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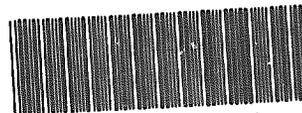
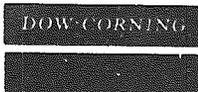
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OFFICE OF TOXIC SUBSTANCES
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Washington, D.C. 20460
Attn: 8(d) Health and Safety Data Reporting Rule

Re: 58 FR 28511 (May 14, 1993) [OPPTS-82040; FRL-4182-1]
Health and Safety Data Reporting
Submission of Lists and Copies of Health and Safety Studies

Dear Sir:

The enclosed information is submitted on behalf of Dow Corning Corporation, Midland, Michigan, 48686-0994, in compliance with the Sunset Provision issued under Section 8(d) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2607(d) and with an effective date of June 14, 1993 (Sunset Date June 14, 2003), and in accordance with 40 CFR 716 (Health and Safety Data Reporting).

Listed Chemical Substance:

Hexamethyldisilazane
CASRN 999-97-3

Title of Recently Completed Study:

AN ACUTE SKIN IRRITATION/CORROSION STUDY OF DOW CORNING® Z-6079
IN ALBINO RABBITS

Dow Corning Corporation
November 9, 1993

Manufacturer:

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

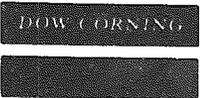
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Page 2

If you require further information concerning this matter, 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

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



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**TSCA SECTION 8(d) HEALTH AND SAFETY DATA REPORTING
TOXICOLOGICAL STUDIES
TSCA CONFIDENTIAL BUSINESS INFORMATION CLAIMS**

For purposes of Health and Safety Data Reporting under Section 8(d) of the Toxic Substances Control Act (TSCA), the general PROPRIETARY designation on the attached toxicological study has been waived by Dow Corning Corporation.

Submitter: _____

Rhys G. Daniels

Date: _____

15/November/1997

Rhys G. Daniels, Ph.D.
Regulatory Compliance Specialist
Health and Environmental Sciences
DOW CORNING CORPORATION

DOW CORNING



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AN ACUTE SKIN IRRITATION/CORROSION STUDY OF
DOW CORNING® Z-6079 IN ALBINO RABBITS

Dow Corning Corporation
November 9, 1993

REPORT NO.: 1993-10000-38549
FILE NO.: 7773
REFERENCE NO.: TX-93-040-25
REF. NO.: BT 073154
AUTHORS: Earnestine Stanton
Simon L. Cassidy
SUBMITTED BY: E. T. Rasmussen
REPORTED BY: Earnestine Stanton
CHECKED BY: Simon L. Cassidy
DEPARTMENT: Health and Environmental Sciences
SUPERVISOR: Simon L. Cassidy
LOCATION: Midland, Michigan
DATE: November 9, 1993
TITLE: AN ACUTE SKIN IRRITATION/CORROSION STUDY OF DOW CORNING®
Z-6079 * IN ALBINO RABBITS

ABSTRACT

An acute skin irritation study was conducted to determine the skin irritation potential of DOW CORNING® Z-6079 in male albino rabbits. The procedure followed fulfills the requirements of the O.E.C.D. Guidelines for Testing of Chemicals, "Acute Dermal Irritation/Corrosion," section 4, No. 404, adopted May 12, 1981.

Three male rabbits were utilized in this study. A single dose of 0.5 ml of the test material was uniformly applied to one intact test site of each animal. The test sites were covered in a semi-occlusive fashion for a period of four hours. No irritation was seen in any of the rabbits at the 1 hour observation period following the four hour exposure. Erythema was observed at 24, 48 and 72 hours in two rabbits. All signs of irritation had subsided by the seventh day observation period. On the basis of the data presented in this report, it is concluded that DOW CORNING® Z-6079 is minimally irritating to the skin of rabbits and produced no evidence of skin corrosion.

* Hexamethyldisilazane

TABLE OF CONTENTS

	<u>Page</u>
Abstract.....	2
Test Material	4
Method	4
Results and Conclusions.....	4
Reference	4
Signature Of Authors.....	5
Quality Assurance Statement	6

TABLES

- I. Evaluation of Skin Reaction
- II. Mean Skin Irritation Scores
- III. Individual Skin Irritation Scores

APPENDICES

- 1. Determination of Primary Dermal Irritation Score
- 2. Descriptive Rating Table For Skin Irritancy

TEST MATERIAL

A liquid identified as DOW CORNING® Z-6079 was submitted to the Toxicology Department to assess its toxicological properties and industrial handling hazards associated with acute exposure.

METHOD

The procedure followed fulfills the requirements of the O.E.C.D. Guidelines for Testing of Chemicals, "Acute Dermal Irritation/Corrosion," Section 4, No. 404, adopted May 12, 1981. Male albino rabbits of the New Zealand White strain obtained from Hazleton, Kalamazoo, Michigan and weighing between 2.98 and 3.09 kg were used in this study. Animals purchased from the vendor were quarantined for seven days prior to study initiation and only suitable animals were used. All rabbits were housed individually in conventional design stainless steel cages in a temperature, humidity and light controlled room. The animals were fed an appropriate amount of Purina Rabbit Chow HF® for maintenance and had fresh water available ad libitum. Each rabbit was identified by an individual numbered ear tag.

Approximately twenty-four hours prior to dermal application, the hair of each rabbit was closely clipped from the dorsal body surface area of the trunk with electric clippers. The animals were then rested to allow any abrasion to heal completely.

A single dose of 0.5 ml of the test material was applied to one intact test site of each animal. The test material was administered as received. Adjacent areas of untreated skin served as the control. The application site was covered with a porous gauze dressing and the animals were then wrapped in a semi-occlusive fashion with a cotton bandage taped to the hair. After a four hour exposure period, the bandages were removed and the test sites were washed with tap water. Animals were observed frequently after dosing and twice a day thereafter, up to 7 days, following the exposure for signs of toxicity, mortality and general activity. The degree of skin irritation was scored according to Table I at 1, 24, 48, 72 hours and 7 days after washing for erythema, edema, and other evidence of irritation or injury.

RESULTS and CONCLUSION

No obvious effects on clinical conditions or food consumption were noted and no abnormalities in test animal behavior or signs of toxicity were observed during the study. Tables II and III presents the mean and individual skin irritation scores. A single, semi-occlusive contact of 0.5 ml of DOW CORNING® Z-6079 with the intact skin of three male albino rabbits for four hours produced no irritation at the one hour reading following the four hour exposure. Erythema was seen in two of the three animals at the 24, 48 and 72 hour readings (12845 and 12884); all signs of irritation had subsided by the seventh day observation period. The third animal showed no signs of irritation during the study.

The primary dermal irritation score was calculated according to Appendix 1 to be 1.22; this score yields a descriptive rating (according to Appendix 2) of minimally irritating to the skin of rabbits. Under the condition of this test and according to O.E.C.D. definition, DOW CORNING® Z-6079 did not cause significant skin irritation and was not corrosive to rabbit skin.

REFERENCE

O.E.C.D. Guideline for Testing Chemicals, "Acute Dermal Irritation/Corrosion," Section 4, No. 404, adopted May 12, 1981.

This report constitutes pages 1-11 including Tables I-III and Appendices 1-2.

Earnestine Stanton Date: 10/29/93
Earnestine Stanton
Principal Investigator

Simon L. Cassidy Date: 8th November 1993.
Simon L. Cassidy Ph.D. D.A.B.T.
Study Director

Robert G. Meeks Date: 11/2/93
Robert G. Meeks Ph.D. D.A.B.T.
Toxicology Manager
Health & Environmental Sciences

Typed By:

Michelle L. Snook
Michelle L. Snook

QUALITY ASSURANCE STATEMENT

This report represents data generated by the Toxicology Department Dow Corning Corporation, Midland, Michigan. This study was conducted according to EPA Toxic Substances Control Act; Good Laboratory Practice Regulations, 40 CFR, Part 792, Thursday, August 17, 1989. The results reported accurately reflect the data generated. All raw data is located at Dow Corning Corporation Midland, Michigan.

Study Started: October 04, 1993
Study Completed: November 8, 1993
Experimental Start: October 05, 1993
Experimental Termination: October 12, 1993
Study Audited: September 29, 1993, October 5, 1993, and
October 28, 1993
Audit Report to Management: September 29, 1993, October 5, 1993, and
October 28, 1993
Report Issued: November 9, 1993

Carolyn A. Hunter
Quality Assurance
Health & Environmental Sciences
Dow Corning Corporation
Midland, MI 48686-0994

October 28, 1993
Report Audit Date

Simor L. Cassidy. 8th November 1993.
Simor L. Cassidy, Ph.D. Date:
Study Director

TABLE I

EVALUATION OF SKIN REACTION

<u>Erythema and Eschar Formation</u>	<u>Value</u>
No erythema.....	0
Very slight erythema (barely perceptible).....	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in dept).....	4
 <u>Edema Formation</u>	
No edema	0
Very slight edema (barely perceptible).....	1
Slight edema (edges of area well defined by definite raising).....	2
Moderate edema (raised approx. 1 millimeter).....	3
Severe edema (raised more than 1 mm and extending beyond the area of exposure).....	4
Severe eschar and /or corrosion.....	Note occurrence

TABLE II

Acute Skin Irritation of DOW CORNING® 2-6079

Mean Skin Irritation Scores*

Mean Scores

Parameter	<u>Reading Interval (Time Post Wash. Hours)</u>				
	1	24	48	72	7 days
Erythema & Eschar:	0	1.3	1.3	1.0	0
Edema Formation :	0	0	0	0	0

Primary Dermal Irritation Score^a: 1.22

* Scored according to Table I

^a Calculated according to Appendix I

TABLE III

Acute Skin Irritation Study of DOW CORNING® Z-6079
Individual Skin Irritation Scores*

Individual Scores

Animal Number

<u>Parameter</u>	<u>Interval</u> <u>(Hours)</u>	<u>12884</u>	<u>12893</u>	<u>12845</u>
I. Erythema & Eschar:	1	0	0	0
	24	2	0	2
	48	2	0	2
	72	2	0	1
	7 days	0	0	0
II. Edema Formation:	1	0	0	0
	24	0	0	0
	48	0	0	0
	72	0	0	0
	7 days	0	0	0

* Scored according to Table I

APPENDIX 1

DETERMINATION OF PRIMARY DERMAL IRRITATION SCORE
(SEE SOP NO. 06-055-00)

1. From the individual score of erythema (0-4) and edema (0-4) recorded for each animal according to Table I, calculate a total of all individual scores for both erythema and oedema recorded at 24, 48, and 72 hours after dosing. For studies using three animals, this gives a total maximum score possible of 36 for both erythema and oedema. Add these two totals to give a final irritation score total (maximum possible = 72).
2. Divide this final irritation score total by 9* to yield a primary dermal irritation score (PDIS; maximum = 8.0).
3. Use the PDIS obtained in Step 2 above to obtain a descriptive rating according to Appendix 2. Record this assigned rating in the final report for the study.

NOTES:

1. The descriptive rating obtained by this calculation method can be supplemented or even adjusted, by additional observations (e.g. appearance of unusual effects, persistence of effects to 7 days or beyond, discrepancy between erythema and oedema scores, etc.)
2. Corrosivity is not specifically addressed in this scheme and would be classified separately, superceding the use of this scheme.
3. Although principally designed for primary (single exposure) irritancy assessment, it may under suitable circumstances be used in repeat application irritation studies.

* The product of the number of animals X the number of observation times; in studies using three animals, this product = 9.

APPENDIX 2

DESCRIPTIVE RATING TABLE FOR SKIN IRRITANCY

<u>Mean Primary Dermal Irritation Score</u>	<u>Descriptive Rating (Grade)</u>
0	Non-irritating (0)
0.1 - 1.5	Minimally Irritating (1)
1.6 - 3.0	Mildly Irritating (2)
3.1 - 5.0	Moderately Irritating (3)
5.1 - 8.0	Severely Irritating (4)



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