8EHQ - 0997 - 1047

MR# 9012

DOW CORNING

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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

PDLN: 900814

8EHQ-90-1047

Re: Supplemental Submission to 8EHQ-0890-1047
TSCA Section 8(e) Notification
Hexamethoxydisilylethane (HMDSE) - Corrected Chemical Identity

Dear Sir:

In our TSCA Section 8(e) supplemental submission of August 26, 1997, concerning a 14-day repeated dose inhalation toxicity study of DOW CORNING® X1-6145A Additive in albino rats, we inadvertently incorrectly identified the subject chemical substance as hexamethyldisilylethane. Attached is a corrected version of our supplemental submission in which we provide the proper chemical identity of the test substance as hexamethoxydisilylethane.

As before, if you have any questions concerning any of the studies cited in the attached submission, please contact me at 517-496-4057 or at the address provided herein. If you require further general information regarding this supplemental submission, please contact Dr. Rhys G. Daniels, Regulatory Compliance Specialist, Product Stewardship and Regulatory Compliance Department, at 517-496-4222 or at the address provided herein.

Sincerely,

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Michael P. Hill
Americas Vice-President and Corporate Director
Health and Environmental Sciences
(517)496-4057

EPA-OTS
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Dow Corning Corporation
Midland, Michigan 48686-0994
Phone: (517) 496-4000

DOW CORNING

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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

Re: Supplemental Submission to 8EHQ-0890-1047
TSCA Section 8(e) Notification
Hexamethoxydisilylethane (HMDSE)

Dear Sir:

In accordance with the provisions of Section 8(e) of the Toxic Substances 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 as a supplemental submission to our TSCA Section 8(e) Notification of August 10, 1990 (8EHQ-0890-1047).

Chemical Substance:

18406-41-2 Hexamethoxydisilylethane

Manufacturer:

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

Submitted Study:

A 14-DAY REPEATED DOSE INHALATION TOXICITY STUDY OF DOW CORNING® X1-6145A ADDITIVE IN ALBINO RATS

Dow Corning Corporation
Report No. 1996-I0000-41496
August 19, 1997

Dow Corning Corporation
Midland, Michigan 48686-0994
Phone: (517) 496-4000

Background:

In a letter dated August 10, 1990, Dow Corning submitted a Notification of Substantial Risk under TSCA Section 8(e) concerning preliminary results obtained in an acute vapor phase inhalation toxicity study of DOW CORNING® X1-6145A Additive in rats. A copy of the final report was submitted to EPA August 21, 1990. In response to an Agency request, Dow Corning provided additional follow-up to our initial notification (8EHQ-0890-1047) and has continued to submit new data on this chemical substance as such data were developed or became known to Dow Corning.

As an additional supplement to 8EHQ-0890-1047, we are providing EPA with a copy of a recent Dow Corning report on a 14-day repeated dose inhalation toxicity study of DOW CORNING® X1-6145A Additive in rats.

Summary:

A 14-day repeated dose inhalation toxicity study was conducted to investigate the inhalation toxicity of DOW CORNING® X1-6145A Additive, chemically described as hexamethoxydisilylethane (HMDSE, CASRN 18406-41-2), in rats. Four groups of ten male and ten female Fischer 344 rats were exposed to target concentrations of 0, 50, 100, and 200 ppb HMDSE for six hours a day, for ten exposures over 14 days (excluding weekends). Animals were observed for treatment-related signs of toxicity, growth, and mortality. At termination of the study, rats were sacrificed and examined for changes in organ weights, gross pathology, and histopathology.

No mortality was observed in the study. Very slight to moderate rales were observed in several animals exposed to 100 and 200 ppb HMDSE. No apparent treatment-related clinical signs were observed in animals exposed to 50 ppb HMDSE. Statistically significant decreases in body weights were observed in males exposed to 200 ppb on day 8, 15, and at sacrifice. Female body weights were decreased in animals exposed to 200 ppb HMDS on day 8 only. Statistically significant increases in liver/body weight ratios were observed in males exposed to 100 and 200 ppb of the test material. Statistically significant increases in kidney/body weight ratios were observed in males exposed to 200 ppb of the test material. A statistically significant increase in the liver/body weight ratio and in the adrenal/body weight ratio was observed in females exposed to 200 ppb of the test material. There were no other statistically significant differences in organ weights between test and control animals.

There were no apparent test article-related gross pathological changes in animals exposed to HMDSE. Test article-related changes were observed microscopically in the respiratory tract of all animals exposed to the test material. The nares,

nasal cavity, and pharynx were the most common sites of test article-related changes with the larynx and trachea only infrequently affected. Squamous metaplasia and acute inflammation of the nasal cavity were the most common findings in the 200 ppb group and also occurred, with somewhat reduced incidence and severity, in many rats from the 50 and 100 ppb groups. An increased activity of mucus goblet cells of the respiratory epithelium, characterized by increased height and prominence of goblet cells with formation of microcysts, was the most common finding in all sections of the nasal cavity from the 50 and 100 ppb groups. All lesions in the lung and other organs examined microscopically were considered agonal and spontaneous and unrelated to test article exposure.

Based on these results, a No-Observable-Adverse-Effect-Level (NOAEL) was not established for the test material in Fischer 344 rats under the conditions of this study.

Actions:

Dow Corning will continue to notify EPA of any further pertinent information that may be developed concerning hexamethoxydisilylethane. Dow Corning has ceased efforts to commercialize this substance and has taken actions to ensure that it is not present as an unintentional byproduct in other materials we make.

If you have any questions concerning any of the aforementioned studies, please contact me at 517-496-4057 or at the address provided herein. If you require further general information regarding this supplemental submission, please contact Dr. Rhys G. Daniels, Regulatory Compliance Specialist, Product Stewardship and Regulatory Compliance Department, at 517-496-4222 or at the address provided herein.

Sincerely,

Best Available Copy

Michael P. Hill
Americas Vice-President and Corporate Director
Health and Environmental Sciences
(517)496-4057

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