

MED4-4516

High consistency silicone elastomer

DESCRIPTION

- Pre-catalyzed, high consistency elastomer
- High durometer
- Strained through a 400-mesh screen (minimum)

APPLICATION

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

NuSil™ MED4-4516 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 |
| Plasticity | 120 mils (3.0 mm) | ASTM D926 | 058 |
| Cured: 5 minutes at 116°C (241°F) | | | |
| Specific Gravity | 1.21 | ASTM D792 | 003 |
| Post Cured: 2 hours at 249°C (480°F). Stabilize for 3 hours minimum at ambient temperature and humidity | | | |
| Durometer, Type A | 70 | ASTM D2240 | 006 |
| Tensile Strength | 1,300 psi (9.0 MPa) | ASTM D412 | 007 |
| Elongation | 450% | ASTM D412 | 007 |
| Tear Strength | 130 ppi (22.9 kN/m) | ASTM D624 | 009 |
| Stress at 200% Strain | 500 psi (3.4 MPa) | ASTM D412 | 007 |
| 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

In general, freshly softened elastomers have better processing characteristics, therefore milling to a smooth consistency before use is advised, regardless of the age of the elastomer. After the peroxide has been added, it is important to minimize heating of the material when milling to prevent premature partial curing. Maintain the temperature of the elastomer at less than 43°C (109°F) during milling.

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 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.

Post-curing

The post-cure period serves two distinct purposes. Post-curing removes the volatile components and other by-products generated by the decomposition of the peroxide during vulcanization. Post-curing also stabilizes and enhances the physical properties of the elastomer.

Accomplish post-curing by heating the vulcanized material in a hot air circulating oven to a predetermined temperature for the required length of time. The oven must have an exhaust system of sufficient capacity to prevent volatiles from reaching an explosive level. The exhaust system should be vented so as to prevent worker exposure. The time required for post-curing at a

Packaging

1 Pound (450 g)
5 Pound (2.27 kg)
25 Pound (11.34 kg)

Warranty

6 Months

given temperature depends upon the rate at which the volatiles can escape from the elastomer, which in turn depends upon the thickness of the part, the exposed surface area and the oven loading.

HANDLING PRECAUTIONS

During vulcanization, oven-curing, and post-curing of silicones catalyzed with peroxide, vapors containing polychlorinated biphenyl (PCB), and other residual volatile byproducts of vulcanization may be released in small amounts. Studies have been conducted and conclude that minimal to no PCBs are released during cure; however, these vapors, if present, may be harmful and appropriate precautions should be taken. Work areas must be well ventilated, and workers should avoid inhalation of vapors. Review the Material Safety Data Sheets for specific information.

FDA MASTER FILE

A Master File for MED4-4516 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 6 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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