



8EHQ-0897-13966S

CERTIFIED # Z 228 397 632

July 18, 1997 PDCN: 88970000216

SANITIZED VERSION

TSCA Document Processing Center (7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
401 M Street S.W.
Washington, D.C. 20460

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Re: Supplemental Submission to 8EHQ-97-13966
TSCA Section 8(e) Notification of Substantial Risk
[CONFIDENTIAL]

Dear Sir:

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, March 16, 1978), Dow Corning is submitting the following information concerning an ongoing study as a supplemental submission to our Notification of Substantial Risk of June 13, 1997 (8EHQ-97-13966).

Chemical Substance:

The test substance, SYL-OFF® 7231 Inhibitor, generically described as an alkoxy-silane, is described chemically as [CONFIDENTIAL] and was the subject of TSCA Premanufacture Notification (PMN) P-97-564.

Manufacturer:

Dow Corning Corporation
2200 West Salzburg Road
Midland, Michigan 48686-0994

COMPANY SANITIZED

Ongoing Study:

TWENTY-EIGHT DAY INHALATION TOXICITY STUDY WITH SYL-OFF® 7231 INHIBITOR IN RATS

Dow Corning Corporation Study No. 8798

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Background:

In a letter dated June 13, 1997, Dow Corning provided EPA with information obtained in a twenty-eight day inhalation toxicity study of SYL-OFF® 7231 Inhibitor in rats (Dow Corning Corporation Study No. 8595). Due to the unexpected toxicity and deaths observed at the highest exposure concentration (750 ppm), in which two female rats died

during exposure to the test material on day one, the 28-day study was terminated and changed to a four-day inhalation toxicity range-finding study of SYL-OFF® 7231 Inhibitor in rats. The information obtained in the latter study then was used to determine exposure levels for a subsequent 28-day inhalation toxicity study (Dow Corning Corporation Study No. 8798) which is the subject of this supplemental submission.

Executive Summary:

In a twenty-eight day inhalation toxicity study which was initiated to determine the potential toxicity of SYL-OFF® 7231 Inhibitor, four groups of male and female rats were exposed to 0, 50, 200, and 400 ppm of the test material. Other than increased activity and/or aggressive behavior in three rats in the high concentration group, no significant clinical signs were observed. Whereas in our initial notification, we reported that some neurotoxic effects were observed, primarily in animals exposed at 750 ppm, and included loss of equilibrium, (i.e., wobbly gait and spasmodic-like behavior) and repetitive gnawing, neither loss of equilibrium nor repetitive gnawing, or other neurotoxic effect, was observed in the 28-day study.

Actions:

Dow Corning will inform EPA of any pertinent information that may be developed concerning this material and will provide the Agency with a copy of the final report for the cited 28-day inhalation toxicity study.

If you have any questions concerning this study, please contact me at the address provided herein. If you require further general information regarding this submission, please contact Dr. Rhys G. Daniels, Regulatory Compliance Specialist, Regulatory Compliance Department, at 517-496-4222 or at the address provided herein.

Sincerely,



Michael P. Hitt
Americas Vice President and Corporate Director
Health and Environmental Sciences
(517) 496-4059

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