



# Safety Statement

info@activeconceptsllc.com • Phone: +1-704-276-7100 • Fax: +1-704-276-7101

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Product Name: SilDerm® Conditioning Cashmere

Code: 30324

INCI Name: Dimethicone & Polymethylsilsesquioxane & *Lilium Candidum* Bulb/Malva Sylvestris/*Cymbidium Grandiflorum* Flower Extract & Wool Powder & *Lactobacillus/Eriodictyon Californicum* Ferment Filtrate

SilDerm® Conditioning Cashmere is manufactured by first blending Dimethicone and Polymethylsilsesquioxane. *Lilium candidum* bulbs, *Malva sylvestris*, and *Cymbidium grandiflorum* flowers undergo mechanical grinding/milling in a separate vessel prior to extraction and blending with silicone mix. *Eriodictyon californicum* is then macerated and fermented with *Lactobacillus* separately before addition. Lastly, wool powder is then added to the blend.

The Cosmetic Ingredient Review (CIR) 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.<sup>1</sup>

Polymethylsilsesquioxane is a silicone used in several industries. It is commonly used in cosmetics to impart a smooth feel, but it's also utilized in transdermal drug delivery patches, oral drug encapsulations, wound healing materials, and delivery of sunscreens.<sup>2</sup>

In 2013, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) published a report concerning Tapioca Starch Polymethylsilsesquioxane, the reaction product of starch and polymethylsilsesquioxane. The report included a safety assessment, which concluded that the product is not irritating to the eyes or skin, and does not need to be monitored under any chemical regulatory systems.<sup>3</sup>

The potential health effect of Polymethylsilsesquioxane was further investigated and summarized by an industry standard Material Safety Data Sheet (MSDS). This MSDS states that polymethylsilsesquioxane is not expected to show any adverse skin, inhalation, ingestion, or eye effects under normal conditions of use. The MSDS also concluded that this ingredient, when present at 0.1% or more, is not listed as a carcinogen or suspected carcinogen by NTP, IARC, or OSHA.<sup>4</sup>

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The CAS number for wool powder categorizes this compound as a protein hydrolysate. The CIR published a report which included the safety of multiple protein hydrolysates as used in cosmetics. Ocular and dermal irritation studies showed that hydrolyzed proteins of various origins are both non-irritating and non-sensitizing. Most hydrolyzed proteins are also found in the foods we consume daily.<sup>5</sup> Therefore, it may also be classified as Generally Recognized as Safe (GRAS) according to the FDA's Federal Food, Drug and Cosmetic Act.<sup>6</sup>

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.<sup>6</sup>

*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.<sup>7</sup> *Cymbidium grandiflorum* flower, is a species in the orchid family. Orchids have customarily been used in food and traditional medicines.<sup>8</sup> Therefore, *Malva sylvestris* (mallow), *Lilium candidum* bulb and *Cymbidium grandiflorum* flower extracts may all be classified as GRAS according to the above FDA's Federal Food, Drug and Cosmetic Act.<sup>6</sup>

*Lactobacillus/eriodictyon californicum* ferment filtrate 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<sup>®</sup> Conditioning Cashmere 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.<sup>6</sup> 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.<sup>9</sup>

SilDerm<sup>®</sup> Conditioning Cashmere 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<sup>®</sup> Conditioning Cashmere in cosmetic applications at use levels of 1.0 - 30.0%. No further testing is required at this time.

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1. "Final Report on the Safety Assessment of Stearoy 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>
2. "Polymethylsilsesquioxane". ToxNet. <http://toxnet.nlm.nih.gov/cgi-bin/sis/search>
3. "Siloxanes and Silicones, Me hydrogen, reaction products with starch (INCI name: Tapioca Starch Polymethylsilsesquioxane). National Industrial Chemicals Notification and Assessment Scheme (NICNAS). June 2013.
4. "Tospear120A methylsilsesquioxane resin". Momentive MSDS Version 1.4 – 10/02/2013
5. "Hydrolyzed Source Proteins as Used in Cosmetics" Cosmetic Ingredient Review. <http://www.cir-safety.org/sites/default/files/hprtms052012slr.pdf>
6. Federal Food, Drug and Cosmetic Act. U.S Food and Drug Administration. [www.fda.gov](http://www.fda.gov).
7. NLM (National Library of Medicine). 2012. PubMed online scientific bibliography data. <http://www.pubmed.gov>.
8. "Orchidaceae." Wikipedia. <http://en.wikipedia.org/wiki/Orchid#Uses>
9. 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.

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