

DOW CORNING® 360 Medical Fluid

FEATURES

- Available in five standard viscosities
- High water repellency/hydrophobicity
- Good stability over a broad range of temperatures
- Excellent lubricating characteristics
- Low surface tension
- Low order of toxicity and skin sensitization
- Tested according to and complies with all National Formulary (NF) requirements for Dimethicone and European Pharmacopeia (EP) requirements for Dimeticone or Silicone Oil Used as a Lubricant, depending on viscosity

COMPOSITION

- Clear, colorless polydimethylsiloxane fluid

Hydrophobic lubricant for medical devices

APPLICATIONS

- Silicone fluid for lubrication and siliconization of glass, metals, plastics and rubber.

TYPICAL PROPERTIES

Specification writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales representative prior to writing specifications on this product.

CTM ¹	ASTM ²	Property	Unit	Value
0176		Visual appearance		Clear as water
0005	D1209	Color (APHA)		<15
0001A	D1298	Specific gravity at 25°C (77°F)		
		20cs		0.951
		100cs		0.967
		350cs and over		0.972
0002	D1298	Refractive index		
		20cs		1.4018
		100cs		1.4032
		350cs		1.4042
		1,000cs		1.4046
		12,500cs		1.4047
0004	D445	Viscosity at 25°C (77°F)		
		20cs	% of nominal	±10
		100 and 350cs	% of nominal	±5
0050	D445	Viscosity at 25°C (77°F)		
		1,000cs	% of nominal	±5
		12,500cs	% of nominal	±5
0051		Acid number	BPB (Bromophenyl Blue)	<0.02
0079		Infrared indentifiactaion		Matches reference spectrum for specific viscosity

1. CTM: Corporate Test Method, copies of CTMs are available on request.

2. ASTM: American Society for Testing and Materials.

DESCRIPTION

DOW CORNING 360 Medical Fluid is a clear, colorless polydimethylsiloxane liquid that is available in five standard viscosities.

IMPORTANT NOTICE

Dow Corning neither represents nor tests this material for specific medical device or pharmaceutical applications. Purchaser is fully responsible to determine end-use suitability.

REGULATORY AND PHARMACOPEIAL STATUS

DOW CORNING 360 Medical Fluid is not to be used as a “new drug” or “new device” as defined by regulatory authorities (e.g., the U.S. Food and Drug Administration) 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.

Each lot of DOW CORNING 360 Medical Fluid is tested and complies with the current monograph requirements for Dimethicone NF, Dimeticone EP, or Silicone Oil Used as a Lubricant EP, depending on the fluid viscosity.

A certification of these test results is available upon request.

Dow Corning also maintains a Drug Master File with the U.S. FDA and holds a Certificate of Suitability to support European registrations.

MANUFACTURING ENVIRONMENT

DOW CORNING 360 Medical Fluid is manufactured, tested and packaged under strict quality control guidelines at the Healthcare Industries Materials Site (HIMS). The HIMS (Hemlock, Mich.) is dedicated to the production of silicone materials for healthcare applications. It is registered with the U.S. Food and Drug Administration (FDA) as a drug establishment (CFN 1816403). The site quality system for active pharmaceutical ingredients (APIs) is in compliance with current Good Manufacturing Practices for Bulk Pharmaceutical Products. The site is also ISO registered by BSI.

HOW TO USE¹

DOW CORNING 360 Medical Fluid can be applied directly to surfaces by techniques such as dipping, spraying or wiping to provide a lubricious and/or hydrophobic coating.

When a very thin film of fluid is desired, DOW CORNING 360 Medical Fluid can be diluted to the desired silicone fluid concentration (such as 0.1 to 2%) in a nonpolar solvent. After DOW CORNING 360 Medical Fluid has been applied, allow sufficient time to permit the solvent to evaporate. Solvents that can be used with DOW CORNING 360 Medical Fluid are discussed in the “Compatibility” section.

Although DOW CORNING 360 Medical Fluid possesses excellent lubricant characteristics, the fluid may not provide satisfactory lubrication when used in situations such as metal against metal. On temperature-resistant materials, such as glass, ceramic and metal, this fluid film can be heated to provide a more durable hydrophobic film.

DOW CORNING 360 Medical Fluid can be applied to silicone elastomers for temporary lubricity. Before exposing a silicone elastomer to a silicone fluid, the user should evaluate the effect of the exposure on the performance.

1. For additional information on uses, toxicity, analysis and methods of applying polydimethylsiloxane fluids in parenteral applications, read Technical Report No. 12, “Siliconization of Parenteral Drug Packaging Components,” Journal of Parenteral Science and Technology, Volume 42, No. 4S, 1988.

Sterilization

Sterilization of the bulk fluid is not recommended. If sterilization is necessary for a given application, the sterilization process should be done on the treated article.

Steam autoclaving – sterilization of bulk fluid by steam autoclaving is not recommended. Excess water diffuses into the fluid, causing the fluid to become hazy. Thin films of fluid may be satisfactorily sterilized by this method.

Gamma irradiation – the exposure of polydimethylsiloxane fluids, such as DOW CORNING 360 Medical 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. This effect is most noticeable in the higher-viscosity fluids (e.g., 12,500cSt). As with any exposure of a product to radiation, one should evaluate product performance after exposure to determine if such treatment has detrimental effects.

Dry heat – sterilization of bulk fluid is not recommended. Thin films of fluid may be satisfactorily sterilized by this method. The temperature of the fluid should not exceed 200°C (392°F) because small amounts of formaldehyde may be generated.

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 360 Medical Fluid permits any desired viscosity between 20 and 12,500cSt.

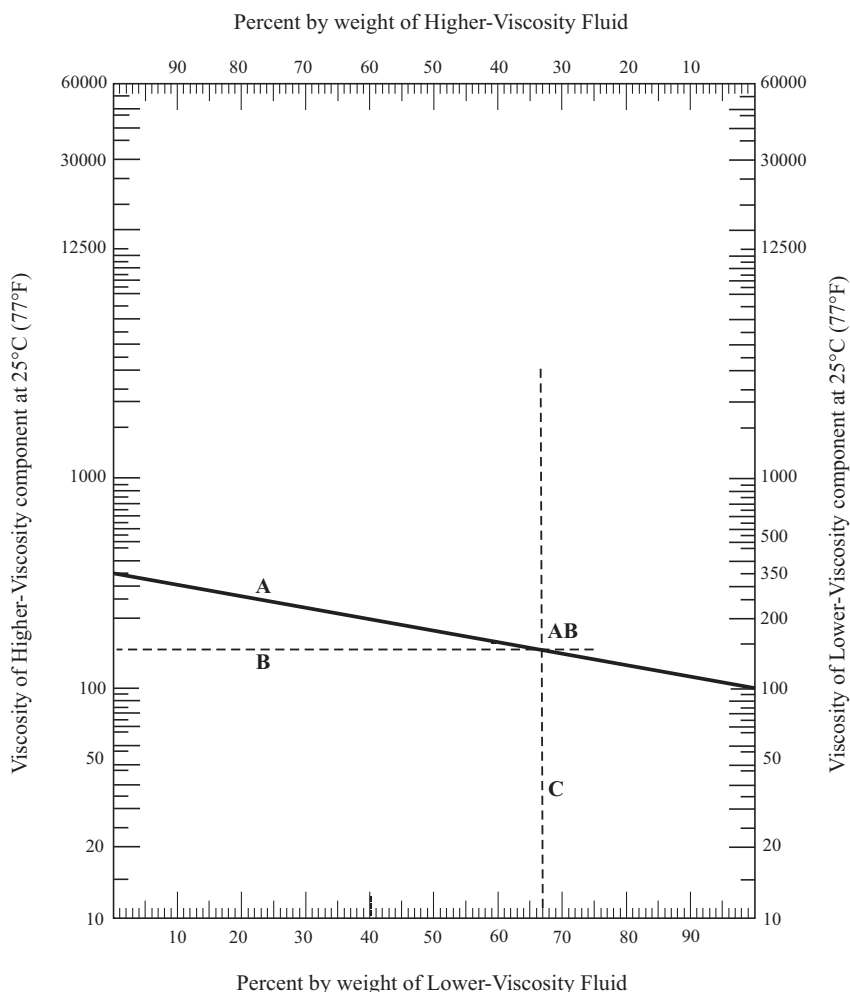
The blending chart (Figure 1) is a guideline for preparing intermediate fluid viscosities. To use the blending chart:

- 1) Draw a line between two points – one on the left-hand 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 obtain the desired viscosity.

Accuracy is increased 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.

The example shown in Figure 1 is as follows: 150cSt fluid is desired. The standard viscosities immediately bracketing 150cSt are 100 and 350cSt. Draw line A connecting 350cSt on the left-hand scale with 100cSt 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 100cSt viscosity fluid (67%) is read on the bottom scale; the proportion of 350cSt viscosity fluid (33%) is read on the top scale.

Figure 1. Blending chart for Dow Corning 360 Medical Fluid.



COMPATIBILITY

DOW CORNING 360 Medical Fluid is soluble in all proportions in nonpolar solvents:

- Aliphatic hydrocarbon (e.g., hexane, heptane, mineral spirits)
- Aromatic hydrocarbon (e.g., toluene, xylene)

Several ozone-safe, volatile organic compound (VOC)-exempt solvents are compatible with DOW CORNING 360 Medical Fluid:

- DOW CORNING® Q7-9180 Silicone Fluids
- DOW CORNING® OS-10 Fluid, DOW CORNING® OS-20 Fluid, DOW CORNING® OS-30 Fluid
- Vertrel®² X-Si Cleaning Agent
- Lenium®³ DF

2. Vertrel is a registered trademark of E.I. du Pont de Nemours & Co

3. Lenium is a registered trademark of Petroferm, Inc

Solvents selected from this list are frequently used to dilute DOW CORNING 360 Medical Fluid as a means of applying the fluid to articles by dipping or spraying. As the polarity of the solvent increases, the solubility of the silicone fluid decreases.

For example, DOW CORNING 360 Medical Fluid is, for all practical purposes, insoluble in glycerin, ethylene glycol, stearyl alcohol, methanol, ethanol and water. Limited solubility of less than 0.5% may be obtained for 20 and 100cSt fluid in anhydrous isopropanol. Lower-viscosity (molecular weight) DOW CORNING 360 Medical Fluid will tend to have a slightly increased solubility in the more polar solvents. Moderate solubility (approximately 10%) is obtained in some ethers (e.g., ethyl ether, esters; amyl acetate and ketones; methyl ethyl ketone).

HANDLING PRECAUTIONS

Product safety information required for safe use is not included.

Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information. The material safety data sheet is available on the Dow Corning website at www.dowcorning.com.

You can also obtain a copy from your local Dow Corning sales representative or Distributor or by calling your local Dow Corning Global Connection.

USABLE LIFE AND STORAGE

When stored in original, unopened containers this product has a usable life of 60 months from the date of production.

PACKAGING

DOW CORNING 360 Medical Fluid is available in five standard viscosities: 20, 100, 350, 1000 and 12,500cSt. The material is supplied in 0.45, 18, and 200kg (1, 40, and 440 lb) containers, net weight.

SHIPPING LIMITATIONS

None.

ORDERING

Dow Corning requires a signed affidavit detailing information on the intended use of DOW CORNING 360 Medical Fluid before acting upon a request for a sample or sales order.

To obtain additional information or to place an order, contact 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 customers' tests to ensure that Dow Corning's 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 the product will meet the Dow Corning 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.

DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

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