

# SilSense<sup>®</sup> SW-12 Silicone Toxicology Studies

## CTFA / INCI Name: Dimethicone PEG-7 Cocoate

No toxicology studies have been conducted with SilSense<sup>®</sup> SW-12 silicone (dimethicone copolyol ester). However, toxicity information is available on the base components, dimethicone copolyol and cocoa fatty acid. These data are supportive of the safety of SilSense SW-12 silicone for cosmetic applications.

## DIMETHICONE COPOLYOL

### Acute Oral Toxicity

The acute oral toxicity of seven undiluted dimethicone copolyol A (DMCA) or dimethicone copolyol B (DMCB) samples was studied in rats (CIR, 1982).<sup>1</sup> The lowest oral LD<sub>50</sub> values for these materials were 12.3 and 11.3 ml/kg, respectively.

### Acute Dermal Toxicity

The acute dermal toxicity of DMCA and DMCB samples was studied in rats and rabbits (CIR, 1982). The dermal LD<sub>50</sub> values for these materials ranged from greater than 2 to greater than 20 ml/kg, respectively. No deaths were observed.

### Acute Inhalation

The inhalation toxicity of one DMCA and three DMCB samples was evaluated in rats (CIR, 1982). Mortality was observed with concentrated vapor for one DMCB at high concentrations with the DMCA (23.47 mg/l) generated under elevated temperatures. It was concluded that little inhalation hazard exists from the ambient temperatures.

<sup>1</sup> CIR (1982). Third Report of the Cosmetic Ingredient Review Expert Panel, J. Amer. College Toxicol., 1(4):33-54.

### Eye Irritation

The eye irritation potential of a number of DMCA and DMCB samples was studied (CIR, 1982). An undiluted DMCA was evaluated in rabbits according to FHSA requirements and scored by the Draize method. Irritation scores at 24, 48, and 72 hours were determined to be 7.9, 0.7, and 0.0, respectively. Irritation scores for undiluted DMCA 193 that was tested similarly and scored at 24, 48, and 72 hours were determined to be 3.0, 0.0, and 0.0, respectively. Two other DMCA samples and three other DMCB samples also were evaluated in rabbits and classified as not causing severe eye irritation.

### Skin Irritation

The skin irritation potential of two undiluted DMCA samples was evaluated in rabbits according to FHSA requirements and was scored by the Draize method (CIR, 1982). The primary irritation scores for these two samples were determined to be 1.6 and 2.7 (maximum of 8.0). Five other samples also were evaluated in rabbits and were not found to cause any significant skin irritation.

### Subacute Dermal Toxicity

Male rabbits were administered 200 mg/kg/day of undiluted DMCA 190 for 28 days (CIR, 1982). No mortality, adverse behavioral reactions, or gross pathological alterations were observed. Irritation was limited to slight to moderate erythema and edema after two treatments and thereafter. A depression in spermatogenesis was observed in one of the ten animals. Similar results were observed with DMCA 193. However, depression of spermatogenesis was the same in the control and test animals (2/10).

Lubrizon Advanced Materials, Inc. / 9911 Brecksville Road, Cleveland, Ohio 44141-3247 / TEL: 800.379.5389 or 216.447.5000

The information contained herein is being furnished for informational purposes only, upon the express condition that the User makes its own assessment of the appropriate use of such information. While the information contained herein is believed to be reliable, no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for a particular application or the results to be obtained herefrom. Lubrizon Advanced Materials, Inc. ("Lubrizon") cannot guarantee how any products associated with this information will perform in

combination with other substances or in the User's process. Due to variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the information or products for the applications disclosed. Lubrizon shall not be liable and the User assumes all risk and responsibility for any use or handling of any material beyond Lubrizon's direct control. LUBRIZOL MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO,

THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. It is the User's sole responsibility to determine if there are any issues relating to patent infringement of any component or combination of components relating to the supplied information. **Nothing contained herein is to be considered as permission, recommendation, nor as an inducement to practice any patented invention without permission of the patent owner.**

For further information, please visit: [www.lubrizon.com/personalcare](http://www.lubrizon.com/personalcare)

## **Subchronic Oral Toxicity**

A DMCB sample was administered to groups of rats in diets containing 1% or 4% of the test material (0.64 and 2.88 g/kg/day in male and 0.74 and 3.08 g/kg/day in females) for 89 days (CIR, 1982). No mortality or deleterious effects were reported for any group.

## **Human Clinical Studies**

### **Skin Irritation and Sensitization**

The skin irritation and sensitization of dimethicone copolyol has been evaluated in a number of studies with human volunteers (CIR, 1982). A 40% aqueous solution and an undiluted sample was tested with 19 and 20 subjects, respectively. A score of 0.5 out of 4.0 was observed in one of the 19 subjects exposed to the dilute sample while none of the subjects exposed to the undilute sample exhibited any irritation. Dimethicone copolyol also was evaluated in panels of 50 and 201 subjects. No irritation or sensitization was noted.

### **Cocoa Fatty Acid**

Cocoa fatty acid is considered to have a low acute toxicity. It is practically non-toxic via oral exposure to rats ( $LD_{50} >22$  g/kg). It produced mild skin irritation in humans following a 24 hour ocular patch test and mild transient eye irritation in rabbits.