

MED-460

Silicone fluid

DESCRIPTION

- A clear liquid copolymer consisting of dimethylisiloxane and trifluoropropylmethylsiloxane to provide a lubricious and/or hydrophobic coating, for lubricating the surfaces of molded dimethyl silicone elastomer parts
- Available in standard viscosities of: 350 cP, 1,000 cP, and 12,500 cP
- Custom viscosities available upon request

APPLICATION

- For applications requiring a material that is highly water repellent and resists decomposition from heat and oxidation
- Has reduced solubility, good wetting properties and good lubricative characteristics in contact with plastics, rubber and skin

NuSil™ MED-460 may be considered for use in human implantation for a period of greater than 29 days

PROPERTIES

| Typical Properties | Average Result | | | Standard | NT-TM |
|---------------------------------------|----------------|-------------|-------------|-------------------------|-------|
| Uncured: | 350 cP | 1,000 cP | 12,500 cP | | |
| Appearance | Translucent | Translucent | Translucent | ASTM D2090 | 002 |
| Volatile Content | <0.2 % | <0.2 % | <0.3 % | ASTM D2288 | 004 |
| Refractive Index | 1.382 | 1.382 | 1.383 | ASTM D1218, D1747 | 018 |
| Tissue Culture (Cytotoxicity Testing) | Pass | Pass | Pass | USP <87> ISO 10993-5 | 061 |

The above properties are tested on a lot-to-lot basis. Do not use as a basis for preparing specifications. Please <u>contact</u> NuSil Technology for assistance and recommendations in establishing particular specifications.



INSTRUCTIONS FOR USE

Application

Apply directly to surfaces by dipping, spraying, brushing, or wiping. When a very thin film is desired, dilute to 1-5% weight silicone solids in a compatible solvent. Apply this solution to a surface using the above techniques. After applying, allow sufficient time for the solvent to evaporate.

Although MED-460 fluid possesses excellent lubricative characteristics, it may not provide satisfactory lubrication in load-bearing situations, especially those involving metal-to-metal contact.

Thin films of MED-460 fluid on plastics, metal and glass provide a temporary, water-repellent barrier. On materials resistant to thermal distortion, such as glass, ceramics, and metals, 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.

FDA MASTER FILE

A Master File for MED-460 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must <u>contact</u> NuSil Technology.

REACH COMPLIANCE

Please <u>contact</u> NuSil Technology's Regulatory Compliance department with any questions or for further assistance.

SPECIFICATIONS

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

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC (hereinafter "NuSil Technology") 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 all other expressed or implied warranties, including, but not limited

Packaging

2 Ounce (57 g) 1 Pint (455 g)

1 Gallon (3.64 kg) 5 Gallon (18.2 kg) Warranty
36 Months

to, 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.

WARNINGS ABOUT PRODUCT SAFETY

NuSil Technology believes, to the best of its knowledge, that the information and data contained herein are accurate and reliable. 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, the user is advised to obtain available product safety information and take the necessary steps to ensure safety of use.

BIOMATERIALS IMPLANT LINE



PATENT / INTELLECTUAL PROPERTY WARNING

NuSil Technology disclaims any expressed or implied warranty against the infringement of any domestic or international patent/intellectual property right. NuSil Technology does not

warrant the use or sale of the products described herein will not infringe the claims of any domestic or international patent/intellectual property right covering the product itself, its use in combination with other products, or its use in the operation of any process.



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