



Safety Statement

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Product Name: SilDerm[®] Formulating Base

Code: 30304

INCI Name: Cyclopentasiloxane & Dimethicone & Cyclohexasiloxane & Isohexadecane & Ammonium Polyacryloyldimethyl Taurate & Tocopheryl Acetate & Polysorbate 20 & Polysorbate 80

SilDerm[®] Formulating Base is manufactured by first blending Cyclopentasiloxane, Dimethicone, Cyclohexasiloxane, Isohexadecane and Ammonium Polyacryloyldimethyl Taurate. In a separate vessel Tocopheryl Acetate, Polysorbate 20, and Polysorbate 80 are pre-mixed prior to blending together with silicone mixture.

The Cosmetic Ingredient Review (CIR) published a safety assessment for cyclopentasiloxane and cyclohexasiloxane, along with other polysiloxane compounds. In acute inhalation toxicity and acute oral toxicity studies, cyclopentasiloxane and cyclohexasiloxane were found to be non-toxic. They are also not genotoxic, and are proven non-irritants to the skin. This information, along with several other safety test results, caused the CIR to declare cyclopentasiloxane and cyclohexasiloxane 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

A CIR safety assessment was published for isohexadecane and other isoparaffin compounds as well. In acute oral toxicity studies, isohexadecane was found to be non-toxic. Isohexadecane is also not genotoxic, and is classified as noncomedogenic and nonirritating as proven in various skin and ocular irritation studies. This information, along with several other safety results, caused the CIR to conclude that isohexane is safe as currently used in cosmetics.³

The Cosmetics Database rates ammonium polyacryloyldimethyl taurate as a low hazard ingredient, but notes 100% data gaps, indicating that there is no available research for this ingredient.⁴ No studies were found that listed negative side effects of ammonium polyacryloyldimethyl taurate, although ammonium can be considered toxic in high concentrations, the CIR safety assessment for ammonium polyacrylate and related compounds found that acrylate copolymers are considered safe for use in cosmetic formulations when formulated to avoid irritation.⁵

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A CIR safety assessment for tocopheryl acetate declared that this compound would not cause any acute oral toxicity based on the fact that cosmetic use of tocopheryl acetate is not expected to exceed the current levels found safe for food use. Tocopheryl acetate is also not genotoxic, and classified as nonirritating as proven in various skin irritation studies. This information, along with several other safety results, led CIR to conclude that tocopheryl acetate is safe as currently used in cosmetics.⁶ Tocopheryl acetate is also Generally Recognized as Safe (GRAS) according to the FDA's Federal Food, Drug and Cosmetic Act.⁷

The act states:

Any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.⁷

The CIR published a safety assessment for polysorbate 20 and polysorbate 80 along with other polysorbate compounds. A low order of toxicity was observed in acute and long-term oral toxicity studies, while polysorbate 80 was also shown to be nonmutagenic in Ames and micronucleus tests. Polysorbates were noncarcinogenic in animal models, while extensive clinical skin tests showed polysorbates to have little potential for human skin irritation or evidence of skin sensitization of phototoxicity. This information, along with several other safety test results, caused the CIR to declare polysorbate 20 and polysorbate 80 as safe as currently used in cosmetic formulations.⁸

SilDerm[®] Formulating Base 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[®] Formulating Base in cosmetic applications at use levels of 1.0 - 30.0%. 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>
3. "Safety Assessment of Isoparaffins as Used in Cosmetics." Cosmetic Ingredient Review <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr579.pdf>
4. "Ammonium Polyacryloyldimethyl Taurate" The Cosmetics Database. <http://www.ewg.org/skindeep/>
5. "Final Report on the Safety Assessment of Acrylates Copolymer and 33 Related Cosmetic Ingredients." Cosmetic Ingredient Review <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr283.pdf>
6. "Final Report on the Safety Assessment of Tocopherols and Tocotrienols as Used in Cosmetics." Cosmetic Ingredient Review <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR667.pdf>
7. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.
8. "Final Report on the Safety Assessment of Polysorbates 20, 21, 40, 60, 61, 65, 80, 81, and 85." Cosmetic Ingredient Review <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr201.pdf>

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