

Dow Corning® Silmogen Carrier

FEATURES & BENEFITS

- Film former
- Long lasting substantivity
- Soft smooth feel
- Non-occlusive
- Spreading agent
- Wash off resistant
- High volatility fluid as carrier

COMPOSITION

- Dimethiconol in hexamethyldisiloxane
- INCI name: Dimethiconol and Hexamethyldisiloxane
- Cas number: 107-46-0; 70131-67-8

REGULATORY SUPPORT

Dow Corning can provide the following information

- Letter of Authorization to Drug Master File maintained with the United States Food and Drug Administration (U.S. FDA)
- Product Regulatory Information
- Elemental Impurities
- Summary of Health Data

Excipient for pharmaceutical applications

APPLICATIONS

- *Dow Corning*® Silmogen Carrier can be used as carrier for topical sprays due to its anti-caking effect, high volatility and substantivity.
- *Dow Corning* Silmogen Carrier can be used as a pharmaceutical excipient for various topical formulations, such as creams, lotions, sprays and gels, for the delivery of active drugs.
- When use as an excipient in topical pharmaceutical formulation, *Dow Corning* Silmogen Carrier can provide short term lubrication, smooth feel, emolliency, ease of spreading and substantivity.

TYPICAL PROPERTIES

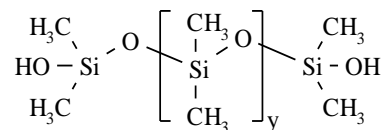
Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

Property	Unit	Result
Appearance		Crystal clear liquid
Silicone content	%	100
Dimethiconol content	%	1
Viscosity at 25°C (77°F)	mm ² /s	2
Specific gravity at 25°C (77°F)		0.761
Refractive index at 25°C (77°F)		1.375
Flash point - closed cup	°C (°F)	0 (32)

DESCRIPTION

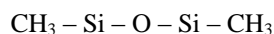
Dow Corning Silmogen Carrier is a blend of ultrahigh viscosity hydroxyl terminated polydimethylsiloxane (Dimethiconol) in a volatile silicone fluid (hexamethyldisiloxane).

Figure 1: The Chemical structure of these compounds are as follows:



where y = approx. 8000

and



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

- *Dow Corning* Silmogen Carrier may be used alone or blended with other silicone or organic excipients to provide a base for variety of formulations types.

- *Dow Corning* Silmogen Carrier is compatible with a range of materials and exhibits a broad solubility range that makes formulating relatively easy.
- Unlike other volatile carriers used in the pharmaceutical industry, volatile silicone fluids do not cool the skin when they evaporate. This is a consequence of their unusually low heat of vaporization.

REGULATORY INFORMATION

Dow Corning Silmogen Carrier is produced, 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 a 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. The site is 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 original unopened containers *Dow Corning* Silmogen Carrier has a usable life of 18 months from the date of production.

Dow Corning Silmogen Carrier is highly flammable. Therefore, it must be stored in a flameproof, well-ventilated area. Keep containers tightly closed and away from heat, sparks, open flames and other sources of ignition.

PACKAGING INFORMATION

Dow Corning Silmogen Carrier is available in pails.

Samples for *Dow Corning* Silmogen Carrier 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

DOT classification: Flammable

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 Data

Type of material	10% <i>Dow Corning</i> [®] Silmogen Carrier	50% <i>Dow Corning</i> [®] Silmogen Carrier	90% <i>Dow Corning</i> [®] Silmogen Carrier
Alcohols and polyols			
Ethanol	NC	NC	NC
Isopropanol	NC	NC	NC
Ethoxydiglycol	NC	NC	NC
Glycerin	NC	NC	NC
Octyldodecanol	NC	C	C
Propylene Glycol	NC	NC	NC
Squalane	NC	C	C
Esters			
Caprylic/Capric Triglyceride	NC	NC	C
C12-C15 Alkyl Benzoate	NC	C	C
Coco-Caprylate/Caprate	NC	C	C
Isopropyl Myristate	C	C	C
Isopropyl Palmitate	Not tested	C	Not tested
Hydrocarbons			
Mineral oil	C	NC	C
Isododecane	NC	NC	C
Petrolatum	C	C	C
Silicones			
Hexamethyldisiloxane	C	C	C
Octamethyltrisiloxane	C	C	C
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	NC	NC	NC
Alkoxyated Alcohol			
PEG-15 Stearyl Ether	NC	NC	C
PEG 8	NC	NC	NC

C = Compatible, NC = Non Compatible (form 2 phases)