MED-6640-55

ADDITION CURE HIGH TEAR SILICONE DISPERSION

DESCRIPTION

- Two-part, medium viscosity silicone elastomer dispersed in xylene
- 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-6640-55 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	20%	ASTM D2288	004
Viscosity	3,000 cP (3,000 mPas)	ASTM D1084, D2196	001
Cured: 30 minutes at ambient temperature and humidity, 45 minutes at 75°C (167°F), and 135 minutes at 150°C (302°F)			
Refractive Index	1.41	ASTM D1747, D1218	018
Durometer, Type A	40	ASTM D2240	006
Tensile Strength	1,700 psi (11.7 MPa)	ASTM D412	007
Elongation	1,045%	ASTM D412	007
Tear Strength	300 ppi (52.9 kN/m)	ASTM D624	009
Stress at 100% Strain	150 psi (1.03 MPa)	ASTM D412	007
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061

TYPICAL PROPERTIES	AVERAGE RESULT	STANDARD	NT-TM
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 contact 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 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-6640-55 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 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 NuSil recommends keeping the dispersion in its original container when possible, tightly sealed and stored below 40º 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-6640-55 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

MED-6640-55 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACh) regulation (European Union 1907/2006). MED-6640-55 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 contact 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.

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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 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

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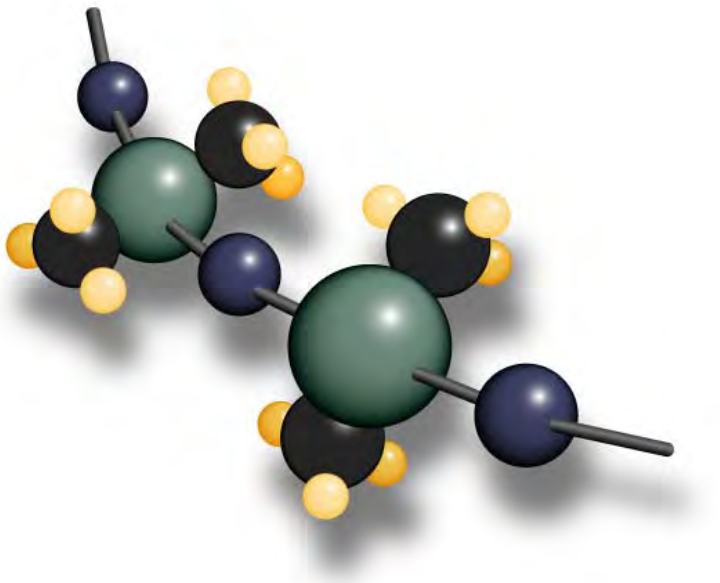
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