

Dow Corning[®] Silky Wax 10

FEATURES & BENEFITS

- Semi-occlusive
- Lubricant
- Rheology modifier
- Smooth feel

COMPOSITION

- INCI Name:
Stearoxytrimethylsilane and stearyl alcohol
- Cas number: 18748-98-6 and 112-92-5

REGULATORY SUPPORT

Dow Corning can provide the following information:

- Product Regulatory Information
- Elemental Impurities
- Summary of Health Data

Excipient for pharmaceutical applications

APPLICATIONS

- Dow Corning[®] Silky Wax 10 is commonly used in topical formulations due to its broad compatibility with organic and silicone materials and because of its semi-occlusive property.
- When used as an excipient in topical formulations, Dow Corning Silky Wax 10 can modify the rheology of the formulation; provide lubrication, smooth feel and matifying effect.
- This wax is currently used in a range of dermatological treatment and pharmaceutical forms as creams, gels and sticks.

TYPICAL PROPERTIES

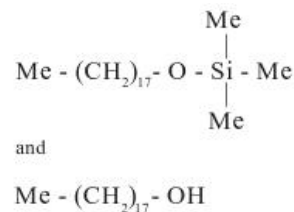
Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

Property	Unit	Result
Appearance at room temperature		Soft white to light straw, semi-crystalline
Appearance at 60°C (140°F)		Clear liquid with no precipitate
Melting range	°C °F	50–55 122–131
Acid number	mg KOH/g	0.0–0.5
Free stearyl alcohol	%	35.0–48.0
Flash point (closed cup)	°C °F	75 167
Infrared identification (match standard spectrum)		688

DESCRIPTION

- Dow Corning Silky Wax 10 is a soft solid mixture of stearoxytrimethylsilane and stearyl alcohol.
- Dow Corning Silky Wax 10 is a semi-occlusive and low melting point (53°C/127°F) silicone wax.

Figure 1: The average chemical structure of these two compounds:



SPECIFIC TESTING

- Infrared identification on each batch
- Tested for elemental impurities according to <232> and ICH Q3D guideline for metal impurities, every 2 years.

HOW TO USE

- Melt and blend the *Dow Corning* Silky Wax 10 with the other oil phase components. In the case of emulsions, ensure that the wax is completely melted into the oil phase by heating it to 60°C (140°F). Ensure that the temperature of the aqueous phase is also 60°C (140°F) before adding it to the oil phase. Avoid any significant and quick decrease in temperature; allow it to cool down at a slow, consistent rate until 40°C (104°F) has been reached while maintaining efficient mixing to keep the blend uniformly homogeneous.
- The level of *Dow Corning* Silky Wax 10 depends on the application but it can be as low as 2% and high as 20% for structuring an emulsion and modified its rheology.

REGULATORY INFORMATION

Dow Corning Silky Wax 10 is produced at the Dow Corning Midland plant in Midland, Michigan and further tested and packaged at the Dow Corning Healthcare Industries Materials Site (HIMS) in Hemlock, Michigan. The HIMS facility is dedicated to the production of silicone materials for healthcare application. The Healthcare Industries Materials Site is registered as drug establishment with the United States Food and Drug Administration. The site registration number is 1816403. The site quality system for pharmaceutical excipients utilizes principle of current Good Manufacturing Practices for Bulk Pharmaceutical Products. Both the Dow Corning Midland and Hemlock facilities are registered as part of Dow Corning's global quality system according to ISO 9001:2008.

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HANDLING PRECAUTIONS

PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT AND SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE SAFETY DATA SHEET IS AVAILABLE ON THE DOW CORNING WEBSITE AT DOWCORNING.COM, OR FROM YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.

USABLE LIFE AND STORAGE

When stored at or below 25°C (77°F) in the original unopened containers, this product has a usable life of 30 months from the date of production.

At temperatures above 40°C (104°F), *Dow Corning* Silky Wax 10 will start to melt and separation may occur. This is a physical separation of the product, not a quality or chemistry issue. This is a typical property for this product. To prevent this separation, it is suggested to store the drums in a cool location (< 30°C/< 86°F). If separation does occur, the product should be remelted to 65–70°C (149–158°F) and mixed thoroughly to form a homogeneous mixture prior to use. Once the drum is re-melted, remixed, and cooled to less than < 30°C (< 86°F), the liquid phase will re-solidify. The rate of solidification is dependent upon the cooling temperature. There is no change of product chemistry and properties after this re-melting process.

PACKAGING INFORMATION

Dow Corning Silky Wax 10 is available in pails.

Samples for *Dow Corning* Silky Wax 10 are available in bottles.

LIMITATIONS

This product is not tested for specific pharmaceutical use(s). Should you wish to use this product in a pharmaceutical application, please contact Dow Corning to discuss such potential use.

It remains the User's responsibility to ensure the safety, efficacy and legal and regulatory compliance in each relevant jurisdiction (including targeted geographic regions of manufacture and supply) of these materials for its intended uses. Dow Corning makes no representation concerning the suitability of these products for any particular medical or pharmaceutical application. Under no circumstances should these materials be considered for implantation into the human body for periods that exceed 30 days in duration.

SHIPPING LIMITATIONS

Shipping: none

HEALTH AND ENVIRONMENTAL INFORMATION

To support customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our website, dowcorning.com or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION – PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to

be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customer's tests to ensure that our products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that our products will meet the sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Table 1: Compatibility of Dow Corning® Silky Wax 10

Type of Material	10% <i>Dow Corning</i> Silky Wax 10	50% <i>Dow Corning</i> Silky Wax 10	90% <i>Dow Corning</i> Silky Wax 10
Alcohols and polyols			
Ethanol	C	C	C
Isopropanol	C	C	C
Ethoxydiglycol	C	C	C
Glycerin	NC	NC	NC
Octyldodecanol	C	C	C
Propylene Glycol	C	C	C
Squalane	C	C	C
Oils			
Almond oil	C	C	C
Esters			
Caprylic/Capric Triglyceride	C	C	C
C12-C15 Alkyl Benzoate	C	C	C
Diisopropyl Adipate	C	C	C
Isopropyl Myristate	C	C	C
Isopropyl Palmitate	C	C	C
Hydrocarbons			
Mineral oil	C	C	C
Isododecane	C	C	C
Petrolatum	C	C	C
Silicones			
Dimethicone (20 cSt)	C	C	C
Dimethicone (100 cSt)	C	C	C
Dimethicone (350 cSt)	C	C	C
Dimethicone (1000 cSt)	C	C	C
Dimethicone (12,500 cSt)	C	C	C
Dimethicone and Dimethiconol	C	C	C
Cyclopentasiloxane	C	C	C
Glyceryl Esters			
Apricot Kernel Oil PEG-6 Esters	C	C	C

C = Compatible, NC=Non Compatible (form 2 phases)
At 60°C (140°F) if not specified otherwise.

Table 1: Compatibility of Dow Corning® Silky Wax 10 (continued)

Type of Material	10% <i>Dow Corning</i> Silky Wax 10	50% <i>Dow Corning</i> Silky Wax 10	90% <i>Dow Corning</i> Silky Wax 10
Alkoxylated Alcohol			
PEG-15 Stearyl Ether	C	C	C
PEG 8	NC	NC	C
Waxes			
Beeswax	C	C	C
Oleic acid	C	C	C
Paraffin wax	C	C	C
Stearic Acid	C	C	C

C = Compatible, NC=Non Compatible (form 2 phases)
At 60°C (140°F) if not specified otherwise.