute Oral Toxicity Study and Methyltriacetoxysilane: Acute Oral Toxicity Study in Rats

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) submits, on behalf of its member companies, information regarding acute oral toxicity studies for two acetoxysilane compounds—ethyltriacetoxysilane (CAS No. 17689-77-9) and methyltriacetoxysilane (CAS No. 4253-34-3).

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 (Florida) LSM, Inc.; Degussa-Hüls Corporation; Dow Corning Corporation; General Electric Silicones; Goldschmidt Chemical Company; OSi Specialties, a Crompton business; Rhodia Inc.; Shin-Etsu Silicones of America; and Wacker Silicones.

**Chemical Substances**

17689-77-9 Ethyltriacetoxysilane  
4253-34-3 Methyltriacetoxysilane



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**Studies**

Ethyltriacetoxysilane: Acute Oral Toxicity Study. Huntingdon Life Sciences Study No. 99-0590

Methyltriacetoxysilane: Acute Oral Toxicity Study in Rats. Huntingdon Life Sciences Study No. 99-0610

TSCA Section 3(e) Coordinator  
US Environmental Protection Agency  
January 22, 2001  
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### Summary

Two structurally related acetoxysilanes, ethyltriacetoxysilane (ETA; CAS No. 17689-77-9) and methyltriacetoxysilane (MTA; CAS No. 4253-34-3), were evaluated for their acute oral toxicity in male and female albino rats following OECD Testing Guideline No. 401. Both of these acetoxysilanes are manufactured in the United States under highly engineered, closed systems. Therefore, worker exposure to these two materials is minimal. The two acetoxysilanes are not sold to the public in pure form. However, they are formulated into finished acetoxo sealants sold to the consumer.

Treatment was by oral gavage with the neat test substance. The calculated LD<sub>50</sub> for ETA was approximately 1460 mg/kg of body weight with 95% confidence limits of approximately 1270 – 1680 mg/kg. The calculated LD<sub>50</sub> for MTA was approximately 1600 mg/kg of body weight with 95% confidence limits of approximately 1516 – 1694 mg/kg.

For ETA, test substance related mortality was as follows: 6/10 and 8/10 at dose levels of 1500 and 2000 mg/kg, respectively. There were no test substance related mortalities at the dose levels of 300, 600, and 1000 mg/kg. MTA test substance related mortalities were as follows: 1/5 (males), 5/10, 4/5 (females), and 10/10 at dose levels of 1450, 1600, 1750, and 2000 mg/kg, respectively.

Clinical signs observed in all dose groups for both test substances included red stained snout, lacrimation, excessive salivation, rales, decreased activity/lethargy, hunched appearance, labored breathing, and red urine. Additional clinical signs observed, generally at dose levels of  $\geq$  1000 mg/kg of body weight for both test substances, included yellow ano-genital stains and black/brown ano-genital stains.

Other clinical signs, observed primarily in moribund animals, included irregular gait, body tremors, hypothermia, limb impairment, and prostration. However, in the ETA study, one female animal at the 1000 mg/kg dose level exhibited irregular gait at days 14 and 15 of the study. A second female at the 1500 mg/kg dose level also demonstrated irregular gait up to day 5 of the study and survived to the scheduled necropsy.

In the MTA study, a male animal dosed with 1450 mg/kg exhibited irregular gait up to day 6 of the study and survived to the scheduled necropsy. A second male treated with 1600 mg/kg exhibited irregular gait on days 2 – 8 of the study and also survived to study termination.

If you have questions concerning these studies, please contact me at (703) 904-4322 or at rmenning@sehsc.com.

Sincerely,



Reo Menning  
Deputy Director