LIFE SCIENCES IMPLANT LINE

MED-6400
ADDITION CURE SILICONE DISPERSION

# **DESCRIPTION**

- Two-part, low viscosity, heat curable silicone dispersion
- Cures via addition-cure chemistry
- 1:1 Mix Ratio (Part A: Part B)

# **APPLICATION**

- Suitable for dip casting and heat-curing of thin elastomeric films
- Low viscosity makes dispersions ideal for use as sprayable coatings

NuSil Technology's MED-6400 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	Translucent	ASTM D2090	002
Non-Volatile Content	35%	ASTM D2288	004
Viscosity	860 cP (860 mPas)	ASTM D1084, D2196	001
Cured: 30 minutes at 25°C (77°F), 45 minutes at 75°C	(167°F), and 135 minutes at 150°C (302°F)		
Durometer, Type A	30	ASTM D2240	006
Refractive Index	1.43	ASTM D1747, D1218	018
Tensile Strength	1,600 psi (11.3 MPa)	ASTM D412, D882	007
Elongation	850%	ASTM D412, D882	007
Tear Strength	160 ppi (28.2 kN/m)	ASTM D624	009
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87>	061
		ISO 10993-5	
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

For two-part, platinum catalyzed dispersions, mixing Part A into Part B (instead of Part B into Part A) is important especially when using a dispersion with high solids content. Thoroughly stir individual components prior to addition to ensure homogeneity. Mix in a 1:1 ratio by weight. Do not use wooden spatulas to mix and avoid the use of latex gloves. Exercise care to prevent solvent loss during dealring. 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. mixed dispersion.

Warning: Consult the MSDS for MED-6400 prior to use as its solvent carrier is hazardous.

#### **Packaging**

- 2 Pint Kit (910 g)
- 2 Gallon Kit (7.28 kg)
- 10 Gallon Kit (36.4 kg)
- 2 Drum Kit (360 kg)

#### Warranty

12 Months

#### Vacuum Deaeration

Remove air entrapped during mixing by common vacuum deaeration procedure, observing all applicable safety precautions. Slowly apply full vacuum to a suitable container of at least four times the volume of material being de-aired. Hold vacuum until bulk deaeration is complete.

#### **Substrate Considerations**

Cures in contact with most materials common to biomedical assemblies. Exceptions include: sulfur-cured organic rubbers, latex, chlorinated rubbers, some RTV silicones and unreacted residues of some curing agents.

#### 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 <u>A Guide to Silicone Dispersions – Strategies for Processing and Troubleshooting</u>.

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 <a href="https://www.nusil.com">www.nusil.com</a> and review <a href="https://www.nusil.com">Choosing a Silicone Primer/Adhesive System</a>.

#### Storage

Most dispersions are stored prior to application. It is important to note that NuSil 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-6400 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-6400 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACh) regulation (European Union 1907/2006). MED-6400 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 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.



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.

