

# Product Information Healthcare Solution

DOW CORNING

## Dow Corning® ST-Dimethiconol 40

### FEATURES & BENEFITS

- Excellent spreading
- Provide lubricity
- Low surface tension
- Non-occlusive

### COMPOSITION

- Hydroxy-terminated polydimethylsiloxane
- INCI name: Dimethiconol
- CAS number: 70131-67-8, 556-67-2, 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)
- Product Regulatory Information
- Elemental Impurities
- Summary of Health Data

Excipient for pharmaceutical applications

### APPLICATIONS

- As an excipient, *Dow Corning*® ST-Dimethiconol 40 can provide excellent spreading, a non-greasy feel and lubrication in applications including dermatological and pharmaceutical treatments, such as creams, gels, and sticks for skin.
- *Dow Corning* ST-Dimethiconol 40 can improve the bioavailability of active drug, the aesthetics and the process ability of topical pharmaceutical formulations.

### 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                      |           | Clear, colorless liquid |
| Viscosity at 25°C (77°F)        | mPa.s     | 41                      |
| Specific gravity at 25°C (77°F) |           | 0.98                    |
| Refractive index at 25°C (77°F) |           | 1.404                   |
| Flash point (Closed cup)        | °C (77°F) | 122 (252)               |

### DESCRIPTION

*Dow Corning* ST-Dimethiconol 40 is a clear, colorless, hydroxyl terminated polydimethylsiloxane fluid. Because of its hydroxyl functionality, it is more hydrophilic than polydimethylsiloxane, making it more suitable siloxane for hydrophilic active.

- *Dow Corning* ST-Dimethiconol 40 is compatible with a wide range of materials that make formulating relatively easy. It also helps the compatibility of hydrophilic actives and features good solubility in most anhydrous alcohol and many solvents common in pharmaceutical formulations.

### 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* ST-Dimethiconol 40 may be used alone or blended with other silicone or organic excipients to provide a base for variety of formulations.

### REGULATORY INFORMATION

*Dow Corning* ST-Dimethiconol 40 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 original unopened containers *Dow Corning* ST-Dimethiconol 40 has a usable life of 12 months from the date of production.

## PACKAGING INFORMATION

*Dow Corning* Dimethiconol 40 is available in pails and in drums.

Samples for *Dow Corning* ST-Dimethiconol 40 are available in bottles.

## LIMITATIONS

*Dow Corning* ST-Dimethiconol 40 is not intended for human injection.

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](http://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.**

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**Table 1: Compatibility data**

| Type of Material                      | 10%<br><i>Dow Corning</i> <sup>®</sup><br>ST-Dimethiconol 40 | 50%<br><i>Dow Corning</i> <sup>®</sup><br>ST-Dimethiconol 40 | 90%<br><i>Dow Corning</i> <sup>®</sup><br>ST-Dimethiconol 40 |
|---------------------------------------|--|--|--|
| <b>Alcohols and polyols</b>           |  |  |  |
| Ethanol                               | C  | C  | C  |
| Ethoxydiglycol                        | C  | C  | C  |
| Glycerin                              | NC   | NC   | NC   |
| Octyldodecanol                        | C  | C  | C  |
| Propylene Glycol                      | NC   | NC   | NC   |
| Squalane                              | NC   | NC   | NC   |
| <b>Esters</b>                         |  |  |  |
| Caprylic/Capric Triglyceride          | NC   | C  | C  |
| C12-C15 Alkyl Benzoate                | NC   | NC   | C  |
| Coco-Caprylate/Caprates               | C  | C  | C  |
| Diisopropyl Adipate                   | C  | C  | C  |
| Isopropyl Myristate                   | C  | C  | C  |
| Isopropyl Palmitate                   | C  | C  | C  |
| <b>Hydrocarbons</b>                   |  |  |  |
| Mineral oil                           | NC   | NC   | NC   |
| Isododecane                           | C  | C  | C  |
| Petrolatum                            | C  | C  | C  |
| <b>Silicones</b>                      |  |  |  |
| 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  |
| <b>Glyceryl Esters</b>                |  |  |  |
| Apricot Kernel Oil PEG-6 Esters       | C  | C  | C  |
| <b>Alkoxyated Alcohol</b>             |  |  |  |
| PEG-15 Stearyl Ether                  | C  | C  | C  |
| PEG 8                                 | NC   | NC   | NC   |

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