



## Safety Statement

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Product Name: SilDerm® Emulsifying BG

Code: 30314

INCI Name: Butylene Glycol & Polymethylsilsesquioxane

SilDerm® Emulsifying BG is manufactured by blending butylene glycol and polymethylsilsesquioxane under controlled conditions.

Butylene glycol is a synthetic compound commonly used as a solvent. In 1985, the Journal of the American College of Toxicology published a report entitled "Final Report on the Safety Assessment of Butylene Glycol, Hexylene Glycol, Ethoxydiglycol, and Dipropylene Glycol".<sup>1</sup>

This report concluded that butylene glycol is safe for topical use in cosmetic products. This claim was substantiated by the results of several toxicity and irritation tests. Butylene glycol tested at 100% caused minimal to mild irritation of skin and eyes in test animals. Human skin patch tests on undiluted butylene glycol produced a very low order of primary skin irritation. An RIPT (Repeated Insult Patch Test) produced no evidence of skin sensitization.<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>

SilDerm® Emulsifying BG 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® Emulsifying BG in cosmetic applications at use levels of 0.5 - 15.0%. No further testing is required at this time.

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This information is offered solely for your investigation, verification, and consideration.



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1. "Final Reports on the Safety Assessment of Butylene Glycol, Hexylene Glycol, Ethoxydiglycol, and Dipropylene Glycol". Journal of the American College of Toxicity. Volume 4, Number 5. 1985
2. "Polymethylsilsequioxane". ToxNet. <http://toxnet.nlm.nih.gov/cgi-bin/sis/search>
3. "Siloxanes and Silicones, Me hydrogen, reaction products with starch (INCI name: Tapioca Starch Polymethylsilsequioxane). National Industrial Chemicals Notification and Assessment Scheme (NICNAS). June 2013.
4. "Tospearl120A methylsilsequioxane resin". Momentive MSDS Version 1.4 – 10/02/2013

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