

Product Information Healthcare Solution



DOW CORNING

Dow Corning® Q7-9120 Silicone Fluid

FEATURES & BENEFITS

- Clear, emollient
- Non-occlusive, skin protectant
- Water repellent
- Smooth feel, spreadability
- Lubricity

COMPOSITION

- Chemical name:
Polydimethylsiloxane
- INCI name: Dimethicone
- CAS number: 63148-62-9

REGULATORY COMPLIANCE

- Meets the requirements of the Skin Protectant Drug Products for Over-the-Counter Human Use final monograph (21 CFR 347.10)
- Tested according to and complies with all National Formulary (NF) non-parenteral requirements for Dimethicone monograph
- Tested according to and complies with the European Pharmacopoeia requirements for Dimethicone or Silicone Oil Used as Lubricant monograph, depending on viscosity

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
- Certificate of Suitability to the European Pharmacopoeia
- Product Regulatory Information
- Elemental Impurities

Excipient for pharmaceutical applications

APPLICATIONS

- As an excipient (inactive ingredients), *Dow Corning*® Q7-9120 Silicone Fluid in topical pharmaceutical applications, including dermatological treatments, can provide emolliency, ease of spreading, smooth feel, long lasting lubrication and reduced tackiness.
- *Dow Corning* Q7-9120 Silicone Fluid is currently used in a range of dermatological treatments and pharmaceutical applications such as creams, gels and sticks.
- As a skin protectant active ingredient in over-the-counter topical applications, *Dow Corning* Q7-9120 Silicone Fluid helps prevent and temporarily protects skin and lips against chafing, chapping, cracking and windburn in accordance with FDA guidelines.

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	Results					
Viscosity at 25°C	mm ² /s	20	100	350	500	1,000	12,500
Refractive index at 25°C		1.4018	1.4032	1.4042	-	1.4046	1.4047
Specific gravity at 25°C		0.951	0.967	0.971	-	0.973	-
Volatile content	%	< 20*	0.02	0.05	0.02	0.01	0.17

*According to and complying with all National Formulary (USP-NF) non-parenteral requirements for Dimethicone monograph.

DESCRIPTION

Dow Corning Q7-9120 Silicone Fluid is a clear, colorless polydimethylsiloxane liquid, available in a range of six narrow viscosities: 20 cSt, 100 cSt, 350 cSt, 500 cSt, 1,000 cSt and 12,500 cSt.

Dow Corning Q7-9120 Silicone Fluid is used to formulate with other organic and inorganic material for topical applications.

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 Q7-9120 Silicone Fluid is soluble in organic solvents such as aliphatic and aromatic hydrocarbons. *Dow Corning* Q7-9120 Silicone Fluid is compatible with a range of materials that make formulation relatively easy (refer to Table 1).

Dow Corning Q7-9120 Silicone Fluid can be used alone or blended with other silicone to provide a fluid base for a variety of formulations and provide a smooth, long lasting film on the skin.

The fluid is easily emulsified in water with standard emulsifiers and normal emulsification techniques.

BLENDING

Although the fluid is available in a number of standard viscosities, occasionally an application calls for a fluid of an intermediate viscosity. Blending of different viscosities of *Dow Corning Q7-9120 Silicone Fluid* permits any desired viscosity between 20 cSt and 12,500 cSt.

The blending chart (see Figure 1) is a guideline for preparing intermediate fluid viscosities.

Accuracy is obtained by blending the two fluids that immediately bracket the desired viscosity. If a very accurate blend is required, it may be necessary to adjust the viscosity of the mixture by a second blending.

REGULATORY INFORMATION

Dow Corning Q7-9120 Silicone Fluid is 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 and 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 sites 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 Harmonisation Common Technical Document) format
- Certificate of Suitability to the European Pharmacopoeia
- Product Regulatory Information
- Elemental Impurities
- Summary of Health Data

Dow Corning Q7-9120 Silicone Fluid meets the requirements of the Skin Protectant Drug Products for Over-the-Counter Human Use final FDA monograph (21 CFR Part 347.10) as a skin protectant active ingredient.

Dow Corning Q7-9120 Silicone Fluid is tested according to and complies with the European Pharmacopoeia requirements for Dimeticone and Silicone Oil Used as a Lubricant monograph, depending on the fluid viscosity.

Dow Corning Q7-9120 Silicone Fluid is tested according to and complies with the all National Formulary (NF) non-parenteral requirements for Dimethicone monograph.

STERILIZATION

Steam Autoclaving

Sterilization of bulk fluid by steam autoclaving is not recommended. Excess water diffuses into the fluid, causing the fluid to become hazy.

Dry Heat

Sterilization of bulk fluid is not recommended. Thin layers of fluid may be satisfactorily sterilized by this method. The temperature of the fluid should not exceed 150°C because of the potential for small amounts of formaldehyde to be generated.

Gamma Irradiation

The exposure of polydimethylsiloxane fluids, such as *Dow Corning Q7-9120 Silicone Fluid*, to 25 kGy of cobalt-60 radiation has the effect of introducing small levels of cross-linking into the fluid and is observed as an increase in fluid viscosity. As with any exposure of the product to radiation, product

performance and stability should be evaluated after exposure to determine if such treatment has detrimental effects.

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 between -50°C and 150°C and in original unopened containers *Dow Corning Q7-9120 Silicone Fluid*, 20 cSt and 1000 cSt have a usable life of 60 months from the date of production.

When stored between -20°C and 50°C and in original unopened containers *Dow Corning Q7-9120 Silicone Fluid*, 100 cSt and 350 cSt have a usable life of 60 months from the date of production.

When stored between -30°C and 60°C and in original unopened containers *Dow Corning Q7-9120 Silicone Fluid*, 12500 cSt has a usable life of 60 months from the date of production.

PACKAGING INFORMATION

Dow Corning Q7-9120 Silicone Fluid is available in pails and in drums.

Samples for *Dow Corning Q7-9120 Silicone Fluid* are available in bottles.

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SHIPPING LIMITATIONS

None.

LIMITATIONS

Dow Corning Q7-9120 Silicone Fluid is not intended for use in parenteral drug applications. This material is not to be used as a new drug or new device as defined by regulatory authorities until the user has obtained appropriate approval from those regulatory authorities. This fluid is not approved by the FDA for tissue augmentation and Dow Corning does not support this use. *Dow Corning* Q7-9120 Silicone Fluid 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 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.

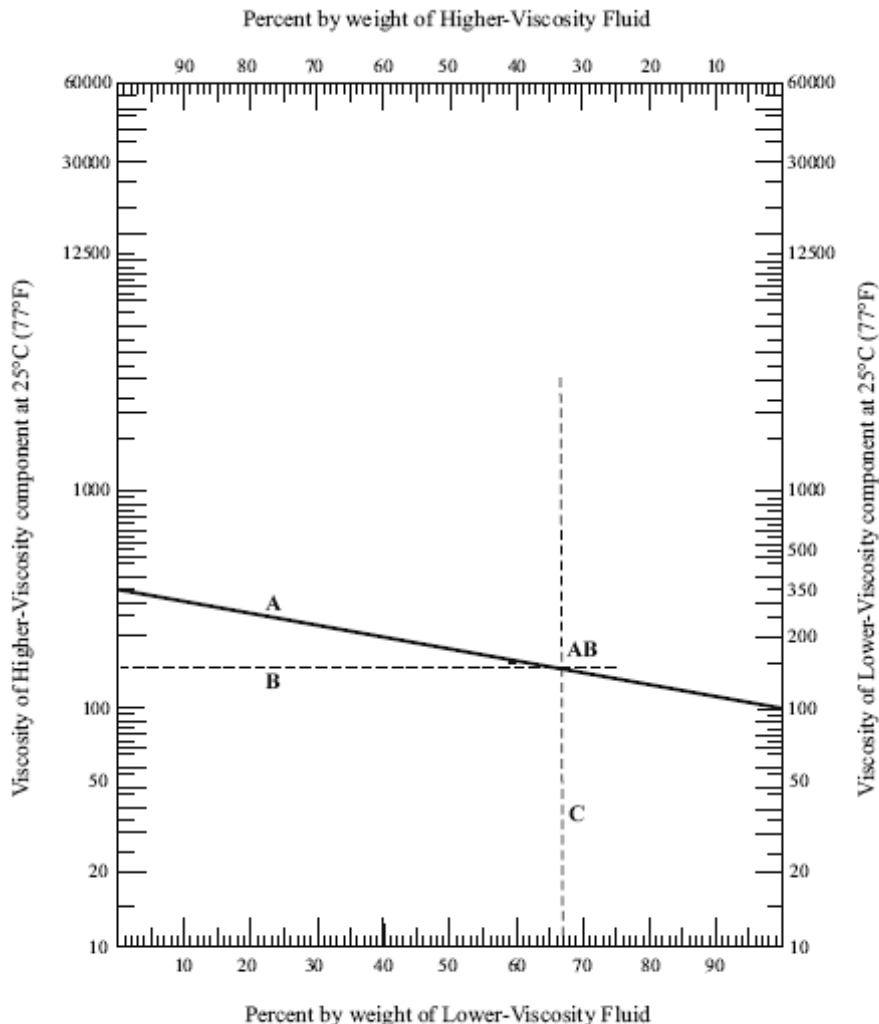
TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Figure 1: Blending Chart for Dow Corning® Q7-9120 Silicone Fluid.



To use the blending chart:

1. Draw a line between two points, one on the left hand side of the scale representing the higher- viscosity fluid available, and one on the right, the lower-viscosity fluid.
2. Draw another line horizontally across the chart at the desired viscosity rating.
3. Draw a third line vertically through the intersection of the first two lines.
4. Read from the top and bottom scales the proportions of the available fluids to blend to achieve the desired viscosity.

The example shown in Figure 1 is as follows: 150 cSt fluid is desired. The standard viscosities immediately bracketing 150 cSt are 100 and 350 cSt. Draw line A connecting 350 cSt on the left-hand scale with 100 cSt on the right-hand scale. Draw line B horizontally at the desired viscosity of 150. At the point of intersection, AB, draw vertical line C. The proportion of 100 cSt viscosity fluid (67%) is read on the bottom scale; the proportion of 350 cSt viscosity fluid (33%) is read on the top scale.

Table 1: Compatibility data

Chemical name	Dow Corning® Q7-9120 Silicone Fluid																		
	20 cSt			100 cSt			350 cSt			500 cSt			1,000 cSt			12,500 cSt			
	Silicone level %	10	50	90	10	50	90	10	50	90	10	50	90	10	50	90	10	50	90
Alcohol and polyols																			
Ethanol	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Ethoxydiglycol	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Glycerin	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Lauryl Alcohol	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Octyldodecanol	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Oleyl Alcohol	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Propylene Glycol	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Squalane	C	C	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Oils																			
Almond oil	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Castor oil	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Coconut oil	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Corn oil	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Jobba oil	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Lanolin oil	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Palm oil	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Sesame oil	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Soybean oil	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Sun flower	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Esters																			
Caprylic/Capric Triglyceride	NC	NC	C	NC	NC	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
C12-C15 Alkyl Benzoate	NC	NC	C	NC	NC	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Coco-Caprylate/Caprate	C	C	C	C	C	C	NC	NC	C	NC	NC	C	NC	NC	C	NC	NC	NC	NC
Diisopropyl Adipate	C	C	C	C	C	C	NC	NC	C	NC	NC	C	NC	NC	C	NC	NC	NC	C
Diisopropyl Fumarate	C	C	C	C	C	C	NC	NC	C				NC	NC	C	NC	NC	C	
Diisostearyl Malate	C	C	C	C	NC	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Dioctyl Maleate	C	C	C	C	C	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Isocetyl Sterarate	C	C	C	NC	NC	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Isopropyl Myristate	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	NC	NC	C	C
Isopropyl Palmitate	C	C	C	C	C	C	C	C	C	C	C	C	NC	C	C	NC	C	C	C
Isopropyl Isostearate	C	C	C	C	C	C	NC	C	C	NC	C	C	NC	C	C				
Isopropyl Laureate	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Isopropyl Stearate	C	C	C	C	C	C	C	C	C				NC	NC	C				
Isostearyl Benzoate	NC	NC	C	NC	NC	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Myristyl Ether Acetate	C	C	C	C	C	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Myristyl Lacate	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC

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

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Table 1: Compatibility data (continued)

Chemical name	Dow Corning® Q7-9120 Silicone Fluid																		
	20 cSt			100 cSt			350 cSt			500 cSt			1,000 cSt			12,500 cSt			
	Silicone level %	10	50	90	10	50	90	10	50	90	10	50	90	10	50	90	10	50	90
Esters (continued)																			
Octyldodecyl Steraroyl Stearate	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Octyl Stearate	C	C	C	C	C	C	NC	NC	C				NC	NC	NC	NC	NC	NC	NC
Tridecyl Neopentanoate	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Triisocetyl Citrate	C	NC	NC	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Hydrocarbon																			
Mineral oil	C	C	C	NC	NC	C	NC	NC	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Isododecane	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Isopar H	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Polydecene	C	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Petrolatum	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Sunscreen Agent																			
Octyl Dimehtyl PABA	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Octyl Salicylate	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Silicone																			
Hexamethyldisiloxane	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Octamethyltrisiloxane	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Dimethicone (20 cSt)	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Dimethicone (100 cSt)	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Dimethicone (350 cSt)	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Dimethicone (1,000 cSt)	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Dimethicone (12,500 cSt)	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Dimethicone and Dimethiconol	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Hexamethyldisiloane and Dimethiconol	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Cyclopentasiloxane	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Glyceryl Esters																			
Apricot Kernel Oil PEG-6 Esters	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Alkoxylated Alcohol																			
PEG-15 Stearyl Ether	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
PEG 8	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC

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