EXHIBIT M

EH7309013600

DOW CORNING

December 27, 1996

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: TSCA Section 8(e) Notification of Substantial Risk
DOW CORNING® 3-8015 Intermediate

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 as a Notification of Substantial Risk.

Test Material:

The test substance, DOW CORNING® 3-8015 Intermediate, is a solution of platinum 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes (CASRN 68478-92-2, 1.5 weight percent) in a mixture of 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane (CASRN 2627-95-4, 5 weight percent) and vinyl group-terminated di-Me siloxanes (CASRN 68083-19-2, 93 weight percent).

Manufacturer:

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

Submitted Study:

SKIN SENSITIZATION STUDY OF DOW CORNING® 3-8015 INTERMEDIATE (PLATINUM #2) USING THE GUINEA PIG MAXIMIZATION TEST (GPMT)

Dow Corning Corporation
1996-10000-42261
October 30, 1996

Executive Summary:

A guinea pig sensitization study was conducted to determine the dermal sensitization potential of DOW CORNING® 3-8015 Intermediate. This study was performed according to the OECD Guidelines No. 406 (July, 1992) and U.S. EPA Good Laboratory Practice Standards Part 792 (TSCA), 40 CFR 792, Final Rule, August, 1989. The test material was administered by intradermal (i.d.) injection of the dosing formulation (5% w/v) in DOW CORNING® 360 Medical Fluid to the shaved shoulder region of 20 male guinea pigs. Another group of 10 male vehicle control guinea pigs was handled in a similar manner, but was treated (i.d.) with DOW CORNING® 360 Medical Fluid only. A third group of 10 male guinea pigs was treated with dinitrochlorobenzene (DNCB) in propylene glycol and served as a positive control. One week following i.d. injection of the first induction dose, a second induction dose of undiluted (100%) test material was applied topically to the test group animals for 48 hours. Animals in the vehicle control and positive control groups were dosed topically with DOW CORNING® 360 Medical Fluid and DNCB, respectively. Three weeks following the first induction dose, test and vehicle control guinea pigs received a topical challenge dose (75% w/v) of test material/ DOW CORNING® 360 Medical Fluid formulation for 24 hours. Positive control guinea pigs were dosed similarly with 0.1% DNCB in propylene glycol. A second challenge was performed one week following the first challenge and a 50% (w/v) test material/ vehicle formulation was applied to the test and vehicle control animals. The skin response of all guinea pigs was evaluated at approximately 24 and 48 hours following completion of the challenge dose. The results were expressed in terms of the incidence and severity of the skin response.

All of positive control animals exhibited a positive reaction at the DNCB challenge control site with a severity index of 3.40. A positive response was observed in 1 of 10 (10%) vehicle control group animals. A positive response in the test substance-treated animals resulted in incidence and severity of 50% and 1.10, respectively, at the forty-eight hour scoring interval following the second challenge dose.

Actions:

For purposes of notification of substantial risk under TSCA Section 8(e), the general INTERNAL designation on the attached health and safety study is waived by Dow Corning.

If you have any questions concerning this study, please contact Dr. Waheed Siddiqui , Associate Toxicology Scientist, Product Safety and Toxicology Department, at 517-496-4884 or at the address provided herein. If you require further general information regarding this 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.

DOW CORNING

Stephanie A. Burns, Ph.D.
Manager:
FDA and Women's Health Issues

January 28, 1997

Mr. Joseph Levitt, Esq.
Deputy Director Regulations and Policy
FDA/CDRH
9200 Corporate Boulevard
Suite 100, HFZ-2
Rockville, MD 20850

Dear Joe,
As part of our on-going communications with the FDA, relative to health and safety testing of silicones, I want to make you aware of two submissions that Dow Corning recently made to the Environmental Protection Agency (attached). The information submitted is in accordance with Section 8(e) of the Toxic Substances and Control Act. The submissions report the results of skin sensitization studies using the guinea pig maximization test. Two platinum catalysts were tested: Dow Corning® 3-8015 Intermediate and Dow Corning® 2-0707 Intermediate. We are planning further analytical testing in an effort to better understand these results.

I am in the process of arranging a meeting with the FDA on our "non-epidemiology" silicone breast implant research program. I have requested that Dr. Kimber Richter, Dr. Lori Brown, Dr. John Langone, Dr. Mary Beth Jacobs and Dr. Raju Kammula attend this review. Through discussions with Dr. Langone, I have suggested that an overview of platinum containing products (including breast implants) and results of sensitization testing be included in the meeting agenda. We are targeting mid to late February for the meeting.

Should you or anyone else at the FDA have questions or like to discuss this prior to our meeting, please contact me.

Regards,

Stephanie Burns

Stephanie Burns, Ph.D.

Attachments (2)

cc: Lori Brown, Ph.D.
Raju Kammula, Ph.D.
Mary Beth Jacobs, Ph.D.,
John Langone, Ph.D.

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DOW CORNING CORPORATION
FDA MEETING
MARCH 18, 1997

I. IMMUNE COMPETENCE/IMMUNOTOXICITY.....KLYKKEN

A. BREAST IMPLANT MATERIALS

B. D4

II. ADJUVANCY.....KLYKKEN

A. HUMORAL

B. RAT ARTHRITIS MODEL

III. AUTOIMMUNITY.....KLYKKEN

A. ANIMAL MODELS

B. "ANTI-SILICONE" ANTIBODIES

C. PROTEINS AT THE SURFACE OF SILICONES

IV. HYPERSENSITIVITY.....KLYKKEN/MEEKS/BURNS/PETERS

A. Pt CATALYSTS - SENSITIZATION STUDIES

B. DC's MEDICAL MATERIALS
   1. Pt LEVELS
   2. GPSS TESTING

C. SILICONE BREAST IMPLANTS
   1. Pt LEVELS
   2. GPSS TESTING ON COMPONENTS

V. SBI CHEMICAL ANALYSES.....PETERS

A. FORMULATION/COMPOSITION

B. EXTRACTABLE SILOXANES - GEL AND ELASTOMER

C. BLEED
   1. COMPOSITION
   2. DIFFUSION RATE MODELS

MAMMARY IMPLANT MATERIAL FORMULATION — Q7-2222

Ingredient Name	Internal Material Name	Net Mats
Dimethyl Siloxane, Dimethylvinyl-terminated	SGM-26	51.30%
Silica, Amorphous	CAB-O-SIL S-17D SILICA	24.64%
Dimethyl Methylvinyl Siloxane, Dimethylvinyl-terminated	SGM-33	12.85%
Dimethylsiloxane, Hydroxy-terminated	4-2797 INT (PA FLD)	8.63%
Chloroplatinic Acid	3-8015 INT (PLATNM2)	1.25%
Dimethyl, Methylhydrogen Siloxane	6-3570 INT	1.12%
Dimethyl, Methylvinyl Siloxane	4-2826 INT (PR FLD)	0.22%
Ethynyl Cyclohexanol (a)	ETCH 1-ETHYNYL 1-CYCLOHEXANOL	---
Water (a)	WATER	---
		100.00%

(a) denotes ingredient removed during manufacturing process.