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Document Title	REPORT TO DOW CORNING CORPORATION IRRITATION STUDIES ON SEVEN SAMPLES (TX-46A, TX-46B, TX-46C, TX-46D, TX-46E, TX-47A, TX-47B) WITH COVER LETTER DATED 042094		
Chemical Category	SILOXANES AND SILICONES, DI-ME (63148-62-9)		

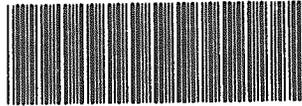
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DOW CORNING



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OFFICE OF POLLUTION
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April 20, 1994

TSCA Document Processing Center (TS-790)
Office of Prevention, Pollution and Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
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; 40 CFR Part 716
ITC 30-Listed Siloxanes and Silicones

Dear Sir:

The enclosed information is submitted on behalf of Dow Corning Corporation, Midland, Michigan, 48686-0994, in compliance with the referenced health and safety data reporting rule.

Listed Chemical Substance(s):

141-62-8 Decamethyltetrasiloxane identified as
TX-46a
63148-62-9 Siloxanes and silicones, di-Me (Dimethyl
silicones and siloxanes) identified as
TX-46b and TX-46c and TX-46d

Title of Submitted Study:

REPORT TO DOW CORNING CORPORATION IRRITATION STUDIES ON SEVEN
SAMPLES

Dow Corning Corporation
May 1, 1964

Contains No CBI

Manufacturer:

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

-2-

If you require further general information concerning this submission, please contact Dr. Rhys G. Daniels at 517-496-4222. For further information concerning the submitted study or the toxicological properties of the listed chemical substance, please contact Dr. Robert G. Meeks at 517-496-8629.

Sincerely,

Alvin E. Bey

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

Industrial **BIO-TEST** *Laboratories, Inc.*

1810 FRONTAGE ROAD

NORTHBROOK, ILLINOIS 60062

Telephone CRestwood 2-3030

ORIGINAL REPORT

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REPORT TO
DOW CORNING CORPORATION
IRRITATION STUDIES ON
SEVEN SAMPLES

1964-3005-1063-2

REPORT TO
DOW CORNING CORPORATION
IRRITATION STUDIES ON
SEVEN SAMPLES

I. Introduction

Seven samples identified as TX-46a, TX-46b, TX-46c, TX-46d, TX-46e, TX-47a and TX-47b respectively were received from Dow Corning Corporation for the purpose of conducting eye irritation tests employing albino rabbits as test animals. In addition skin irritation tests were performed on samples TX-47a and TX-47b.

II. Procedures

The procedures followed in the evaluation of each material were essentially the same and are described below.

A. Eye Irritation Test - Albino Rabbits

A group of five albino rabbits was used to evaluate the eye irritating properties of the test materials. Young adult, New Zealand strain animals were selected for the test.

The test method employed was patterned after that of Draize et al*. Exactly 0.1 ml of undiluted test material was instilled into the conjunctival sac of the right eye of each test rabbit in a group of five animals. The left eye of each animal served as a scoring control.

One, 24, 48, 72, 96 hours, and 7 days following the initial instillations, the cornea, iris, and palpebral conjunctiva were examined individually and graded for irritation and injury according to a standard scoring system*. The maximum possible score at any one examination and scoring period is 110 points which indicates maximal irritation and damage to all three ocular tissues. Zero score indicates no irritation whatever.

After the completion of the test, the scores were analyzed and a descriptive eye irritation rating was assigned to the test material. The criteria used for assignment of the descriptive rating were the frequency, the extent, and the persistence of irritation or damage which occurred to the three ocular tissues. In the classification system used, special emphasis was placed upon irritation or damage to

* "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes", Draize, John H., Woodard, Geoffrey, and Calvery, Herbert O., J. Pharm. & Exp. Ther., 82, 4, December 1944.

the cornea. Correspondingly less stress was placed upon conjunctival and iridial effects.

The descriptive rating assigned was one of the following, each of which characterizes a particular level of ophthalmic irritation and damage:

Non-Irritating
Practically Non-Irritating
Minimally Irritating
Mildly Irritating
Moderately Irritating
Severely Irritating
Extremely Irritating
Maximally Irritating.

B. Skin Irritation Test - Albino Rabbits

Four albino rabbits were used in the evaluation of primary skin irritating properties of the test materials. The test procedure employed was modeled after that of Draize et al*.

Prior to the application of the test material, the hair was clipped from the backs and flanks of each of the four rabbits. Two test sites located at the midline of the back approximately ten centimeters apart were selected on each rabbit. One of the two sites selected was abraded by making four epidermal incisions, two perpendicular to the other two while the other skin site remained intact.

The test material was applied undiluted to the skin of the prepared exposure sites on each of four rabbits. Applications were in the form of square gauze patches, 2.5 cm on a side, containing 0.5 ml of undiluted test material. These were affixed directly over the skin test sites and secured in place by means of thin strips of adhesive tape.

In the above manner, the test material was evaluated for primary irritation on each of four rabbits, a total of eight sites (four intact and four abraded) being employed.

* "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes", Draize, John H., Woodard, Geoffrey, and Calvery, Herbert O., J. Pharm. & Exp. Ther., 82, 4, December 1944.

Following the patch applications, the entire trunk of each test animal was wrapped in an impervious plastic sheeting. This helped to hold the patches in position and retarded evaporation during the 24-hour exposure period.

At the end of 24 hours, the plastic wrappings and patches were removed. The skin sites were then individually examined and scored separately for both erythema and edema on a graded scale of 0 to 4. After 72 hours had elapsed, the sites were re-examined and rescored.

In evaluating the average irritation present, scores for individual intact and abraded sites were recorded separately for each of the two scoring time intervals. The mean scores for the 24- and 72-hour grading periods were then averaged to obtain separate mean irritation grades for both intact and abraded skin. Finally, the latter two means were averaged to give a combined average irritation score.

The scoring criteria for erythema and edema are shown in Table I.

TABLE I

Scoring Criteria for Skin Reactions

<u>Erythema and Eschar Formation</u>	
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 depth)	4
Total Possible Erythema Score	4
<u>Edema Formation</u>	
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Total Possible Edema Score	4
Total Possible Primary Irritation Score	8

III. Results

A. Eye Irritation Test - Albino Rabbits

The eye irritation scores and ratings are presented in Tables II thru VIII.

TABLE II
 TEST MATERIAL: TX-46a
 Eye Irritation Test - Albino Rabbits

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	96 Hours	7 Days	Maximum Possible Score
Cornea	1	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		0	0	0	0	0	0	20
Total		0	0	0	0	0	0	110
Cornea	2	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		0	0	0	0	0	0	20
Total		0	0	0	0	0	0	110
Cornea	3	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		2	0	0	0	0	0	20
Total		2	0	0	0	0	0	110
Cornea	4	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		2	0	0	0	0	0	20
Total		2	0	0	0	0	0	110
Cornea	5	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		0	0	0	0	0	0	20
Total		0	0	0	0	0	0	110
<u>Averages</u>								
Cornea		0.0	0.0	0.0	0.0	0.0	0.0	80
Iris		0.0	0.0	0.0	0.0	0.0	0.0	10
Conjunctiva		0.8	0.0	0.0	0.0	0.0	0.0	20
Total		0.8	0.0	0.0	0.0	0.0	0.0	110

Rating: Practically Non-Irritating

TABLE III

TEST MATERIAL: TX-46b

Eye Irritation Test - Albino Rabbits

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	96 Hours	7 Days	Maximum Possible Score
Cornea	1	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		4	0	0	0	0	0	110
Cornea	2	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		2	0	0	0	0	0	20
Total		2	0	0	0	0	0	110
Cornea	3	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		2	0	0	0	0	0	20
Total		2	0	0	0	0	0	110
Cornea	4	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		2	0	0	0	0	0	20
Total		2	0	0	0	0	0	110
Cornea	5	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		2	2	0	0	0	0	20
Total		2	2	0	0	0	0	110
<u>Averages</u>								
Cornea		0.0	0.0	0.0	0.0	0.0	0.0	80
Iris		0.0	0.0	0.0	0.0	0.0	0.0	10
Conjunctiva		2.4	0.4	0.0	0.0	0.0	0.0	20
Total		2.4	0.4	0.0	0.0	0.0	0.0	110

Rating: Minimally Irritating

TABLE IV

TEST MATERIAL: TX-46c

Eye Irritation Test - Albino Rabbits

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	96 Hours	7 Days	Maximum Possible Score
Cornea	1	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		4	2	0	0	0	0	20
Total		4	2	0	0	0	0	110
Cornea	2	0	0	0	0	0	0	80
Iris		5	5	0	0	0	0	10
Conjunctiva		4	2	0	0	0	0	20
Total		9	7	0	0	0	0	110
Cornea	3	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		6	2	0	0	0	0	20
Total		11	2	0	0	0	0	110
Cornea	4	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		6	2	0	0	0	0	20
Total		11	2	0	0	0	0	110
Cornea	5	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		6	2	0	0	0	0	20
Total		11	2	0	0	0	0	110
<u>Averages</u>								
Cornea		0.0	0.0	0.0	0.0	0.0	0.0	80
Iris		4.0	1.0	0.0	0.0	0.0	0.0	10
Conjunctiva		5.2	2.0	0.0	0.0	0.0	0.0	20
Total		9.2	3.0	0.0	0.0	0.0	0.0	110

Rating: Minimally Irritating

TABLE V

TEST MATERIAL: TX-46d

Eye Irritation Test - Albino Rabbits

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	96 Hours	7 Days	Maximum Possible Score
Cornea	1	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Cornea	2	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		2	0	0	0	0	0	20
Total		2	0	0	0	0	0	110
Cornea	3	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	2	0	0	0	0	20
Total		9	2	0	0	0	0	110
Cornea	4	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	4	0	0	0	0	20
Total		9	4	0	0	0	0	110
Cornea	5	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	2	0	0	0	0	20
Total		9	2	0	0	0	0	110
<u>Averages</u>								
Cornea		0.0	0.0	0.0	0.0	0.0	0.0	80
Iris		4.0	0.0	0.0	0.0	0.0	0.0	10
Conjunctiva		3.6	1.6	0.0	0.0	0.0	0.0	20
Total		7.6	1.6	0.0	0.0	0.0	0.0	110

Rating: Minimally Irritating

TABLE VI

TEST MATERIAL: TX-46c

Eye Irritation Test - Albino Rabbits

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	96 Hours	7 Days	Maximum Possible Score
Cornea	1	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Cornea	2	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Cornea	3	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Cornea	4	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	2	0	0	0	0	20
Total		9	2	0	0	0	0	110
Cornea	5	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
<u>Averages</u>								
Cornea		0.0	0.0	0.0	0.0	0.0	0.0	80
Iris		5.0	0.0	0.0	0.0	0.0	0.0	10
Conjunctiva		4.0	0.4	0.0	0.0	0.0	0.0	20
Total		9.0	0.4	0.0	0.0	0.0	0.0	110

Rating: Minimally Irritating

TABLE VII

TEST MATERIAL: TX-47a

Eye Irritation Test - Albino Rabbits

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	96 Hours	7 Days	Maximum Possible Score
Cornea	1	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	2	0	0	0	0	20
Total		9	2	0	0	0	0	110
Cornea	2	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Cornea	3	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Cornea	4	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Cornea	5	0	0	0	0	0	0	80
Iris		0	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		4	0	0	0	0	0	110
<u>Averages</u>								
Cornea		0.0	0.0	0.0	0.0	0.0	0.0	80
Iris		4.0	0.0	0.0	0.0	0.0	0.0	10
Conjunctiva		4.0	0.4	0.0	0.0	0.0	0.0	20
Total		8.0	0.4	0.0	0.0	0.0	0.0	110

Rating: Minimally Irritating

TABLE VIII

TEST MATERIAL: TX-47b

Eye Irritation Test - Albino Rabbits

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	96 Hours	7 Days	Maximum Possible Score
Cornea	1	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	2	0	0	0	0	20
Total		9	2	0	0	0	0	110
Cornea	2	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Cornea	3	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Cornea	4	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	2	0	0	0	0	20
Total		9	2	0	0	0	0	110
Cornea	5	0	0	0	0	0	0	80
Iris		5	0	0	0	0	0	10
Conjunctiva		4	0	0	0	0	0	20
Total		9	0	0	0	0	0	110
Averages								
Cornea		0.0	0.0	0.0	0.0	0.0	0.0	80
Iris		5.0	0.0	0.0	0.0	0.0	0.0	10
Conjunctiva		4.0	0.8	0.0	0.0	0.0	0.0	20
Total		9.0	0.8	0.0	0.0	0.0	0.0	110

Rating: Minimally Irritating

B. Skin Irritation Test - Albino Rabbits

The results of the skin irritation tests are presented in Tables

IX and X.

TABLE IX

TEST MATERIAL: TX-47a

Primary Skin Irritation

Results

Animal Number	Irritation Scores				Combined Average
	Intact Skin		Abraded Skin		
	24 Hours	72 Hours	24 Hours	72 Hours	
1	3.0	1.0	4.0	1.0	
2	3.0	1.0	4.0	1.0	
3	3.0	1.0	3.0	1.0	
4	3.0	1.0	4.0	1.0	
Mean	2.0		2.4		2.2

Primary Irritation Rating: Mildly Irritating

TABLE X

TEST MATERIAL: TX-47b

Primary Skin Irritation

Results

Animal Number	Irritation Scores				Combined Average
	Intact Skin		Abraded Skin		
	24 Hours	72 Hours	24 Hours	72 Hours	
1	4.0	2.0	4.0	2.0	
2	2.0	1.0	2.0	1.0	
3	2.0	1.0	2.0	1.0	
4	4.0	2.0	4.0	2.0	
Mean	2.2		2.2		2.2

Primary Irritation Rating: Mildly Irritating

IV. Summary

The results of the eye and skin irritation tests are summarized below:

<u>Test Material</u>	<u>Eye Irritation Rating</u>	<u>Skin Irritation Rating</u>
TX-46a	Practically Non-Irritating	-
TX-46b	Minimally Irritating	-
TX-46c	Minimally Irritating	-
TX-46d	Minimally Irritating	-
TX-46e	Minimally Irritating	-
TX-47a	Minimally Irritating	Mildly Irritating
TX-47b	Minimally Irritating	Mildly Irritating.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Richard J. Palazzolo

Report prepared by: Richard J. Palazzolo, B.S.
Departmental Director
Acute Toxicity Department

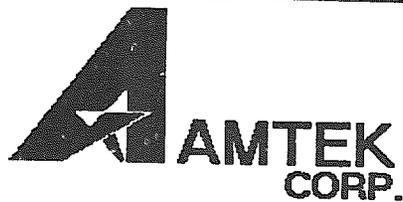
John H. Kay

Report approved by: John H. Kay, Ph. D.
Associate Director

J. C. Calandra

J. C. Calandra, M. D., Ph. D.
Director

May 1, 1964



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