LIFE SCIENCES IMPLANT LINE

MED-368 SILICONE FLUID

DESCRIPTION

- A clear polydimethylsiloxane liquid to provide a lubricious and/or hydrophobic coating
- Available in standard viscosities of:
- 20 cP and 50 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 good wetting properties and good lubricative characteristics in contact with plastics, rubber and skin

NuSil Technology's MED-368 may be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

TYPICAL PROPERTIES	AVERAGE RESULT		STANDARD	NT-TM
	20 cP	50 cP		
Uncured:				
Appearance	Transparent	Transparent	ASTM D2090	002
Volatile Content	1.7 %	0.4 %	ASTM D2288	004
Specific Gravity, Hydrometer	0.95	0.96	ASTM D1298	097
Refractive Index	1.40	1.40	ASTM D1218, D1747	018
Tissue Culture (Cytotoxicity Testing)	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-368 fluid possesses excellent lubricative characteristics, it may not provide satisfactory lubrication in load-bearing situations, especially those involving metal-to-metal contact. Applying MED-368 fluid to dimethyl silicone elastomers is not advised. The fluid may diffuse into the elastomer, rapidly reducing the lubricative characteristics.

Exposing a dimethyl elastomer to MED-368 fluid may cause the elastomer to swell. Fluid may diffuse into the elastomer, rapidly reducing the lubricative characteristics. It is recommended that NuSil Technology LLC's MED-400, MED-420, and MED-460 (fluorosilicone polymer and dimethylfluorosilicone copolymer) be considered for such applications.

Packaging

- 2 Ounce (57 g)
- 1 Pint (455 g)
- 1 Gallon (3.64 kg)
- 5 Gallon (8.2 kg)

Warranty

36 Months

Thin films of MED-368 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-368 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

MED-368 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACh) regulation (European Union 1907/2006). MED-368 does not contain any of the chemicals or substances identified as Substances of Very High Concern (SVHC) by the European Chemicals Agency (ECHA), which oversees REACh compliance.

Please contact 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 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 <u>contact</u> 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 <u>contact</u> 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.

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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