

Dow Corning® ST-Cyclomethicone 5-NF

FEATURES & BENEFITS

- Volatile siloxane
- Ease of spreading
- Non-occlusive
- Non-greasy
- Leave non-oily residue
- Imparts soft smooth feel on the skin
- Detackifier
- Solvent
- Non-cooling effect on skin

COMPOSITION

- Decamethylcyclopentasiloxane (D5)
- INCI name: Cyclopentasiloxane
- CAS number: 541-02-6

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)
- Technical File based on ICH CTD (International Conference on Harmonisation Common Technical Document) format
- Product Regulatory Information
- Elemental Impurities
- Summary of Health Data

Excipient for pharmaceutical applications

APPLICATIONS

- Dow Corning® ST-Cyclomethicone 5-NF is commonly used as a base fluid in topical formulations because of its volatility, spreading and sensory benefits – namely their smooth, dry and non-greasy feel on the skin.
- Dow Corning ST-Cyclomethicone 5-NF is currently used in a range of dermatological treatments and pharmaceutical applications, such as creams and gels, and in medicated treatments for skin and scalp applications.

TYPICAL PROPERTIES

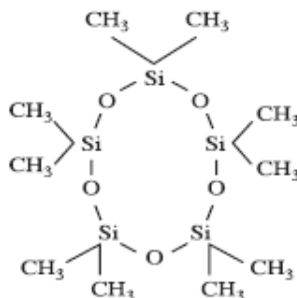
Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

Property	Unit	Result
Appearance		Colorless liquid
Viscosity at 25°C	mm ² /s	4
Specific gravity at 25°C		0.95
Refractive index at 25°C		1.397
Flash point (closed cup)	°C	77
Surface tension	mN/m	18

DESCRIPTION

Dow Corning ST-Cyclomethicone 5-NF is a clear, colorless, volatile polydimethylcyclosiloxane composed mainly of decamethylcyclopentasiloxane.

The chemical structure of decamethylcyclopentasiloxane (D5) component is as follows:



SPECIFIC TESTING

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

HOW TO USE

- Dow Corning ST-Cyclomethicone 5-NF may be used alone or blended with other silicone or organic excipients to provide a base for a variety of formulations.
- Dow Corning ST-Cyclomethicone 5-NF features good solubility in most anhydrous alcohols and in many solvents commonly used in pharmaceutical products.

- 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 Cyclomethicone 5-NF is produced at the Dow Corning Carrollton plant in Carrollton, Kentucky 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 applications. 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. Both the Dow Corning Carrollton and Hemlock facilities are registered as part of Dow Corning's global quality system according to ISO 9001:2008.

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)
- Technical File based on ICH CTD (International Conference on Harmonization Common Technical Document) format
- Product Regulatory Information
- Elemental Impurities
- Summary of Health Data

HANDLING PRECAUTIONS

Do not handle *Dow Corning* ST-Cyclomethicone 5-NF at temperatures above 77°C.

As with any combustible material, containers should be kept tightly closed and away from heat, sparks,

open flames and other sources of ignition.

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 in original unopened containers *Dow Corning* ST-Cyclomethicone 5-NF has a usable life of 30 months from the date of production.

PACKAGING INFORMATION

Dow Corning ST-Cyclomethicone 5-NF is available in pails and in drums.

Samples for *Dow Corning* ST-Cyclomethicone 5-NF 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.

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 as of the date of the document. 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.

We help you invent the future.™

dowcorning.com

Table 1: Compatibility Data

Type of material	10% <i>Dow Corning®</i> ST- Cyclomethicone 5-NF	50% <i>Dow Corning®</i> ST- Cyclomethicone 5-NF	90% <i>Dow Corning®</i> ST- Cyclomethicone 5-NF
Alcohols and polyols			
Ethanol	C	C	C
Isopropanol	C	C	C
Ethoxydiglycol	C	NC	NC
Glycerin	NC	NC	NC
Octyldodecanol	C	C	C
Propylene Glycol	NC	NC	NC
Squalane	C	C	C
Esters			
Caprylic/Capric Triglyceride	C	C	C
C12-C15 Alkyl Benzoate	C	C	C
Coco-Caprylate/Caprates	C	C	C
Diisopropyl Adipate	C	C	C
Isopropyl Myristate	C	C	C
Isopropyl Palmitate			
Hydrocarbons			
Mineral oil	C	C	C
Isododecane	C	C	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
Hexamethyldisiloxane and Dimethiconol	C	C	C
Glyceryl Esters			
Apricot Kernel Oil PEG-6 Esters	C	C	C
Alkoxyated Alcohol			
PEG-15 Stearyl Ether	C	C	C
PEG 8	NC	NC	NC

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