

MED1-4161

Silicone dispersion

DESCRIPTION

- A solution containing aminofunctional polydimethylsiloxane copolymer dispersed in Xylene
- Cures at room temperature upon exposure to atmospheric moisture

APPLICATION

- Suitable for dip casting
- Low viscosity makes dispersions ideal for use as sprayable coatings
- Provides excellent lubricity for cutting edges, needle cannula or other applications requiring friction reduction

NuSil™ MED1-4161 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:			
Appearance	Clear to Amber	ASTM D2090	002
Specific Gravity	0.87	ASTM D891, D1475	022
Non-Volatile Content	33%	ASTM D2288	004
Kinematic Viscosity	140 cSt (121 mPas)	ASTM D445, D446	025
Cured: 5 days minimum at 25°C ambient to	mperature and humidity (77°F)		·
Durometer, Type 00	25	ASTM D2240	006
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061
Elemental Analysis of Trace Metals	Pass	ASTM E305	131

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

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 MED1-4161 prior to use, as its solvent carrier is hazardous.

Coating & Use

Dispersions are more commonly used in dip molding processes, but can also be sprayed or cast. 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 A Guide to Silicone Dispersions – Strategies for Processing and Troubleshooting.

Note: Some bonding applications may require the use of a primer. NuSil Technology's MED1-161 is recommended. For more information on primer selection, visit www.nusil.com and review Choosing a Silicone Primer/Adhesive System.

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 MED1-4161 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.

Packaging

2 ounce (50 g) 1 Pint (380 g) 1 Gallon (3.12 kg) 5 Gallon (15.6 kg)

Warranty

12 Months

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 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.

BIOMATERIALS IMPLANT LINE



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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