Dow Corning® 360 Medical 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 office or your Global Dow Corning Connection before writing specifications on this product.

<table>
<thead>
<tr>
<th>CTM</th>
<th>ASTM</th>
<th>Property</th>
<th>Unit</th>
<th>Result</th>
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<td>Color (APHA)</td>
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<td>Specific gravity at 25°C</td>
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<td>Infrared identification</td>
<td>Matches reference spectrum for specific viscosity</td>
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</table>

1CTM: Corporate Test Method, copies of CTMs are available on request.
2ASTM: 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 USE

*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.

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 Fluids, 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., 12,500 cSt). 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 because small amounts of formaldehyde may be generated.

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® OS XSi Cleaning Agent
- Lenium® DF


2Vertrel® is a registered trademark The Chemours Company.

3Lenium is a registered trademark of Vantage Specialties 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 100 cSt fluid in anhydrous isopropyl alcohol. 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).

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 12,500 cSt.

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: 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.

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

PACKAGING INFORMATION
Dow Corning 360 Medical Fluid is available in five standard viscosities: 20, 100, 350, 1000 and 12,500 cSt. The material is supplied in 0.45, 18, and 200 kg (1, 40, and 440 lbs) 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.

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.

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