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Submitting Organization		
DOW CORNING CORP		
Contractor		
INDUS BIO-TEST LABS INC		
Document Title		
TOXICITY STUDIES ON HEXAMETHYLDISILOXANE (DC 200 FLUID) WITH COVER LETTER DATED 013086		
Chemical Category		
ORGANOSILANES		

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DOW CORNING

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January 30, 1986

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SEQUENCE C

ATTN: T. O'Bryan
Document Control Officer
Information Management Division (TS-793)
Office of Toxic Substances
401 M Street, S.W.
Washington, D.C. 20460

2/14/86
TOB/CSB

Dear Mr. Kover:

Dow Corning Corporation, Midland, Michigan wishes to provide unpublished information concerning chemicals you have recently selected for preparation of Chemical Hazard Information Profiles (CHIPS).

CAS No. 75-76-3
Name: Tetramethylsilane

1) Acute Toxicologic Properties and Industrial Handling Hazards of Tetramethylsilane

CAS No. 107-46-0
Name(s): Hexamethyldisiloxane, DOW CORNING® 200 Fluid, 0.65 cs.

1) Toxicity Studies on TX-135A

2) Range Finding Eye Irritation Test on TX-212A

3) Comparison of the Primary Skin Irritation Potential and the Effects of Repeated, Prolonged Skin Exposures to Various Volatile Experimental Cosmetic Fluids with SD Alcohol 40 When Tested According to Federal Hazardous Substances Act (FHSA) Procedures

4) Mutagenic Evaluation of Hexamethyldisiloxane

5) Tissue Cell Biocompatability of Hexamethyldisiloxane

DOW CORNING CORPORATION, MIDLAND, MICHIGAN 48640-0994 TELEPHONE 517 496-4000

CAS No. 681-84-5
Name: Tetramethoxysilane

1) A comparison Study of the Tetramethoxysilane Eye Injury Potential Following Through Irrigation with pH 6.9^{tm} Sterile Phosphate Buffer Eye Wash or Tap Water

2) The Acute Vapor Inhalation Toxicity and Comparison of Tetramethoxysilane and Trimethoxysilane with Rats

3) A Rangefinding Study of the Subchronic Toxicity of Inhaled Tetramethoxysilane in the Rat

CAS No. 1185-55-3
Name: Diphenylsilanediol

1) Mutagenic Evaluation of Diphenylsilanediol in the Ames Bacterial Assay System

2) Diphenylsilanediol Oral Toxicity Study in Beagle Dogs

3) Subacute Oral Toxicity of Diphenylsilanediol in Rats

CAS No. 2157-45-1
Name(s): beta-Methoxyethoxyorthosilicate, SYL-OFF® 7223

1) Genetic Evaluation of SYL-OFF® 7223 in the Ames Bacterial Assay

CAS No. 2487-90-3
Name: Trimethoxysilane

1) Results of Range Finding Toxicological Tests on Trimethoxy Silane (A-907-58F, Cut 2)

2) An Evaluation of the Potential Toxicity of Inhaled Trimethoxysilane in the Albino Rat (Previously Submitted under Section 8(e) of TSCA)

3) A Five-Day Subchronic Inhalation Study with Rats, Mice, Rabbits, and Syrian Hamsters Exposed to Trimethoxysilane Vapors.

4) Acute Toxicity of Trimethoxysilane Following Intravenious (I.V.) and Intraperitoneal (I.P.) Injection in the Rat

5) See CAS No. 681-84-5 Report No. 2

6) Evaluation of Trimethoxysilane Via Acute Vapor Inhalation in the Rodent Micronucleus Assay

CAS No. 2530-85-0
Name: Methacryloxypropyltrimethoxysilane, Z-6030

1) Results of Range Finding Toxicological Tests on Dow Corning A1096-121-6 (Z-6030)

2) Toxicologic Properties and Industrial Handling Hazards of DOW CORNING® Z-6030 Silane

3) Mutagenic Evaluation of DOW CORNING® Z-6030 in the Ames Bacterial Assay System

CAS No. 3027-21-2
Name: Dimethoxymethylphenylsilane

1) Acute Toxicological Properties and Industrial Handling Hazards of DOW CORNING® XP-8-5314, an Acrylic Paint Additive

2) Acute Inhalation Properties of DOW CORNING® XP-8-5314, an Acrylic Paint Additive

CAS No. 4130-08-9
Name(s): Vinyltriacetoxysilane, DOW CORNING® Z-6075 Silane

1) Acute Toxicological Properties and Industrial Handling Hazards of Vinyltriacetoxysilane

2) Mutagenic Evaluation of DOW CORNING® Z-6075 in the Ames Bacterial Assay System

3) Acute Static Toxicity of DOW CORNING® Z-6075 Silane to Daphnia, Bluegill, Rainbow Trout, and Two Species of Algae

CAS No. 69155-42-6
Name(s): DOW CORNING® XZ8-5024, DOW CORNING® Q8-5024 INT

1) Mutagenic Evaluation of DOW CORNING® XZ8-5024 in the Ames Bacterial Assay System

2) Acute Toxicologic Properties and Industrial Handling Hazards of DOW CORNING® Q8-5024 INT

CAS No. 556-67-2
Name: Octamethylcyclotetrasiloxane (OMCTS)

Dow Corning Corporation and the Silicone Industry have previously submitted extensive amounts of information on this chemical via the ITC, 8(a), 8(d), recorded meetings with EPA and Docket Number OPTS-42071.

Should any questions arise, we would welcome a discussion with you at your convenience.

Regards,

DOW CORNING CORPORATION

E J Hobbs

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EJH/kld

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ORIGINAL REPORT
Do not remove
from file.

REPORT TO

DOW CORNING CORPORATION

TOXICITY STUDIES ON
TX-135A

IBT NO. A4525

D.C. 200 FLUID, 0.65 CS
LOT AA 6387

RECEIVED

At the end of the observation period, all data were collected and arrangements were made to calculate, if possible, the acute oral mean lethal dose (LD_{50}) of the test material using the techniques of Weil*. Thompson**, and Thompson and Weil***.

B. Acute Dermal Toxicity - Albino Rabbits

The procedure followed was in accordance with the evaluation of acute dermal toxicity specified in Section 191.1 (f) (3) of the Federal Regulations****. A group of ten albino rabbits was tested at a selected dose of 2.0 g/kg.

C. Eye Irritation Test - Albino Rabbits

The procedure followed was in accordance with the evaluation of eye irritation in Sections 191.1 (g) (3) and 191.12 of the Federal Regulations****. These regulations require examination for irritation at 24, 48 and 72 hour intervals after ocular instillation.

Eye irritation was scored quantitatively using the method of Draize et al***** which is consistent with the descriptive criteria for evaluation of eye irritation in the Federal Regulations.

* Weil, Carrol S.: Tables for Convenient Calculation of Median-Effective Dose (LD_{50} or ED_{50}) and Instructions in Their Use. Biometrics, Sept. 1952.

** Thompson, William R.: Use of Moving Averages and Interpolation to Estimate Median-Effective Dose. Bact. Rev., Nov. 1947.

*** Thompson, William R. and Weil, Carrol S.: On the Construction of Tables for Moving Average Interpolation. Biometrics, March 1952.

**** See footnote, page 1.

***** "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.

D. Primary Skin Irritation Test - Albino Rabbits

The procedure followed was in accordance with the evaluation of skin irritation specified in the Federal Regulations* for "Irritants", Sections 191.1 (g) (2) and 191.11.

Six albino rabbits were employed in the evaluation of the test material. The general procedural details, method of application, scoring technique, etc. were those cited in the Federal Register and need not be repeated here.

* See footnote, page 1.

III. Results

A. Acute Oral Toxicity - Albino Rats

No deaths or untoward behavioral reactions were noted among any animals dosed orally at levels of 15.4, 23.1 and 34.6 g/kg respectively.

Necropsy of animals which died during the study as well as of those sacrificed at the end of the 14-day observation period did not reveal any significant gross pathologic alterations in the tissues and organs examined.

B. Acute Dermal Toxicity - Albino Rabbits

No deaths or untoward behavioral reactions were noted among animals receiving single dermal applications at a dose level of 2.0 g/kg of TX-135A.

C. Eye Irritation Test - Albino Rabbits

The test material was not found to be an eye irritant. No positive responses were elicited in any of the animals tested.

D. Primary Skin Irritation Test - Albino Rabbits

The results of the primary skin irritation test are presented in Table I.

TABLE I

TEST MATERIAL: TX-135A

Primary Skin Irritation Test - Albino Rabbits

Results

	Exposure Time (Hours)	Exposure Units (Value)
Erythema and Eschar Formation:		
Intact Skin	24	2.3
Intact Skin	72	1.8
Abraded Skin	24	2.3
Abraded Skin	72	2.0
Subtotal		8.4
Edema Formation:		
Intact Skin	24	1.0
Intact Skin	72	0.5
Abraded Skin	24	1.2
Abraded Skin	72	0.5
Subtotal		3.2
Total		11.6

Primary Irritation Score = 2.9

IV. Summary

The results of the acute toxicity studies conducted on TX-135A are summarized below.

Test Conducted	Results Classification under FHSLA*
Acute Oral Toxicity - Albino Rats	Not Toxic and Not Highly Toxic (LD_{50} > 34.6 g/kg)
Acute Dermal Toxicity - Albino Rabbits	Not Toxic and Not Highly Toxic
Eye Irritation Test - Albino Rabbits	Not an Eye Irritant
Primary Skin Irritation Test - Albino Rabbits	Not a Skin Irritant

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Gerald Schoenig

Report prepared by: Gerald Schoenig, B.S.
Departmental Director
Acute Toxicity Department

Otis E. Fancher

Report approved by: Otis E. Fancher, Ph.D.
Director

J. C. Calandra

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

July 13, 1966
AS

* See footnote, page 1.

CODING FORM FOR SRC INDEXING

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4/05/78	2/14/86	

Submitting Organization

DOW CORNING CORP

Contractor

DOW TOX DEPT

Document Title

COMPARISON OF THE PRIMARY SKIN IRRITATION POTENTIAL AND THE EFFECTS OF REPEATED PROLONGED SKIN EXPOSURES TO VARIOUS VOLATILE EXPERIMENTAL COSMETICS FLUIDS WITH SD ALCOHOL 40

Chemical Category

ORGANOSILANES

COMPARISON OF THE PRIMARY SKIN IRRITATION POTENTIAL AND THE EFFECTS OF REPEATED PROLONGED SKIN EXPOSURES TO VARIOUS VOLATILE EXPERIMENTAL COSMETIC FLUIDS WITH SD ALCOHOL 40 WHEN TESTED ACCORDING TO FEDERAL HAZARDOUS SUBSTANCES ACT (FHSA) PROCEDURES

Author: Benjamin H. Franklin

Submitted By: James R. Heffel

Reported By: B. H. Franklin BHF Checked By: C. L. Groh E. J. Hobbs EJH

Date: April 5, 1978

This summary of data and conclusions is based upon the sample received. Additional studies may be required as specific uses and formulations are developed or if process changes occur.

Samples of various volatile experimental cosmetic fluids were submitted to the Biological Services Department for determination of primary skin irritation potential and the effects of repeated prolonged skin contact when evaluated according to procedures promulgated by the Consumer Product Safety Commission in compliance with Federal Hazardous Substances Act (FHSA) Regulations. The test samples were identified as follows:

TX Number	Material	Lot/Reference No.
1445	SD Alcohol-40	E-3089-8A
1446	DOW CORNING® 200 Fluid, 0.65 cs.	AAX-002
1447	DOW CORNING® 344 Fluid	LL-07050
1448	Blend Consisting of:	
	80% Dow Corning 200 fluid, 0.65 cs.	AAX-002
	20% Dow Corning 344 fluid	LL-07052

The FHSA method of evaluating primary skin irritation potential requires exposing laboratory animals to a single application of a test substance. The Dow Corning volatile experimental cosmetic fluids which were employed in this study are intended for use as diluents in cosmetic and personal care products which will likely be applied to the skin in a repeated manner; therefore, in addition to the FHSA test, another study was conducted to permit an assessment of the effect of repeated, prolonged skin exposures to these materials. SD Alcohol-40 is a commonly used, widely accepted diluent for cosmetic formulations and was employed in this series of evaluations as a control.

Procedure

The primary skin irritation potential of the above test materials was evaluated according to FHSA protocol with one exception: In this study each animal received a single skin application (at a different site) of

MICROFILM

each of the fluids being evaluated; a procedure which compensated for individual variation among the test animals. Afterwards, the entire abdomen was covered with an impervious material to retard the evaporation of volatile substances. To study the effects of repeated prolonged skin exposures to the test materials, each laboratory rabbit received ten applications of each material over a 16 day period in a manner similar to the above FHSA study. In this phase, the abdomen was covered with a cloth bandage taped in place to the surrounding hair. In this situation, volatile components were allowed to evaporate from the skin surface through the bandage to simulate the type of skin exposure beneath an article of clothing.

Results

TX-1445 (SD Alcohol-40)

The FHSA test with SD Alcohol-40 produced a slight amount of redness. According to current FHSA definition, SD Alcohol-40 is not a primary skin irritant. Repeated, prolonged skin exposures to this liquid resulted in slight redness and swelling.

TX-1446 (Dow Corning 200 fluid, 0.65 cs.)

The FHSA test with Dow Corning 200 fluid, 0.65 cs. produced a slight amount of redness. According to current FHSA definition, Dow Corning 200 fluid, 0.65 cs. is not a primary skin irritant. Repeated, prolonged skin exposures to this liquid resulted in slight redness and a very slight amount of swelling.

TX-1447 (Dow Corning 344 fluid)

The FHSA test with Dow Corning 344 fluid produced a slight amount of redness. According to current FHSA definition, Dow Corning 344 fluid is not a primary skin irritant. Repeated, prolonged skin exposures to this liquid produced a slight amount of redness and swelling.

TX-1448 (an 80/20% blend of Dow Corning 200, 0.65 cs. and 344 fluids)

The FHSA test with this fluid blend produced a slight amount of redness and swelling. According to current FHSA definition, this material is not a primary skin irritant. Repeated, prolonged skin exposures to this liquid caused a slight amount of redness.

3431-1, 1010-3, 2061-3
I-0005-0565
Benjamin H. Franklin
April 5, 1978

SUMMARY

Primary Skin Irritation Potential of Various Volatile Experimental Cosmetic Fluids When Tested According to FHSA Regulations

Material	FHSA Primary Irritation Score	Classification
TX-1445 (SD Alcohol-40)	0.5/8.0	Not a skin irritant
TX-1446 (DC® 200 fluid/0.65 cs)	0.7/8.0	Not a skin irritant
TX-1447 (DC® 344 fluid)	2.5/8.0	Not a skin irritant
TX-1448 (80%/20% blend DC® 200/344)	2.2/8.0	Not a skin irritant

Comments

The following conclusions can be drawn from the data generated in this series of experiments.

(A) Under the conditions of these tests, no significant differences in either the FHSA or repeated, prolonged skin exposure test response exist between Dow Corning 200 fluid, 0.65 cs. and SD Alcohol-40.

(B) Although Dow Corning 344 fluid and the blend of Dow Corning 200, 0.65 cs. fluids are not primary skin irritants as defined by FHSA regulations, the degree of irritation produced by these materials is higher than that produced by Dow Corning 200 fluid 0.65 cs. alone or by SD Alcohol-40 in both types of exposure. This is probably attributable to the lower volatility of Dow Corning 344 fluid, which permitted a longer period of contact with the skin.

Recommendations

Based upon the relative skin irritation potential of the various volatile experimental cosmetic fluids which were evaluated in this study, it would appear that (provided other criteria, e.g., physical properties, compatibility with other components of the formulation, etc., were met) Dow Corning 200 fluid, 0.65 cs. is a suitable replacement candidate for SD Alcohol-40 in cosmetic and personal care formulations.

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3431-1, 1010-3, 2061-3
I-0005-0565
Benjamin H. Franklin
April 5, 1978

Dow Corning 344 fluid and the blend of Dow Corning 344/200 (0.65 cs.) fluids, while not (by definition) irritating to skin, did elicit sufficient response to require consideration as to the type and nature of cosmetic preparations into which these materials are formulated; because the skin responses of these fluids are probably directly related to the degree and length of confinement to the skin and the volatility of the respective silicone.

The rabbit in most instances is more sensitive than the human to skin irritation. If the potential cosmetic use of Dow Corning 344 and/or Dow Corning 200 fluid, 0.65 cs/Dow Corning 344 is of continued significant interest, it would be appropriate to conduct a similar type evaluation on human subjects for a more definitive answer to the question.

BHF/kld