ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-10-17782	88100000111	12/29/09

COMMENTS:

DOES NOT CONTAIN CBI

DOW CORNING

8EHQ-1209-17782A

88100000111

09 DEC 29 PM 6:00

December 22, 2009

Document Control Office (7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20004

8EHQ-10-17782

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

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 TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, Dow Corning is submitting preliminary information from a contact hypersensitivity (skin sensitization) study for methyltrimethoxysilane in albino guinea pigs. Dow Corning has not made a determination at this time that any significant risk of injury to human health or the environment is presented by the findings within the subject study.

Chemical Substance

1185-55-3 Methyltrimethoxysilane

88100000111

Study Title

Methyltrimethoxysilane: Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test

Study Design

The study design meets or exceeds the requirements of the OECD 406. The non-adjuvant (Buehler) method was used for testing contact hypersensitivity in guinea pigs.

The test article was applied diluted in polyethylene glycol 300 (PEG 300) during induction, challenge and re-challenge phase. Twenty male animals in the test group were treated topically with methyltrimethoxysilane at a concentration of 50% in PEG 300 once per week for a three-week induction phase. During induction, ten animals in the control group were treated with the vehicle (PEG 300) only. Two weeks after the final induction application the control and test animals were challenged with methyltrimethoxysilane at a concentration of 25% in PEG 300 and with PEG 300 alone. Fourteen days after challenge, a re-challenge

Dow Corning Corporation
Midland, Michigan 48686-0994
Phone: (989) 496-4000
www.dowcorning.com

CONTAINS NO CBI

323630

was performed at the concentration of 25% as well as at a lower concentration of 15% in PEG 300 using the same test group and a new, naive control group (II).

Results

Induction phase: No skin effects were seen in the controls treated with PEG 300 only. Discrete/patchy erythema (grade 1) was observed in 60%, 80% and 100% of the test animals during the three weeks of induction.

Challenge phase: No skin effects were observed in the control or test animals after treatment with PEG 300 only. After treatment with 25% methyltrimethoxysilane all control animals showed discrete/patchy erythema (grade 1) at 24hr and 80% of control animals showed grade 1 response after 48 hr indicating irritation. Test animals treated with 25% methyltrimethoxysilane showed discrete/patchy erythema (85% of animals) to confluent/moderate erythema (10% of animals) at 24hr. At 48 hr 45% of test animals showed a grade 1 response. Due to uncertainty over interpretation of the challenge reactions caused by the irritation observed in the controls, a re-challenge was performed two weeks after the 1st challenge.

Re-Challenge phase: No skin reactions were observed in the naïve control group treated with 25% and 15% methyltrimethoxysilane. No skin reactions were observed in the test animals treated with 15% methyltrimethoxysilane. Test animals treated with 25% methyltrimethoxysilane showed discrete/patchy erythema at an incidence of 30% at 24 hr and 20% at 48hr. Based on these findings methyltrimethoxysilane may be classified as a skin sensitizer.

Dow Corning has not made a determination at this time that any significant risk of injury to human health or the environment is presented by the findings within the subject study. Dow Corning Corporation will notify EPA of any further relevant information that may be developed concerning this material. The final report for this study will be submitted after report finalization. If you have any questions concerning this submission, please contact me at (989) 496-8046, Kathy.plotzke@dowcorning.com, or at the address provided herein.

Sincerely,

Kathleen P. Plotzke, Ph.D.
Director, Health and Environmental Sciences
(989) 496-8046