

DOW CORNING
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November 7, 1994

TSCA Document Processing Center (TS-790)
Room L-100
Office of Toxic Substances
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
401 M Street S.W.
Washington, D.C. 20460

Contains No CBI

Re: TSCA Section 8(e) Notification of Substantial Risk
Siloxanes and silicones, 3-[(2-aminoethyl)amino]-2-
methylpropyl Me, di-Me

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 Corporation is submitting the following Notification of Substantial Risk for a pair of ongoing studies.

Chemical Substance:

106842-44-8 Siloxanes and silicones, 3-[(2-aminoethyl)amino]-2-methylpropyl Me, di-Me

Manufacturer:

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

Introduction:

As part of an ongoing program to determine structure/activity relationships for the aerosol toxicity of a series of amino-functional polymers and emulsions, acute (4 hour) inhalation toxicity studies were initiated for a pair of aqueous emulsions of an amino-functional siloxane polymer chemically identified as 3-[(2-aminoethyl)amino]-2-
methylpropyl Me, di-Me siloxane, CASRN 106842-44-8, and the following preliminary results have been obtained:

(1) Ongoing Study:

AN ACUTE (4 HOUR) AEROSOL INHALATION TOXICITY STUDY WITH DOW CORNING® Q2-8167 EMULSION IN RATS

12/15/94

CHIEF OF BUREAU
PERMISSION

Test Material:

DOW CORNING® Q2-8167 Emulsion

CASRN	WEIGHT%	COMPONENT NAME
7732-18-5	80	Water
106842-44-8	13	Siloxanes and silicones, 3-[(2-aminoethyl)amino]-2-methylpropyl Me, di-Me
-----	7	Organic surfactant; preservatives

Executive Summary:

The test substance, DOW CORNING® Q2-8167 Emulsion, was aerosolized and administered for 4 hours by nose only inhalation exposure to groups of five male and five female Sprague-Dawley rats at gravimetrically determined exposure levels of 0.010, 0.141, and 1.358 mg/l. Aerosol particle sizes, determined as mass median aerodynamic diameter (MMAD), were 0.81, 1.03, and 2.17 µm with geometric standard deviations of 1.79, 1.82, and 1.97, respectively. Dosing was followed by a 14-day observation period and gross necropsy after sacrifice of surviving animals.

The observed mortality was as follows:

GRAVIMETRIC CONCENTRATION (mg/l air)	MALES	MORTALITY FEMALES	BOTH SEXES
0.010	2/5	1/5	3/10
0.141	4/5	2/5	6/10
1.358	5/5	5/5	10/10

All deaths occurred between test days 1 - 4, except for one male which died during exposure. Clinical signs of intoxication included hunched posture, tachypnoea labored breathing, sedation, and unkempt fur. At necropsy, macroscopic findings included non-collapse or incomplete collapse of lungs and dark red discoloration of the lungs.

The calculated LC₅₀ values are 0.02 mg/l for males, 0.092 mg/l for females, and 0.043 mg/l for both sexes, based on gravimetrically determined dose.

(2) Ongoing Study:

AN ACUTE (4 HOUR) AEROSOL INHALATION TOXICITY STUDY WITH DOW CORNING® Q2-8467 EMULSION IN RATS

Test Material:

DOW CORNING® Q2-8467 Emulsion

CASRN	WEIGHT%	COMPONENT NAME
7732-18-5	77	Water
106842-44-8	13	Siloxanes and silicones, 3-[(2--aminoethyl) amino]-2--methylpropyl Me, di-Me
-----	10	Organic surfactant; preservatives

Executive Summary:

The test substance, DOW CORNING® Q2-8467 Emulsion, was aerosolized and administered for 4 hours by nose only inhalation exposure to groups of five male and five female Sprague-Dawley rats at gravimetrically determined exposure levels of 0.005, 0.020, 0.595, and 1.104 mg/l. Aerosol particle sizes, determined as mass median aerodynamic diameter (MMAD), were 0.08, 1.45, 1.17, and 5.00 μm with geometric standard deviations of 2.89, 1.51, 2.46, and 3.16, respectively. Dosing was followed by a 14-day observation period and gross necropsy after sacrifice of surviving animals.

The observed mortality was as follows:

GRAVIMETRIC CONCENTRATION (mg/l air)	MALES	MORTALITY FEMALES	BOTH SEXES
0.005	0/5	0/5	0/10
0.020	3/5	1/5	4/10
0.595	3/5	2/5	5/10
1.104	5/5	3/5	8/10

All deaths occurred between test days 1 - 4, except for one male which died during exposure. Clinical signs of intoxication included hunched posture, tachypnoea labored breathing, sedation, and unkempt fur. At necropsy, macroscopic findings included non-collapse or incomplete collapse of lungs and dark red discoloration of the lungs.

The calculated LC₅₀ values are 0.062 mg/l for males, 0.712 mg/l for females, and 0.188 mg/l for both sexes, based on gravimetrically determined dose.

Discussion:

Based on the above discussed preliminary results, the test material clearly was irritating to the respiratory system of the test animals and unexpectedly high mortality was observed, with LC₅₀ values substantially below 2.0 mg/l being obtained, clearly meriting notification under TSCA Section 8(e).

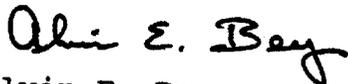
Actions:

As part of our corporate product stewardship program, employees, customers, and members of the Silicones Environmental, Health and Safety Council (SEHSC, the industry trade association) are being informed of these findings. All necessary hazard warnings and information related to these studies will be provided in updated Material Safety Data Sheets (MSDS) and on product labels.

Naturally, Dow Corning will provide EPA with copies of the studies on completion of the final reports and will inform the Agency of any pertinent information that may be developed concerning this chemical substance. In the meantime, if you require further information concerning these studies or the toxicological properties of the test material, please contact Dr. Robert G. Meeks, Manager, Dow Corning Toxicology Department, at the address provided below or by telephone at 517-496-8629.

If you require further information concerning this Notification of substantial risk, please contact Dr. Rhys G. Daniels, Regulatory Compliance Specialist, Dow Corning Product Safety and Regulatory Compliance Department, at the address provided below or by telephone at 517-496-4222.

Sincerely,



Alvin E. Bey
U.S. Area Vice-President
Corporate Director of HES