

# SilSense<sup>®</sup> Copolyol-1 Silicone Toxicology Studies

CTFA / INCI Name: PEG-33 and PEG-8 Dimethicone and PEG-14

No toxicology studies have been conducted with SilSense<sup>®</sup> Copolyol-1 silicone. However, SilSense Copolyol-1 silicone is a blend of personal care grade polyethylene glycol and dimethicone copolyol (a copolymer of a polydimethylsiloxane and polyoxyalkylene ether). The toxicity of dimethicone copolyol has been well studied and is detailed below.

## 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 LD50 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 LD50 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).

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## 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.