

DOW CORNING

924000

8EHQ - 0398 - 13569

February 24, 1998

PDCN: 88960000049

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-0196-~~13559~~ 13569
TSCA Section 8(e) Notification of Substantial Risk
Octamethylcyclotetrasiloxane (OMCTS, D₄)

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 amendment to a recently completed final report for an immunological evaluation of octamethylcyclotetrasiloxane (OMCTS, D₄) using a twenty-eight day exposure in male and female Fischer 344 rats as a supplemental submission to our Notification of Substantial Risk of January 17, 1996 (8EHQ-0196-13559) and ensuing supplemental submissions of May 13, 1996 (8EHQ-0596-13569) and January 8, 1998 (submission of final report).

Chemical Substance:

- 541-02-6 Decamethylcyclopentasiloxane, 4 wt.%
- 541-05-9 Hexamethylcyclotrisiloxane, 0.1 wt.%
- 556-67-2 Octamethylcyclotetrasiloxane, 96 wt.%
in DOW CORNING® 244 Fluid (octamethylcyclotetrasiloxane)

Manufacturer:

Dow Corning Corporation
2200 West Salzburg Road
Midland, Michigan 486867-0994

Contains No CBI



8EHQ-96-13569



89980000141

Recently Issued Study Amendment:

IMMUNOLOGICAL EVALUATION OF OCTAMETHYLCYCLOTETRA-SILOXANE (D4) USING A TWENTY-EIGHT DAY EXPOSURE IN MALE AND FEMALE FISCHER 344 RATS - AMENDMENTS TO REPORT NUMBER 1997-I0000-41338 AND REPORT NUMBER 1998-I0000-44304

Dow Corning Corporation
1998-I0000-44480
February 16, 1998

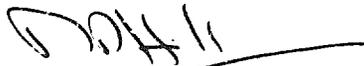
Actions:

A copy of this final report amendment also is being provided to EPA under TSCA Section 8(d) (health and safety data reporting).

For purposes of supplemental reporting under TSCA Section 8(e), the general INTERNAL designation on the attached health and safety report amendment is waived by Dow Corning.

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

RGD98028

Report No: 1998-I0000-44480

Title: Immunological Evaluation of Octamethylcyclotetrasiloxane (D₄) Using a Twenty-Eight Day Exposure in Male and Female Fischer 344 Rats - Amendments to Report Number 1996-I0000-41338 and Report Number 1998-I0000-44304.

Study No.: 8389

External Testing Facility No.: D4-2&-1R-PO

Test Article: Octamethylcyclotetrasiloxane (D₄)

Study Director: Albert E. Munson, Ph.D.
Professor of Pharmacology & Toxicology

Authors: Albert E. Munson, Ph.D.
Professor of Pharmacology & Toxicology

Sponsor: Dow Corning Corporation

Sponsor Representative: Paal C. Klykken, Ph.D.
Associate Scientist

Testing Facility: Medical College of Virginia
Virginia Commonwealth University
Department of Pharmacology & Toxicology
and Program of Biomedical Engineering
Richmond, VA 23298-0613

Report Amendment Date: 02/16/98

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REPORT AMENDMENTS

Dow Corning Report Number 1996-I0000-41338, Pages 1 of 286 through 286 of 286

Amendment:

The Dow Corning Report Number in the header of the report has been changed to 1996-I0000-41338.

Reason for amendment:

The Dow Corning Report Number was inadvertently entered incorrectly as 1997-I0000-41338.

Dow Corning Report Number 1998-I0000-44304 (Report Amendment to Report Number 1996-I0000-41338), Pages 1 and 4 and Revised Pages 1 of 286 and 20 of 286

Amendment:

The Dow Corning Report Number in the header of the report has been changed to 1996-I0000-41338.

Reason for amendment:

The Dow Corning Report Number was inadvertently entered incorrectly as 1997-I0000-41338 on Page 1, and as 1998-I0000-41338 on remaining above mentioned pages.

Note: Due to the insignificance of the errors and in order to save paper, revised pages will not be submitted and a deviation to the SOP will be added to the study file by the study monitor.

Quality Assurance Statement

Amendment:

Included in this amendment is the Quality Assurance Statement which adds the dates of the report amendment audit.

Reason for amendment:

The report amendment was audited by QAU.



APPROVAL SIGNATURES

This report amendment consists of pages 1 through 4.

Albert E. Munson 2/16/98

Albert E. Munson, Ph.D.

Date

Professor of Pharmacology & Toxicology

Study Director

Paal C. Klykken 2/20/98^①

Paal C. Klykken, Ph.D.

Date

Associate Scientist

Sponsor Representative

① The sponsor's Representative discussed the specifics of the Amendment with the Study Director on 2/9/98

Paal C. Klykken 2/20/98



QUALITY ASSURANCE STATEMENT

Title: Immunological Evaluation of Octamethylcyclotetrasiloxane (D₄) Using a Twenty-Eight Day Exposure in Male and Female Fischer 344 Rats - Amendments to Report Number 1996-I0000-41338 and Report Number 1998-I0000-44304.

Study No.: 8389

External Testing Facility No.: D4-28-1R-PO

This report amendment has been audited by the Medical College of Virginia Quality Assurance Unit. The following are the inspection dates and the dates inspection findings were reported.

Date of Inspection

16 Feb 98

Findings Reported
to Study Director

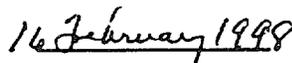
16 Feb 98

Findings Reported
to Management

16 Feb 98



H. Leon Pringle
Manager, Quality Assurance



Date

Best Available Copy

