

MED-4162

Silicone dispersion

DESCRIPTION

- One-part, silicone dispersion containing high molecular weight hydroxyl-functional silicone polymer dispersed in xylene
- Non-curing

APPLICATION

- Suitable for dip coating thin films
- Adjustable viscosity makes dispersions ideal for use as sprayable coatings
- Ideal for use as a suture needle coating
- Provides excellent lubricity for cutting edges, needle cannula, and other applications requiring friction reduction

NuSil™ MED-4162 shall not be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

Typical Properties	Average Result	Standard	NT-TM
Uncured:			
Appearance	Translucent	ASTM D2090	002
Non-Volatile Content	31%	ASTM D2288	004
Viscosity	30,000 cP (30,000 mPas)	ASTM D1084, D2196	001
Cured: 7 days minimum at ambient temper	rature and humidity		·
Tissue Culture (Cytotoxicity Testing)	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. Prior to use, dilute material to desired concentration for the specific application. Experimentation may be required to determine the concentration that yields the appropriate coating thickness.

Solubility

MED-4162 is soluble in many organic solvents including aliphatic and aromatic hydrocarbons, chlorinated solvents, and ethers. This fluid is not water-soluble and hydrolyzes rapidly when placed in contact with water. Any solvents used to dilute this material must be moisture-free.

Mixing

Thoroughly stir material to ensure homogeneity. Exercise care to prevent solvent loss during deairing. Accomplish additional dilution for thin film applications by adding appropriate solvent. Mixer design/size/type, blade/propeller type, shear/RPM levels, and heat generated during mixing, are important parameters and should be addressed in order to have an adequately mixed dispersion.

Warning: Consult the MSDS for MED-4162 prior to use, as its solvent carrier is hazardous.

Coating & Use

Make sure to apply under a fume hood or in a well ventilated environment. Care should be taken before placing coated mandrels or parts in oven due to the presence of solvent. Reference cure schedule for devolitilization times. For further information, please see NuSil's <u>A Guide to Silicone Dispersions</u>—Strategies for Processing and Troubleshooting.

Storage

Most dispersions are stored prior to application. It is important to note that NuSiI recommends keeping the dispersion in its original container when possible, tightly sealed and stored below 40° C. Care should be taken to prevent solvent evaporation and contamination during long or short term storage.

FDA MASTER FILE

A Master File for MED-4162 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.

Packaging

2 Ounce (57 g)

1 Pint (400 g)

1 Gallon (3.4 kg)

5 Gallon (17.0 kg)

1 Drum (180 kg)

Warranty

12 Months

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 12 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

BIOMATERIALS PREMIUM CARE LINE



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.

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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