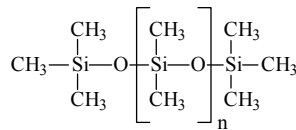


# MED-361

## Silicone Fluid

# Product Profile

### Description



- A clear polydimethylsiloxane liquid
- Available in standard viscosities of 100, 350, 1,000 and 12,500 cP and custom viscosities upon request
- Has controlled volatility, lubrication characteristics and low surface tension
- Highly water repellent and resists decomposition by heat and oxidation

### Applications

- To provide a lubricious and/or hydrophobic coating

**NuSil Technology's MED-361 is a restricted product. It shall not be considered for use in human implantation for a period greater than 29 days.**

**Note:** MED-361 is not available for any long-term ophthalmic application.

Typical Properties	Result	Metric Conv.	ASTM	NT-TM
Chemical Classification	MQ	-	-	-
Appearance	Translucent	-	D-2090	002
Specific Gravity	0.97	-	D-792	003
Refractive Index	1.403	-	D-1747, D-1218	018
Volume Resistivity	1 x 10 <sup>15</sup> ohms-cm	-	D-1169	024
Dielectric Strength	400 volts/mil	-	-	-
Coefficient of Thermal Expansion	0.00096 cc/cc/°C	-	-	-
Collected Volatile Condensable Material (CVCM)	0.05	-	E-595	072
Total Mass Loss (TML)	0.10	-	E-595	072
Pyrogenicity	Pass	-	-	091
Systemic Toxicity	Pass	-	-	090
Intracutaneous Toxicity	Pass	-	-	089
Operating Temperature Range	-40°F to 392°F	-40°C to 200°C	-	-

### Instruction for Use

Apply directly to surfaces by dipping, spraying or wiping. When desiring a very thin film of fluid, dilute to 1-5% weight silicone solids in a non-polar solvent. Then apply this solution to a surface using the above techniques. After applying, allow sufficient time to permit the solvent to evaporate.

Although MED-361 Fluid possesses excellent lubricant characteristics, the fluid may not provide satisfactory lubrication in load-bearing situations, especially metal against metal. The fluid provides temporary lubricity when applied to silicone elastomers. This lubricity lasts 2 to 3 hours, at which time diffusion of the fluid into the elastomer depletes the fluid's surface and reduces or eliminates all lubricating characteristics. Since the fluid's rate of diffusion into a silicone elastomer decreases as the fluid's molecular weight increases, the higher-viscosity fluids lubricate a silicone elastomeric surface for a slightly longer period than the lower viscosity fluids. Polydimethylsiloxane elastomers tend to swell and decrease in durometer when exposed to MED-361. Before exposing a silicone elastomer to a silicone fluid, evaluate the exposure's effect on performance. NuSil Technology's MED-400, MED-420, and MED-460 (Fluorosilicone polymer and MethylFluorosilicone copolymer) may be evaluated for such applications.

### Packaging

2 Ounce  
 1 Pint  
 1 Gallon  
 5 Gallon  
 55 Gallon

### Warranty

36 Months

Thin films of MED-361 Fluid on plastics, metal and glass provide a temporary, water-repellent barrier. On temperature-resistant materials such as glass, ceramic and metal, this fluid film can be converted to a highly durable hydrophobic film by heating the treated surface. Heating 2 hours at 250°C (482°F), 1 hour at 276°C (536°F) or 30 minutes at 300°C (572°F) is satisfactory.

### **Sterilization**

**Dry Heat** – Sterilize thin films of MED-361 by dry heat. The minimum sterilization program recommended is 2 hours at 160°C (320°F). (Note: Add the time necessary to raise the fluid's temperature.)

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

**Gamma Irradiation** - The exposure of polydimethylsiloxane fluids such as MED-361 to 2.5 megarads (25 K. Gray) of Co<sup>60</sup> radiation introduces small levels of cross-linking into the fluid and increases fluid viscosity. This effect is most noticeable in the higher-viscosity fluids. As with any exposure of a product to radiation, evaluate product performance after exposure to determine if such treatment has detrimental effects.

**Ethylene Oxide** - Bulk quantity sterilization of MED-361 by ethylene oxide (ETO) is not recommended. The high solubilities of ETO and the associated ETO by-products in polydimethylsiloxane fluids increase the difficulty of removing these materials from the fluids using normal outgassing procedures. Thin films of MED-361 can be sterilized by ETO procedures because their large surface-to-volume ratios allow them to be relatively easily freed from ETO residues by normal outgassing procedures.

### **Solvent Compatibility**

MED-361 is soluble in all proportions in the following nonpolar solvents: aliphatic hydrocarbon (e.g., hexane, heptane, mineral spirits), aromatic hydrocarbon (e.g., toluene, xylene), and chlorinated hydrocarbon (e.g., methylene chloride, chloroform, carbon tetrachloride, 1,1,1 trichloroethane).

### **FDA Master File**

A Master Access File for MED-361 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master Access File must contact NuSil Technology.

### **U.S.P Monograph & European Pharmacopoeia:**

MED-361 has been tested in accordance with and meets the requirements of: United States Pharmacopoeia (USP) [NF 18] "Dimethicone" Monograph, European Pharmacopoeia (EP) Monograph for "Dimethicone," and European Pharmacopoeia (EP) Monograph for "Silicone Oil Used as a Lubricant."

### **Warnings About Product Safety**

NuSil Technology believes that the information and data contained herein is accurate and reliable. However, the user is responsible to determine the material's suitability and safety of use. NuSil Technology cannot know each application's specific requirements and hereby notifies the user that it has not tested or determined this material's suitability or safety for use in any application. The user is responsible to adequately test and determine the safety and suitability for their application and NuSil Technology makes no warranty concerning fitness for any use or purpose. NuSil Technology has completed no testing to establish safety of use in any medical application.

NuSil Technology has tested this material only to determine if the product meets the applicable specifications. (Please contact NuSil Technology for assistance and recommendations when establishing specifications.) When considering the use of NuSil Technology products in a particular application, review the latest Material Safety Data Sheet and contact NuSil Technology with any questions about product safety information.

Do not use any chemical in a food, drug, cosmetic, or medical application or process until having determined the safety and legality of the use. The user is responsible to meet the requirements of the U.S. Food and Drug Administration (FDA)

and any other regulatory agencies. Before handling any other materials mentioned in the text, obtain available product safety information and take the necessary steps to ensure safety of use.

## **Specifications**

Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please contact NuSil Technology for assistance and recommendations in establishing particular specifications.

## **Patent Warning**

NuSil Technology disclaims any expressed or implied warranty against the infringement of any patent. NuSil Technology does not warrant the use or sale of the products described herein will not infringe the claims of any United States' or other country's patents covering the product itself, its use in combination with other products or its use in the operation of any process.

## **Warranty Information**

NuSil Technology's warranty period is 36 months from the date of shipment when stored below 40°C in original unopened containers. Unless NuSil Technology provides a specific written warranty of fitness for a particular use, NuSil Technology's sole warranty is that the product will meet NuSil Technology's then current specification. NuSil Technology specifically disclaims any other expressed or implied warranty, including warranties of merchantability and fitness for use. The exclusive remedy and NuSil Technology's sole liability for breach of warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted. NuSil Technology expressly disclaims any liability for incidental or consequential damages.