

# MED-6601

# Addition cure silicone elastomer system

# **DESCRIPTION**

- Cures with heat via addition-cure chemistry
- Intended to be dispersed in solvent at a suggested mix ratio of 100parts Part A: 1part Part B: 1part Part C: 234parts Xylene (or other suitable solvent)

# **APPLICATION**

 Once dispersed, the material is suitable for dip casting and heat-curing of thin elastomeric films

NuSil™ MED-6601 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
Cured: 30 min at 25°C (77°F), 45 min at 75°C (167°F), and 135 min at 150°C (302°F), 100pph:1pph:234pph* (Part A: Part B: Part C: Xylene)			
Durometer, Type A	24	ASTM D2240	006
Tensile Strength	1,200 psi (8.3 MPa)	ASTM D412	007
Elongation	800%	ASTM D412	007
Tear Strength	150 ppi (26.4 kN/m)	ASTM D624	009
Stress at 300% Strain	320 psi (2.2 MPa)	ASTM D412	007
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**

Combine 100pph:1pph:234pph (Part A: Part B: Part C: Xylene) mix ratio prior to use. Airless mixing, metering or dispersing equipment is recommended for production operations. If mixing by hand, take care to minimize air entrapment. Do not use wooden spatulas to mix and avoid the use of latex gloves. 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-6601 and solvent of choice prior to use to review potential hazards.

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

# **Packaging**

Warranty

1 Gallon Kit (3.71 kg) 5 Gallon Kit (18.56 kg) 12 Months

evaporation and contamination during long or short term storage.

#### FDA MASTER FILE

A Master File for MED-6601 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must contact 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 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.

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