

VERSASIL³

HIGH CONSISTENCY SILICONE ELASTOMERS

DESCRIPTION

- A unique three-part system, VersaSil³ offers the flexibility of adjustable cure rate and table life for various fabrication requirements
- High tear strength, wide processing parameters, and translucent, non-tacky surfaces
- Developed to be compounded with the inhibitor CAT-40 and the platinum catalyst CAT-55. Advantages include: no volatile by-products, lower cure temperature, and optional post-cure
- 100: 1.0: 1.0 Mix Ratio

APPLICATION

- For mass production with maximum flexibility
- For a wide variety of fabrication techniques for the healthcare industry including: molding, calendaring and extruding

NuSil Technology's VersaSil³ Series shall not be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

TYPICAL PROPERTIES	VERSASIL ³ 30 MED-4032	VERSASIL ³ 40 MED-4042	VERSASIL ³ 50 MED-4052	STANDARD	NT-TM
Cured: 10 min. @ 116°C (241°F)					
Specific Gravity	1.10	1.11	1.16	ASTM D792	003
Durometer, Type A	30	40	50	ASTM D2240	006
Tensile Strength	1,200 psi (8.3 MPa)	1,475 psi (10.2 MPa)	1,400 psi (9.7 MPa)	ASTM D412	007
Elongation	1,100%	1,000%	1,100%	ASTM D412	007
Tear Strength	160 ppi (28.2 kN/m)	160 ppi (28.2 kN/m)	230 ppi (40.6 kN/m)	ASTM D624	009
Stress @ 200% Strain	140 psi (1.0 MPa)	230 psi (1.6 MPa)	280 psi (1.9 MPa)	ASTM D412	007
Tissue Culture (Cytotoxicity Testing)	Pass	Pass	Pass	USP <87> ISO 10993-5	061
Elemental Analysis of Trace Metals	Pass	Pass	Pass	ASTM E305	131



TYPICAL PROPERTIES	VERSASIL ³ 60MED-4062	VERSASIL ³ 70 MED-4072	VERSASIL ³ 80 MED-4082	STANDARD	NT-TM
Cured: 10 min. @ 116°C (241°F)					
Specific Gravity	1.16	1.22	1.22	ASTM D792	003
Durometer, Type A	60	70	80	ASTM D2240	006
Tensile Strength	1,400 psi (9.7 MPa)	1,100 psi (7.6 MPa)	1,150 psi (7.9 MPa)	ASTM D412	007
Elongation	1,000%	875%	900%	ASTM D412	007
Tear Strength	250 ppi (44.1 kN/m)	240 ppi (42.3 kN/m)	200 ppi (35.5 kN/m)	ASTM D624	009
Stress @ 200% Strain	300 psi (2.1 MPa)	450 psi (3.1 MPa)	400 psi (2.8MPa)	ASTM D412	007
Tissue Culture (Cytotoxicity Testing)	Pass	Pass	Pass	USP <87> ISO 10993-5	061
Elemental Analysis of Trace Metals	Pass	Pass	Pass	ASTM E305	131

Properties tested on a lot-to-lot basis. 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.

INSTRUCTIONS FOR USE

Calculations

While a long table life is desirable, slower cure rates associated with long table lives can contribute to porosity in extruded tubing and calendered sheeting. Adjust levels of CAT-40 for variable table life and cure rates. The following table summarizes suggested blended ratios for molding and calendering.

	MOLDING	EXTRUSION
Base Stock	100 pph	100 pph
CAT-40	1-3 pph	0.3-1 pph
CAT-55	1.0 pph	1.0 pph

Packaging

25 Lb Box (11.4 kg)
1000 Lb Gaylor (455 kg)

Warranty

12 Months

Milling

Soften approximately 25% of the total calculated base stock on a cooled 2-roll mill. Add entire calculated quantity of CAT-40 and mill until homogenous. While the base/CAT-40 mixture is turning on the mill, add the CAT-55 in small increments until the entire calculated amount is added. Finally, mill in the remaining base stock. Take caution to avoid over-milling.

Note: CAT-40 and CAT-55 are supplied in highly concentrated masterbatches. Masterbatches are sold separately from product. Desired quantities should be specified when ordering. These masterbatches are provided at a consistency that can be easily cut with a spatula or knife. Be certain that the instrument used is thoroughly cleaned between contact with CAT-40 and CAT-55.



Cure Inhibition

The cure may be inhibited by traces of amines, sulfur, nitrogen oxide, organotin compounds, and carbon monoxide. Examples of materials that should not come in contact with the uncured elastomer include: wooden spatulas, latex gloves, organic rubbers, and residues from RTV or peroxide-cured silicone elastomers.

Curing

These elastomers will cure in a mold cross section up to 0.075" thick in less than 10 minutes @ 116°C (241°F). If desired, implement an optional post-cure, such as 4 hours @ 177°C (351°F). Cure rate may be accelerated by heat. These elastomers cure at a wide range of times and temperatures to accommodate different production needs. Contact NuSil Technology LLC for details. If using peroxide catalysts, reference manufacturer recommendation for establishing proper post cure parameters.

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.

Storage

Reseal unused base materials in supplied packaging and keep at ambient room temperature (~25°C). CAT-40 and CAT-55 are supplied sealed in polypropylene bags and placed in HDPE containers. Store unused portions of CAT-40 and CAT-55 by first re-wrapping in the polypropylene bag and then sealing tightly in the HDPE container.

FDA MASTER FILE

Master Files for the VersaSil³ series have been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must contact NuSil Technology.

NuSil Technology's Master Files contain both a manufacturing and compendium section. The compendia include testing of bulk material properties, mechanical/physical properties, chemical properties, and confirmatory biological testing.

BIO SUPPORT

USP Class VI / ISO 10993 Status

After being cured with CAT-40 and CAT-55, these elastomers are compliant with USP Class VI requirements and applicable ISO 10993 requirements. Please contact NuSil Technology for a complete list of tests performed.

The tables below summarize the biological testing completed on the formulation components of these materials.

TEST	RESULT	EXTRACTS
Cytotoxicity	Non-Cytotoxic	Sodium Chloride Solution (Saline)
Hemolysis	Non-Hemolytic	Alcohol in Saline Solution



TEST	RESULT	EXTRACTS
Systemic Injection Test with Extracts	Non-Toxic	Polyethylene Glycol 400 (PEG)
Intracutaneous Test with Extracts	Non-Irritant	Vegetable Oil
Implantation Test (one week)	Non-Irritant	
Genotoxicity	Non-Mutagenic	
Pyrogenicity	Non-Pyrogenic	
Sensitization	Non-Sensitizer	

REACH COMPLIANCE

VersaSil³ is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACH) regulation (European Union 1907/2006). VersaSil³ 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 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.



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