CODING FORM FOR SRC INDEXING REVISED 10/15/86

Microfiche No.		
OTS0000469-0		
New Doc I.D.	Old Doc I.D.	
	FYI-OTS-0286-0469	
Date Produced	Date Recieved	TSCA section
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

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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

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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
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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
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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.

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