MED-4174

High consistency silicone elastomer

DESCRIPTION

- Uncatalyzed high consistency silicone elastomer
- Catalyze with various peroxides to form a medium durometer rubber
- Strained through a 400-mesh screen (minimum)

APPLICATION

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

NuSil™ MED-4174 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	110 mils (2.78 mm)	ASTM D926	058
Cured: 5 minutes at 116°C (241°F). Catalyzed with 1.0 pph of CAT-102 (Peroxide)			
Specific Gravity	1.15	ASTM D792	003
Post Cured: 2 hours at 177°C (351°F). Stabilize for 3 hours minimum at ambient temperature and humidity			
Durometer, Type A	50	ASTM D2240	006
Tensile Strength	1,300 psi (8.9 MPa)	ASTM D412	007
Elongation	750%	ASTM D412	007
Tear Strength	225 ppi (39.7 kN/m)	ASTM D624	009
Stress at 200% Strain	325 psi (2.2 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 using 2, 4 Dichlorobenzoyl peroxide catalyst. Do not use as a basis for preparing specifications. Please contact NuSil Technology for assistance and recommendations in establishing particular specifications.

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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.

The amount of peroxide required to cure the product is dependent on the type used and the chosen fabrication technique. The most practical way to establish the proper amount of catalyst is for the user to experiment with the elastomer and equipment that will be used for production. Several organic peroxides are suitable for vulcanizing this product. Contact NuSil Technology for information on catalyst selection.

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

Depending on the peroxide catalyst used a post-cure may be required. The post-cure serves two distinct purposes. Post-curing removes the volatile components and other residuals generated from the decomposition of the peroxide during vulcanization. Post-curing also stabilizes and enhances the physical properties of the elastomers.

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 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.

Packaging	Warranty
1 Pound (450 g) 5 Pound (2.27 kg) 25 Pound (11.34 kg)	12 Months

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 MED-4135 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.

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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.

WARNINGS ABOUT PRODUCT SAFETY

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

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.

PATENT / INTELLECTUAL PROPERTY WARNING

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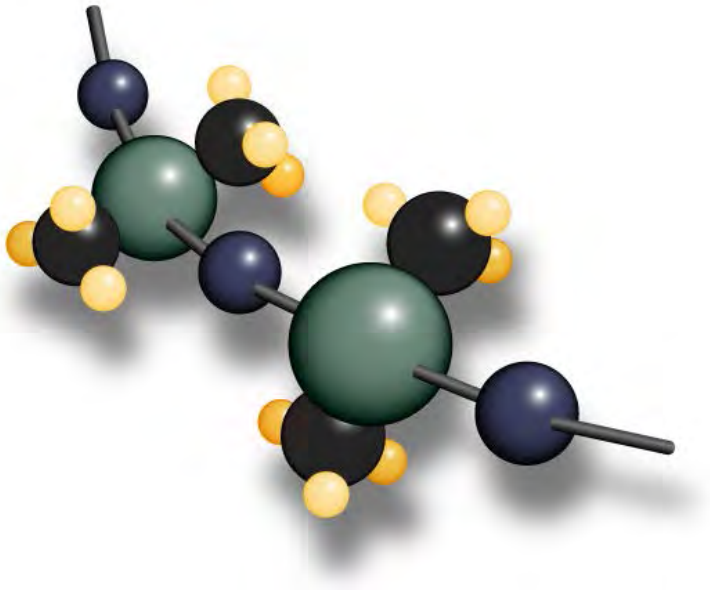

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