

# SilDerm® Smoothing Certificate of Compliance

**Code:** 30301  
**INCI Name:** Cyclomethicone & Dimethicone  
**INCI Status:** Approved  
**CAS #:** 69430-24-6 & 9006-65-9  
**EINECS #'s:** N/A & N/A

The following information on regulatory clearances is believed to be accurate and is given in good faith as a guide to a global use of our ingredients in cosmetic applications. No representation or warranty as to its competences or accuracy is made. Information is offered for use in general cosmetic applications and may vary in particular applications. Users are responsible for determining the suitability of these products for their own particular use. All regulatory decisions should be made on the advice of your regulatory group or legal counsel.

Country / Regulatory Body	Status of Product
EU (REACH)	Compliant
USA (TSCA)	Exempt
Australia (AICS)	Compliant
Japan (METI)	Compliant
Canada (DSL)	Compliant
China (IECSC)	Compliant
Brazil (ANVISA)	Compliant
Korea (KECI)	Compliant
Philippines (PICCS)	Compliant
Mexico (COFEPRIS)	Compliant

## SilDerm® Smoothing Code: 30301

Attention must be paid to the use of SilDerm® Smoothing in the equivalent of OTC formulations (eg. quasi-drugs in Japan, or therapeutic goods in Australia). Some countries maintain restricted inventories of raw materials that can be used in those applications so more detailed guidance may be required.

SilDerm® Smoothing and its components and impurities are in compliance with the rules governing cosmetic products in the European Union (Directive 76/768/ECC & Regulation No. 1223/2009). The recommended use levels for SilDerm® Smoothing is 1.00 – 5.00%.

SilDerm® Smoothing is considered a non-hazardous material. All significant toxicological routes of absorption have been considered as well as the systemic effects and margin of safety (MoS) based on a no observed adverse effects level (NOAEL). Due to the restriction placed on animal testing of cosmetic raw materials, and Active Concepts, LLC's internal non-animal testing policy, this product was not tested for NOAEL.

SilDerm® Smoothing was tested using *in vitro* dermal and ocular irritation models. This product was found to be non-irritating in both models.

To our knowledge the above material is free of CMR (\*) substances, as defined according to Regulation (EC) No 1272/2008 and Cosmetic Regulation (EC) No 1223/2009 as amended.

(\*) Carcinogenic, Mutagenic, toxic for Reproduction

Active Concepts, LLC certifies that to the best of our knowledge our product does not contain any material listed on California Proposition 65.

Active Concepts, LLC certifies that SilDerm® Smoothing does not contain any materials prohibited by Halal laws.

Active Concepts, LLC certifies that all raw materials used to manufacture SilDerm® Smoothing are neither derived nor manufactured from pork derived materials or their derivatives. We further certify that Active Concepts, LLC is a pork-free facility.

SilDerm® Smoothing is REACH Compliant and free of the following:

- Formaldehyde or formaldehyde donors
- Glycol ethers
- Gluten
- Lactose
- Nanoparticles
- Nitrosamines
- Palm oil/palm kernel oil (or derivatives)
- Parabens
- Phthalates
- Polyethylene glycol (PEG)
- Residual solvents
- Sulfates
- Volatile organic compounds

## Raw Component Regulations

Please note that the below are global regulations for the raw materials used to manufacture SilDerm® Smoothing and are not for the product itself.

SilDerm® Smoothing contains 85.00% Cyclomethicone & 15.00% Dimethicone. See below for a list of regulations:

### Cyclomethicone:

- **USA: Safe up to 89.00%**  
\*Journal Citation: Amended Report 12/09 available from CIR, JACT 10(1):9-19, 1991 (original report)

### Dimethicone:

- **USA: Safe up to 80.00% in hair preparations; Safe up to 24.00% in make-up**  
\*Journal Citation: IJT 22(S2):11-35, 2003