

MED-4801

Liquid silicone rubber

DESCRIPTION

- Two-part, translucent silicone system designed for use with injection molding equipment
- Cures with heat via addition-cure chemistry
- 1:1 Mix Ratio (Part A: Part B)

APPLICATION

- For the injection molding of parts requiring a material with a low durometer including: molded rubber stoppers, gaskets, seals, valves, o-rings and other precision parts
- Suitable for over-molding applications
- Can be used with NuSil's Healthcare color masterbatches for applications requiring colored silicones

NuSil™ MED-4801 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 |
| Extrusion Rate, Part A* | 185 g/min | ASTM C603 | 033 |
| Extrusion Rate, Part B* | 210 g/min | ASTM C603 | 033 |
| Work Time | 24 hours | - | 008 |
| Cured: 5 minutes at 150°C (302°F) | | | |
| Durometer, Type 00 | 38 | ASTM D2240 | 006 |
| Tensile Strength | 290 psi (2.0 MPa) | ASTM D412 | 007 |
| Elongation | 1140% | ASTM D412 | 007 |
| Tear Strength | 55 ppi (9.7 kN/m) | ASTM D624 | 009 |
| 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 for assistance and recommendations in establishing particular specifications.

*Performed using a SEMCO® 440 nozzle with a 1/8" orifice and 90+/-5 psi air pressure.

INSTRUCTIONS FOR USE

Mixing

Combine Part A and Part B in a 1:1 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.

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.

Vulcanization

Curing of the blended elastomer is accelerated by heat. The pre-measured catalyst provides a fixed cure rate. Do not attempt to change molding times by mixing the two components in any other than a 1:1 ratio, as this will affect the properties of the elastomer. Only temperature adjustments should be employed to alter the rate of 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 www.nusil.com and review [Choosing a Silicone Primer/Adhesive System](#).

FDA MASTER FILE

A Master File for MED-4801 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must [contact](#) NuSil.

Packaging

50 mL Side-by-Side Kit
200 mL Side-by-Side Kit
400 mL Side-by-Side Kit
2 Pint Kit (910 g)
40 Ounce Kit (1.18 L)
2 Gallon Kit (7.28 kg)
10 Gallon Kit (36.4 kg)

Warranty

12 Months

REACH COMPLIANCE

Please [contact](#) NuSil'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 for assistance and recommendations in establishing particular specifications.

WARRANTY INFORMATION

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

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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 [contact](#) 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 [contact](#) 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 available product safety information and take the necessary steps to ensure safety of use.

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