

MED-4035

High consistency silicone elastomer

DESCRIPTION

- Two-part, high tear strength silicone elastomer
- Soft silicone
- Cures with heat via addition-cure chemistry
- Has a non-tacky surface and no volatile by-products or peroxide residues
- Strained through a 400-mesh screen (minimum)
- 1:1 Mix Ratio (Part A: Part B)

APPLICATION

- For a wide variety of fabrication techniques for the healthcare industry including: molding, calendaring and extruding

NuSil™ MED-4035 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 |
| Plasticity, Part A | 70 mils (1.8 mm) | ASTM D926 | 058 |
| Plasticity, Part B | 70 mils (1.8 mm) | ASTM D926 | 058 |
| Work Time | 2.0 hours | - | 074 |
| Cured: 10 minutes at 116°C (241°F). Stabilize for 24 hours minimum at ambient temperature and humidity | | | |
| Specific Gravity | 1.11 | ASTM D792 | 003 |
| Durometer, Type A | 35 | ASTM D2240 | 006 |
| Tensile Strength | 1,565 psi (10.8 MPa) | ASTM D412 | 007 |
| Elongation | 1,055% | ASTM D412 | 007 |
| Tear Strength | 195 ppi (34.4 kN/m) | ASTM D624 | 009 |
| Stress at 200% Strain | 195 psi (1.3 MPa) | ASTM D412 | 007 |

| Typical Properties | Average Result | Standard | NT-TM |
|---------------------------------------|----------------|-------------------------|-------|
| Tissue Culture (Cytotoxicity Testing) | Pass | USP <87> ISO 10993-5 | 061 |
| 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

Combine Part A and Part B in equal portions on a two-roll mill prior to use. Take care to work in a meticulously clean area with no organic rubbers used on the same equipment, as traces of foreign materials can poison the catalyst, thus inhibiting the cure. Thoroughly clean all equipment at the end of each use to avoid build-up of cured stock. The next material used on unclean equipment may pick-up residue, resulting in "gels" and imperfections.

Blending

First soften Part B on a cooled two-roll mill. Remove from the mill and soften Part A. Add an equal portion by weight of softened Part B and cross blend the components until thoroughly mixed. Keep the temperature of the blended material as low as possible to give maximum table life. Blend only sufficient material required for use in within 2 to 3 hours. Blended material may be stored in a freezer for at least 7 days if carefully wrapped. Warm material stored in a freezer to room temperature before unwrapping to avoid condensation on the elastomer, which may cause voids in molded or extruded parts.

Molding

This product can be formed into cured configurations by compression, transfer or injection molding processes. Molding cycle times are dependent on the mold temperature and cross-sectional thickness of the part. It is best to use highly polished, chrome-plated or stainless steel molds for these operations. Other polished metals will normally require release agents to prevent sticking. If using release agents, clean the molded parts prior to use.

Calendering

Calender the elastomer into sheeting with or without reinforcement. Make sheeting by calendering onto a laminate such as Mylar™ or polyethylene, for vulcanized and unvulcanized sheeting, respectively. If using Mylar™, strip off the Mylar™ after vulcanization while the sheet is still hot. If using polyethylene, strip off the polyethylene before vulcanization. Long lengths of Mylar™ laminated sheeting can

Packaging

2 Pound Kit (900 g)
10 Pound Kit (4.54 kg)
50 Pound Kit (22.68 kg)
1,000 Pound Gaylor Kit (453.6 kg)

Warranty

12 Months

be calendered on a core and vulcanized in a hot air oven or steam autoclave.

Extrusion

For maximum uniformity, re-soften the elastomer on a two-roll mill at time of use. Extrude the elastomer through an unheated die to make rod, tubing and coated wire. Vulcanize after extrusion by passing the material through a horizontal or vertical heated chamber. The residence time will vary based on the temperature of the chamber and the size/thickness of the extrusion.

Vulcanization

Cure of the blended elastomer is accelerated by heat. The pre-measured catalyst gives the stock 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 change the properties of the elastomer. Only adjusting the temperature may vary the rate of cure.

Cure Inhibition

The cure 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.

Post-Curing

Because these materials vulcanize via addition-cure, no residues are present and post-cure is not required for many

applications. The user must confirm that press molding or short oven-cures are suitable for any specific application.

FDA MASTER FILE

A Master File for MED-4035 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 [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 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.

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