LIFE SCIENCES IMPLANT LINE

MED-6670 LOW COEFFICIENT OF FRICTION SILICONE DISPERSION

# **DESCRIPTION**

- Two-part silicone elastomer dispersed in xylene
- Cures to a smooth silicone film that decreases the coefficient of friction (CoF) compared to the uncoated silicone and increases abrasion resistance
- 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
- To provide a heat-cured, low-friction coating on cured silicone substrates
- For tubing (ID/OD). Balloons, valves, stoppers, o-rings, and for moving or sliding parts

NuSil Technology's MED-6670 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, Part A	Translucent	ASTM D2090	002
Appearance, Part B	Translucent to Opaque	ASTM D2090	002
Zahn Cup Viscosity, Cup #2	16 seconds	ASTM D1084	096
Percent Solids, Mixed	25%	ASTM D2369	047
Cured: 5 minutes minimum at ambient temperature	e and humidity, then 5 minutes at 150°C (302°F)		
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 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-6670 prior to use as its solvent carrier is hazardous.

#### **Packaging**

100 Gram Kit (0.1 kg) 2 Pint Kit (675 kg) 2 Gallon Kit (7.28 kg) 10 Gallon Kit (36.4 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 deaired. Hold vacuum until bulk deaeration is complete.

#### Coating and Application

The part being coated with the dispersion should be free of contamination, should not inhibit the cure, and should be able to withstand the cure cycle.

Although the MED-6670 may be applied by means of dipping or brushing, it has been found that optimal results are obtained through spraying techniques.

The following instructions apply to airbrush as well as retouch/refinish type spray equipment on parts up to 8" diameter. Suggested spray equipment includes the Badger Airbrush 400, DeVILBISS JGHV-520, or DeVILBISS EGA-503. Parameters may differ based on spray equipment used and the size and geometry of the part to be coated.

- 1. Clean the surface to be coated thoroughly with an appropriate solvent and lint-free cloth or foam wipe. Allow the solvent to evaporate completely.
- 2. Thoroughly stir or shake individual components prior to blending to ensure homogeneity. Mix in a 1:1 (Part A: Part B) ratio by weight.
- 3. Due to low viscosity of MED-6670, material may be allowed to self-deaerate.
- 4. Set air pressure to approximately 20 psi to give a slow flow of material as opposed to a strong stream. Adjust nozzle opening to the point where the material begins to get atomized.
- 5. Hold the nozzle 2 4 inches from the substrate and apply the coating in a slow and steady up/down or side/side motion. The substrate should be evenly wetted with a fine layer, but not soaked to a point where the coating is pooling or dripping. A final sweeping pass at a distance of 4 6 inches may give the coating a more uniform appearance.
- 6. Allow the bulk of the solvent to evaporate in an area with good airflow and ventilation, such as under a fume hood. This should be accomplished in about 3 10 minutes depending on the ambient temperature and airflow.
- 7. Cure the coating with temperature as suggested on the Standard Material Certification. The material may cure at lower temperatures, but the rate of cure should be determined through trials.



#### **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.

Note: Some bonding applications may require the use of a primer. NuSil Technology's MED-160 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>.

#### 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: Avoid using isopropanol to clean the coated surface as the coating can be removed by this solvent.

#### 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-6670 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-6670 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACh) regulation (European Union 1907/2006). MED-6670 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 <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.

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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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