

***Dow Corning*[®] ST-Elastomer 10**

FEATURES & BENEFITS

- Easy to formulate
- Non-occlusive
- Slight sebum absorption possible
- Acts as thickening agent for water-in-oil and water-in-silicone formulations and silicone fluid
- Provides dry smoothness and non-greasy feel on the skin
- Reduce tackiness of formulation
- Quick absorption
- Cold processing

COMPOSITION

- Mixture of high molecular weight crosslinked silicone(12%) in decamethylcyclopentasiloxane
- INCI name: Cyclopentasiloxane and Dimethicone crosspolymer
- Cas number: 541-02-6; 213629-14-2

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

- Topical formulations based on *Dow Corning*[®] ST-Elastomer 10 have been demonstrated for drug delivery of model drugs.
- *Dow Corning* ST-Elastomer 10 is used in a wide range of dermatological and pharmaceutical treatments, including creams, gels, sticks and sprays for skin contact applications.
- As an excipient in topical pharmaceutical applications, *Dow Corning* ST-Elastomer 10 can provide novel film forming characteristics like pleasant and silky smooth as well as non-tacky feel especially interesting for innovative forms of drug delivery systems.

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 to translucent gel
Viscosity at 25°C (77°F)	mPa.s	350,000 to 490,000
Color		Colorless to light amber
Specific gravity at 25°C (77°F)		0.989
Flash point (Closed cup)	°C (°F)	70 (158)
Silicone content	%	100
Non-volatile content	%	12–13

DESCRIPTION

Dow Corning ST-Elastomer 10 is a mixture of high molecular weight crosslinked silicone (12%) in decamethylcyclopentasiloxane (D5).

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-Elastomer 10 may be formulated into oil-in-water emulsions, water-in-oil and anhydrous gel.
- When formulating emulsions, disperse the oil phase into *Dow Corning* ST-Elastomer 10 using a simple mixing. It may be formulated with organic oil or silicone based materials with the use of mixers and high shear devices, such homogenizers or sonolators.

- *Dow Corning* ST-Elastomer 10 can act as thickening agent for water-in-oil and oil-in-water formulations.
- To improve ease of use, the viscosity of *Dow Corning* ST-Elastomer 10 can be reduced by blending with dimethicone or cyclomethicone.
- Because the elastomer is stable, *Dow Corning* ST-Elastomer 10 may be subjected to heat for a short duration. When heat is used, the material should be processed in an enclosed vessel to prevent the cyclomethicone from volatilizing; the vessel should be inerted at temperature over 60°C (140°F).

Processing

Dow Corning ST-Elastomer 10 is a viscous product but has the unique characteristic of being a sheer thinning material.

The following information will aid in the selection of the proper equipment to use when processing *Dow Corning* ST-Elastomer 10.

Pump recommendation

GRACO BULLDOG® 10:1 Pump with follower plate. For more information, contact GRACO at +1 800 367 4023.

Note: GRACO offers various BULLDOG models, and other pump manufacturers may offer similar equipment equally capable of processing the material efficiently. Users should work directly with the pump manufacturer to determine the best design for their needs.

For Customer-specific pump design considerations

1. **Pressure and flow requirements**
 - a) Air supply pressure: will depend on plant's air supply capabilities.
 - b) Discharge pressure: will depend on total pressure required to move the silicone

elastomer blend from point A to point B. Pressure drops due to elevation, frictional losses within the piping, fittings, valves, filters, etc., will need to be considered.

- c) Flow requirements: will depend on how quickly the user wishes to transfer the silicone elastomer blend from a 208 liter (55-gal) drum into a vessel.

2. Material viscosity at the application temperature

Dow Corning ST-Elastomer 10 is shear thinning. Effective viscosity is 80,000 cP–100,000 cP. This is only an example; it is the responsibility of the user to determine the effective viscosity based on the user's application. Once the material is pushed through the pump by the follower plate and processed in the pump, the product will shear thin and process as a lower-viscosity fluid.

3. Construction material for wetted parts

Stainless steel is recommended but carbon steel may also be used.

4. Construction materials for seals and gaskets.

VITON® or TEFLON® materials are recommended. Please contact Dow Corning for alternatives.

Clean-up

Dow Corning® ST-Cyclomethicone 5-NF, which dilutes the viscosity of *Dow Corning* ST-Elastomer 10 to water thin, is recommended for soaking or cleaning equipment. Other non-polar solvents may work as well.

REGULATORY INFORMATION

Dow Corning ST-Elastomer 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 original unopened containers *Dow Corning* ST-Elastomer 10 has and usable life of 24 months from the date of production.

Dow Corning ST-Elastomer 10 is considered as combustible liquid (per NEPA30 definition) for storage purposes and a flammable solid for transportation purposes.

PACKAGING INFORMATION

Dow Corning ST-Elastomer 10 is available in pails and in drums.

Samples for *Dow Corning* ST-Elastomer 10 are available in cans.

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. 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> [®] ST-Elastomer 10	50% <i>Dow Corning</i> [®] ST-Elastomer 10	90% <i>Dow Corning</i> [®] ST-Elastomer 10
Alcohols and Polyols			
Ethanol	NC	NC	NC
Isopropanol	NC	NC	C
Ethoxydiglycol	NC	NC	NC
Glycerin	NC	NC	NC
Octyldodecanol	NC	NC	NC
Propylene Glycol	NC	NC	C
Squalane	NC	NC	C
Esters			
Caprylic/Capric Triglyceride	NC	NC	C
C12-C15 Alkyl Benzoate	NC	NC	NC
Coco-Caprylate/Caprates	NC	NC	C
Diisopropyl Adipate	NC	NC	C
Isopropyl Myristate	C	C	C
Isopropyl Palmitate	C	C	C
Hydrocarbons			
Mineral Oil	NC	NC	C
Isododecane	C	C	C
Petrolatum	C	C	NC
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
Cyclopentasiloxane	C	C	C
Glycerol Esters			
Apricot Kernel Oil PEG-6 Esters	NC	NC	NC
Alkoxyated Alcohol			
PEG-15 Stearyl Ether	NC	NC	NC
PEG 8	NC	NC	NC

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