

Polymer Systems Technology Limited

UK & Ireland Distributor



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Unit 2. Network 4. Cressex Business Park,
Lincoln Road, High Wycombe, Bucks. HP12 3RF
Phone +44 (0) 1494 446610
Fax: +44 (0) 1494 528611
Web: <http://www.siliconepolymers.co.uk>
Email: sales@silicone-polymers.co.uk



NuSil Technology

1050 Cindy Lane • Carpinteria, CA 93013

805/684-8780 • 805/566-9905 Fax

www.nusil.com

An ISO 9001 Certified Company

Product Profile

MED-361 Silicone Fluid

Description:

NuSil Technology MED-361 Fluid is a clear, colorless polydimethylsiloxane liquid. Available in standard viscosities of 350, 1000 and 12,500 cps. Custom blends are also available.

- Controlled Volatility
- High water repellency
- Resistance to decomposition by heat and oxidation.
- Lubrication characteristics
- Low surface tension
- Low order of toxicity and skin sensitization

NuSil Technology's MED-361 are restricted products. They shall not be considered for use in human implantation for a period of greater than 29 days.

Instructions For Use:

NuSil Technology MED-361 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, NuSil Technology MED-361 Fluid can be diluted to 1 to 5 weight percent silicone solids in a non-polar solvent. This solution can then be applied to a surface using the above techniques. After NuSil Technology MED-361 Fluid has been applied, allow sufficient time to permit the solvent to evaporate.

Although NuSil Technology MED-361 Fluid possesses excellent lubricant characteristics, the fluid

may not provide satisfactory lubrication when used 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 surface of fluid and reduces or eliminates all lubricating characteristics. Since the rate of diffusion of these fluids into a silicone elastomer decreases as the molecular weight of the fluid 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 NuSil Technology MED-361 Fluid. Before exposing a silicone elastomer to a silicone fluid, one should evaluate the effect of the exposure on performance. Nusil Technology's MED-400, MED-420, and MED-460 (Fluorosilicone polymer and MethylFluorosilicone copolymer) may be evaluated for such applications.

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 times and temperatures of 2 hours at 250°C (482°F), 1 hour at 276°C (500°F) or 30 minutes at 300°C (572°F) are satisfactory.

Typical Properties as Supplied:

Chemical Classification	<u>MED-361</u> MQ
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Color	Translucent
Viscosity, cP	100 - 100,000
Refractive Index	1.403
Specific Gravity	0.970
Volume Resistivity ohms-cm	1 x 10 ¹⁵
Dielectric Strength, volts/mil	400
Coefficient of Expansion, cc/cc/°C	0.00096
Operating Temperature Range	-40°C to 200°C
	(-104°F to 395°F)

THE FOLLOWING TEST ARE CONDUCTED ON EVERY LOT OF THE STANDARD VISCOSITIES, 350, 1000, AND 12,500 CENTIPOISE.

Collected Volatile Condensable Material %, (CVCM)	0.01	
Total Mass Loss %, (TML)		0.50
Pyrogenicity	Pass	
Systemic Toxicity		Pass
Intracutaneous Toxicity	Pass	

TOTAL MASS LOSS AND COLLECTED VOLATILE CONDENSABLE MATERIAL ARE TESTED IN ACCORDANCE WITH ASTM E-595 AND NASA SP-R-0022A.

Sterilization:

Dry Heat - Thin films of MED-361 Fluid can be sterilized by dry heat. The minimum sterilization program recommended is 2 hours at 160°C (320°F). (Note: The time necessary to raise the temperature of the fluid must be added.)

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 MED-361 Fluid, to 2.5 megarads (25 K. Gray) of Co⁶⁰ 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. As with any exposure of a product to radiation, one should evaluate product performance after exposure to determine if such treatment has detrimental effects.

Ethylene Oxide - The sterilization of bulk quantities of MED-361 Fluid 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 Fluid 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.

Compatibility:

NuSil Technology MED-361 Fluid is soluble in all proportions in the following nonpolar solvents:

- Aliphatic Hydrocarbon (e.g., hexane, heptane, mineral spirits)
- Aromatic hydrocarbon (e.g., toluene, xylene).
- Chlorinated hydrocarbon (e.g., methylene chloride, chloroform, carbon tetrachloride, 1,1,1 trichloroethane).

Solvents selected from this list are frequently used to dilute NuSil Technology MED-361 Fluid as a means of applying the fluid to articles by dipping or spraying.

Packaging:

NuSil Technology MED-361 Fluid is available with a viscosity range of 100 to 100,000 centipoise. The material is supplied 1 pt., 1 gal., 2 oz., 5 gal., and 55 gal. containers.

FDA Master File:

A Master File for MED-361 has been filed with the U.S. Food and Drug Administration. The Master File contains the results of applicable chemical and mechanical equivalency tested as well as confirmatory biological testing. Customers interested in authorization to reference these files 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 "Dimeticone"
- 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, it is the user's responsibility to determine suitability and safety of use for these materials. NuSil Technology can not know the specific requirements of each application and hereby makes the user aware that it has not tested or determined that these materials are suitable or safe for any application. It is the user's responsibility 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. There has been no testing done by NuSil Technology 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, you should review the latest Material Safety Data Sheets and contact NuSil Technology for any questions about product safety information you may have.

No chemical should be used in a food, drug, cosmetic, or medical application or process until you have determined the safety and legality of the use. It is the responsibility of the user 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, you should obtain available product safety information and take the necessary steps to ensure safety of use.

Specifications:

The typical properties shown in this technical profile should not be used 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 that the use or sale of the products described herein will not infringe the claims of any United States patents or other country's patents covering the product itself or the use in combination with other products or in the operation of any process.

Warranty Information:

NuSil Technology's warranty period is 36 months from date of shipment when stored below 40°C in original unopened containers. Unless NuSil Technology provides you with 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 express or implied warranty, including warranties of merchantability and of fitness for use. Your 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, and NuSil Technology expressly disclaims any liability for incidental or consequential damages.