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Safety Statement

Product Name: SilDerm® Conditioning

Code: 30341

INCI Name: Cyclopentasiloxane & Dimethicone/Silsesquioxane Copolymer & Silk & Malva Sylvestris (Mallow) Extract & Lilium Candidum Bulb Extract & Lactobacillus/Eriodictyon Californicum Ferment Extract & Cymbidium Grandiflorum Flower Extract

SilDerm® Conditioning is manufactured by first blending cyclopentasiloxane and dimethicone/silsesquioxane copolymer. *Malva sylvestris*, *Lilium candidum* bulbs, and *Cymbidium grandiflorum* undergo mechanical grinding/milling in a separate vessel prior to aqueous extraction and blending with silicone mix. *Eriodictyon californicum* is then macerated and fermented with *Lactobacillus* separately before addition. Lastly, silk is then added to the blend.

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/silsesquioxane copolymer and several other dimethicone crosspolymer related compounds. It concluded that dimethicone/silsesquioxane copolymer along with other dimethicone crosspolymer ingredients are safe as currently used in cosmetics. This decision was supported by various data showing that dimethicone/silsesquioxane copolymer is not cytotoxic to mammalian cell cultures, not a skin sensitizer or irritant, and it is not mutagenic or carcinogenic.²

The CIR reviewed ten silk protein ingredients as used in cosmetics to determine their safety. Silk was tested specifically for oral toxicity in rats. The resulting oral LD₅₀ was >16 g/kg, and silk was considered nontoxic. Silk was also tested for ocular irritation potential in rabbits. While redness was observed in a majority of the rabbits whose eyes were left unrinsed after application of silk, no effects on the cornea or iris were observed. Rinsing the eye after application prevented any redness. Silk was therefore classified as a non-irritant in this study. Eight of the ten silk products reviewed were determined to be safe as presently used in cosmetics, including silk, hydrolyzed silk, silk extract, and silk powder.³

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Malva sylvestris, more commonly known as malva, is a spreading herb of natural origin and is also used commonly in food and nutritional wellness products. *Lilium candidum* bulbs, commonly known as the Madonna lily, is a plant of natural origin and is used commonly in food and nutritional wellness products as well.⁵ *Cymbidium grandiflorum* flower, is a species in the orchid family. Orchids have customarily been used in food and traditional medicines.⁷ Therefore, *Malva sylvestris* (mallow), *Lilium candidum* bulb and *Cymbidium grandiflorum* flower extracts may all be classified as GRAS according to the FDA's Federal Food, Drug and Cosmetic Act.⁴

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.⁴

Lactobacillus/eriodictyon californicum ferment extract is an extract of the product obtained by the fermentation of *Eriodictyon californicum* by the organism, *Lactobacillus*. *Lactobacillus* is a genus of microorganisms used to produce a variety of food products. It is a type of Lactic Acid Bacteria (LAB) and converts various sugars into lactic acid. Any existing LAB in SilDerm[®] Conditioning is removed after the fermentation process with *Eriodictyon californicum*.

Due to its status as a product of LAB, the Federal Food, Drug and Cosmetic Act classifies materials such as *Lactobacillus* as GRAS, according to the statement above.⁴ The plant used in this fermentation process, *Eriodictyon californicum*, commonly known as mountain balm, is of natural origin as well and traditionally used in wellness and food flavoring products. Therefore *Eriodictyon californicum* may also be categorized as GRAS.⁶

SilDerm[®] Conditioning 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[®] Conditioning 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. "Safety Assessment of Dimethicone Crosspolymers as Used in Cosmetics." Cosmetic Ingredient Review. <http://www.cir-safety.org/sites/default/files/Dimeth092012rep.pdf>
3. "Safety Assessment of Silk Protein Ingredients as Used in Cosmetics" Cosmetic Ingredient Review. <http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/TR699.pdf>
4. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. www.fda.gov.
5. NLM (National Library of Medicine). 2012. PubMed online scientific bibliography data. <http://www.pubmed.gov>.
6. Ley JP, Krammer G, Reinders G, Gatfield IL, Bertram HJ (July 2005). "Evaluation of bitter masking flavanones from Herba Santa (*Eriodictyon californicum* (H. and A.) Torr., Hydrophyllaceae)". J. Agric. Food Chem. 53 (15): 6061-6.
7. "Orchidaceae." Wikipedia. <http://en.wikipedia.org/wiki/Orchid#Uses>

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