



Safety Statement

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Product Name: SilDerm® Smoothing

Code: 30301

INCI Name: Cyclomethicone & Dimethicone

SilDerm® Smoothing is manufactured by blending cyclomethicone (D5) and dimethicone.

The Cosmetic Ingredient Review (CIR) published a safety assessment for cyclomethicone (D5), along with other polysiloxane compounds. In acute inhalation toxicity and acute oral toxicity studies, cyclomethicone was found to be non-toxic. It is also not genotoxic, and is a proven non-irritant to the skin. This information, along with several other safety test results, caused the CIR to declare cyclomethicone safe as currently used in cosmetics.¹

The CIR also published a safety assessment for dimethicone and several related compounds. It concluded that dimethicone is safe as currently used in cosmetics. This decision was supported by data showing that dimethicone is not a skin sensitizer or irritant, and it is not mutagenic or carcinogenic. Dermal and oral toxicology reports proved that dimethicone is not toxic through either route.²

SilDerm® Smoothing was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models. The full report is attached for reference.

The above information supports the safety of SilDerm® Smoothing in cosmetic applications at use levels of 1.0-5.0%. No further testing is required at this time.

1. "Safety Assessment of Cyclomethicone, Cyclotetrasiloxane, Cyclopentasiloxane, Cyclohexasiloxane, and Cycloheptasiloxane." Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr497.pdf>
2. "Final Report on the Safety Assessment of Stearoyl Dimethicone, Dimethicone, Methicone, Amino Bispropyl Dimethicone, Aminopropyl Dimethicone, Amodimethicone, Amodimethicone Hydroxystearate, Behenoxy Dimethicone, C24-28 Alkyl Methicone, C30-45 Alkyl Methicone, C30-45 Alkyl Dimethicone, Cetearyl Methicone, Cetyl Dimethicone, Dimethoxysilyl Ethylenediaminopropyl Dimethicone, Hexyl Methicone, Hydroxypropyldimethicone, Stearamidopropyl Dimethicone, Stearyl Dimethicone, Stearyl Methicone, and Vinyl dimethicone." Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr307.pdf>

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