

MED-4011

Low consistency silicone elastomer

DESCRIPTION

- Two-part, translucent gray, pourable silicone system
- Cures with heat via addition-cure chemistry
- 10:1 Mix Ratio (Part A: Part B)

APPLICATION

 For use in potting, encapsulating, coating, and injection or transfer molding applications

NuSil® MED-4011 shall not 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
Viscosity, Part A	105,000 cP (105,000 mPas)	ASTM D1084, D2196	001
Viscosity, Part B	1,500 cP (1,500 mPas)	ASTM D1084, D2196	001
Cured: 3 minutes at 150°C (302°F) Post-Cured: 1 hour at 150°C (302°F). Stabilize for	3 hours at ambient temperature and humidity	1	·
Specific Gravity	1.09	ASTM D792	003
Durometer, Type A	27	ASTM D2240	006
Tensile Strength	670 psi (4.6 MPa)	ASTM D412	007
Elongation	530 %	ASTM D412	007
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061
Elemental Analysis of Trace Metals	Pass	ASTM E305	131

The test data shown for this material is the average value for typical properties. All of these properties may not be tested on a lot to lot basis and cannot be used to draft specifications. Please contact NuSil for assistance and recommendations in establishing limits for product specifications.



INSTRUCTIONS FOR USE

Mixing

Combine Part A and Part B in a 10:1 mix ratio prior to use. Airless mixing, metering or dispensing equipment is recommended for production operations. If mixing by hand, take care to minimize air entrapment.

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.

Cure Inhibition

Curing may be inhibited by traces of amines, sulfur, nitrogen oxide, organotin compounds, and carbon monoxide. Because organic rubbers often contain these substances, they should not come in contact with the uncured elastomer. Catalyst residues from silicone RTV elastomers and peroxide-cured silicone elastomers may also inhibit the cure.

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

FDA MASTER FILE

For customers interested in a Master File for this product, please contact NuSil.

REACH COMPLIANCE

Please <u>contact</u> NuSil's Regulatory Compliance department with any questions or for further assistance.

SPECIFICATIONS

Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please <u>contact</u> NuSil for assistance and recommendations in establishing limits for product specifications.

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC is 12 months from the date of shipment when stored below 40°C in

Packaging

Warranty

37 mL SxS Kit (0.0374 kg) 12 Months

1 Pint Kit (0.505 kg)

1 Gallon Kit (4.4 kg)

5 Gallon Kit (20.2 kg)

1 Drum Kit (198.5 kg)

original unopened containers. Unless NuSil provides a specific written warranty of fitness for a particular use, NuSil's sole warranty is that the product will meet NuSil's then current specification. NuSil 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'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 expressly disclaims any liability for incidental or consequential damages.

WARNINGS ABOUT PRODUCT SAFETY

NuSil 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 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 makes no warranty concerning fitness for any use or purpose. NuSil has completed no testing to establish safety of use in any medical application.

NuSil has tested this material only to determine if the product meets the applicable specifications. (Please <u>contact</u> NuSil for assistance and recommendations when establishing specifications.) When considering the use of NuSil products in a particular application, review the latest Material Safety Data Sheet and <u>contact</u> NuSil 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

BIOMATERIALS PREMIUM CARE LINE



available product safety information and take the necessary steps to ensure safety of use.

PATENT / INTELLECTUAL PROPERTY WARNING

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