SIL2-5040

CLASS VI SUPPORTED HIGH CONSISTENCY SILICONE ELASTOMER

DESCRIPTION

- A two-part, high consistency elastomer designed for optimal performance in a wide range of applications
- Produces a tough, durable, translucent elastomer when thermally cured
- Has a non-tacky surface and no volatile byproducts or peroxide residues
- Advantages include: lot-to-lot consistency and cost-effectiveness
- 1:1 Mix Ratio (Part A:B)

APPLICATION

- For a wide variety of fabrication techniques for the healthcare industry including: molding, calendering and extruding
- Can be used with NuSil's Healthcare color masterbatches for applications requiring colored silicones

Regulatory Support

- NuSil Technology's Class VI (C6) products meet the requirements defined in ISO-10993 for Surface Devices with "limited" (<24 hours) or "prolonged" (1 to 30 days) contact duration
- After post-cure, material meets or exceed the extraction requirements for FDA regulation 21 CFR 177.2600 "Rubber Articles Intended for Repeated Use (Food Contact)"

NuSil Technology's SIL2-5040 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
Work Time	4 hours	-	074

TYPICAL PROPERTIES	AVERAGE RESULT	STANDARD	NT-TM
Cured: 15 minutes at 165°C (329°F)			
Specific Gravity	1.15	ASTM D792	003
Durometer (Type A)	39	ASTM D2240	006
Tensile Strength	1,510 psi (10.4 MPa)	ASTM D412	007
Elongation	1,115%	ASTM D412	007
Tear Strength	220 ppi (38.7 kN/m)	ASTM D624	009
Stress at 200% Strain	140 psi (1.0 MPa)	ASTM D412	007

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.

Packaging

50 Pound Kit (22.68 kg)
1000 Pound Gaylor (455 kg)

Warranty

12 Months

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.

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 this material vulcanizes via addition-cure, no residues are present and a 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.

REGULATORY STATUS

USP Class VI, ISO 10993 Status

Testing performed in accordance with USP Class VI <88> and applicable ISO 10993 standards. The tables below summarize the biological testing completed on the formulation components of this material:

TEST	STANDARD/METHOD	TEST RESULTS
USP and ISO Systemic Toxicity Study Extract*	ISO 10993-11 USP <88>	A-Nontoxic
ISO Intracutaneous Study Extract*	ISO 10993-10 USP <88>	A-Nonirritant
ISO Muscle Implantation Study 1 Week*	ISO 10993-6 USP <88>	A-Nonirritant

*Product meets USP Class VI test requirements

FDA 21 CFR 177.2600 Status

After being cured, post-cured for 2 hours at 150°C (302°F), and washed, this elastomer meets the extraction requirements of FDA regulation 21 CFR 177.2600 “Rubber Articles Intended for Repeated Use (Food Contact).” Please contact NuSil Technology LLC for a complete list of tests performed.

REACh COMPLIANCE

SIL2-5040 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACh) regulation (European Union 1907/2006). SIL2-5040 does not contain any of the chemicals or substances identified as Substances of Very High Concern (SVHC) by the European Chemicals Agency (ECHA), which oversees 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 is 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.