MED-4042

High consistency silicone elastomer

DESCRIPTION

- A unique three-part system, MED-4042 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
- Can be compounded with CAT-40 inhibitor and CAT-55 catalyst for use as an Addition (Platinum) Cure system silicone
- MED-4042 can also be compounded with peroxide catalysts

APPLICATION

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

NuSil™ MED-4042 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
Cured: 10 min. at 116°C (241°F). Stabilize for 3 hours minimum at ambient temperature and humidity			
Specific Gravity	1.11	ASTM D792	003
Durometer, Type A	40	ASTM D2240	006
Tensile Strength	1,475 psi (10.2 MPa)	ASTM D412	007
Elongation	1,000%	ASTM D412	007
Tear Strength	160 ppi (28.2 kN/m)	ASTM D624	009
Stress at 200% Strain	230 psi (1.6 MPa)	ASTM D412	007
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061

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Typical Properties	Average Result	Standard	NT-TM
Elemental Analysis of Trace Metals	Pass	ASTM E305	131

The data above represents the properties of the product when cured using the Addition Cure System (CAT-40 and CAT-55).

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

Addition Cure System

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.

Packaging	Warranty
25 Lb Box (11.4 kg) 1000 Lb Gaylord (455 kg)	12 Months

	Molding	Extrusion
MED-4042	100 pph	100 pph
CAT-40	1-3 pph	0.3-1 pph
CAT-55	1.0 pph	1.0 pph

Milling

Soften approximately 25% of the total calculated MED-4042 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 MED-4042. 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

MED-4042 will cure in a molded 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 increased heat. This elastomer cures at a wide range of times and temperatures to accommodate different production needs.

Post-Curing

When curing 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.

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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.

Peroxide Cure System

Various peroxide catalysts can be used to catalyze the MED-4042. Most common are Di(2,4-dichlorobenzoyl) peroxide or Dicumyl peroxide. Post curing may or may not be needed depending on the peroxide used. Contact NuSil Technology for more information.

FDA MASTER FILE

A Master File for MED-4042 has 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, MED-4042 is complaint with USP Class VI requirements and applicable ISO 10993 requirements.

The tables below summarize the biological testing completed on the formulation components of this material.

Test	Result	Method
Cytotoxicity	Non-Cytotoxic	ISO 10993-5
Hemolysis	Non-Hemolytic	ISO 10993-4
Systemic Injection Test with Extracts	Non-Toxic	ISO 10993-11
Intracutaneous Test with Extracts	Non-Irritant	ISO 10993 10
Implantation Test (one week)	Non-Irritant	ISO 10993-6
Genotoxicity	Non-Mutagenic	ISO 10993-3
Pyrogenicity	Non-Pyrogenic	ISO 10993-11
Sensitization	Non-Sensitizer	ISO 10993-10

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

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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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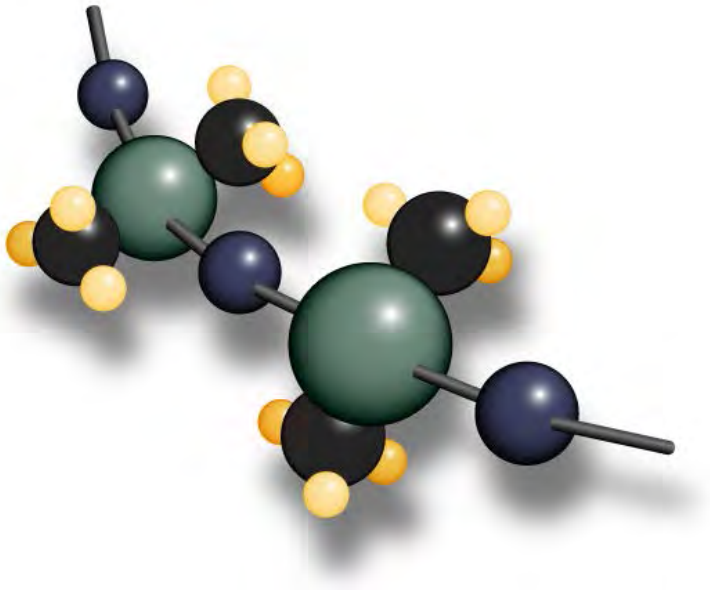

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