MED10-5440

Liquid injection molding fluorosilicone liquid silicone rubber

DESCRIPTION

- Two-part, translucent, fluorosilicone elastomer used with liquid injection molding equipment
- 100 mol % fluorosilicone
- 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 medium durometer including: molded rubber stoppers, gaskets, seals, valves, o-rings and other precision parts
- Suitable for over-molding applications

NuSil™ MED10-5440 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
Extrusion Rate**, Part A	40 g/min	ASTM C603	033
Extrusion Rate**, Part B	40 g/min	ASTM C603	033
Work Time	>24 hours	-	008
Cured: 30 minutes at 150°C (302°F)			
Specific Gravity	1.38	ASTM D792	003
Durometer, Type A	30	ASTM D2240	006
Tensile Strength	1,250 psi (8.6 MPa)	ASTM D412	007
Elongation	380%	ASTM D412	007
Tear Strength	60 ppi (10.6 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 Technology for assistance and recommendations in establishing particular specifications.

** Performed using a Semco model 250-A pneumatic gun with a 1/8" nozzle 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 Technology'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 MED10-5440 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must contact NuSil Technology.

Packaging	Warranty
50 mL Side-by-Side Kit	12 Months
400 mL Side-by-Side Kit	
2 Pint Kit (910 g)	
2 Gallon Kit (7.28 kg)	
10 Gallon Kit (36.4 kg)	

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.

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

NuSil Technology disclaims any expressed or implied warranty against the infringement of any domestic or international patent/intellectual property right. NuSil Technology does not warrant the use or sale of the products described herein will not infringe the claims of any domestic or international patent/intellectual property right covering the product itself, its use in combination with other products, or its use in the operation of any process.