MED2-6300

High purity silicone gel

DESCRIPTION

- A high purity, clear silicone gel manufactured under controlled conditions
- Easy mixing two-component, low viscosity system
- 1:1 Mix Ratio (Part A: Part B)
- NuSil can formulate custom materials to meet specific penetration requirements

APPLICATION

- Ideal for potting, encapsulating, casting, backfilling, and dampening

NuSil® MED2-6300 may be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

Typical Properties	Average Result	Standard	NT-TM
Uncured:			
Viscosity	1,000 cP (1,000 mPas)	ASTM D1084, D2196	001
Appearance	Translucent	ASTM D2090	002
Volatile Content	0.10 %	ASTM D2288	004
Cured: 5 hours at 140°C (284°F)			
Penetration (Lab Line Penetrometer, 19.5g shaft, ¼" diameter foot, 15 seconds. Use a 2 oz. glass squat jar.)	10 mm	-	011
Specific Gravity	0.98	ASTM D891, D1475	022
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061
Elemental Analysis of Trace Metals	Pass	ASTM E305	131

The test data shown for this material is the average value for typical properties. All of these properties may not be tested on a lot to lot basis and cannot be used to draft specifications. Please contact NuSil for assistance and recommendations in establishing limits for product specifications.

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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.

FDA MASTER FILE

A Master File for MED2-6300 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must contact NuSil.

REACH COMPLIANCE

Please contact NuSil's Regulatory Compliance department with any questions or for further assistance.

SPECIFICATIONS

Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please contact NuSil for assistance and recommendations in establishing limits for product specifications.

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC is 12 months from the date of shipment when stored below 40°C in original unopened containers. Unless NuSil provides a specific written warranty of fitness for a particular use, NuSil's sole warranty is that the product will meet NuSil's then current specification. NuSil specifically disclaims all other expressed or implied warranties, including, but not limited to, warranties of merchantability and fitness for use. The exclusive remedy and

Packaging	Warranty
2 Pint Kit (0.910 kg) 2 Gallon Kit (7.28 kg) 10 Gallon Kit (36.4 kg) 2 Drum Kit (340 kg)	12 Months

NuSil'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 expressly disclaims any liability for incidental or consequential damages.

WARNINGS ABOUT PRODUCT SAFETY

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

NuSil has tested this material only to determine if the product meets the applicable specifications. (Please contact NuSil for assistance and recommendations when establishing specifications.) When considering the use of NuSil products in a particular application, review the latest Material Safety Data Sheet and contact NuSil 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 disclaims any expressed or implied warranty against the infringement of any domestic or international patent/intellectual property right. NuSil 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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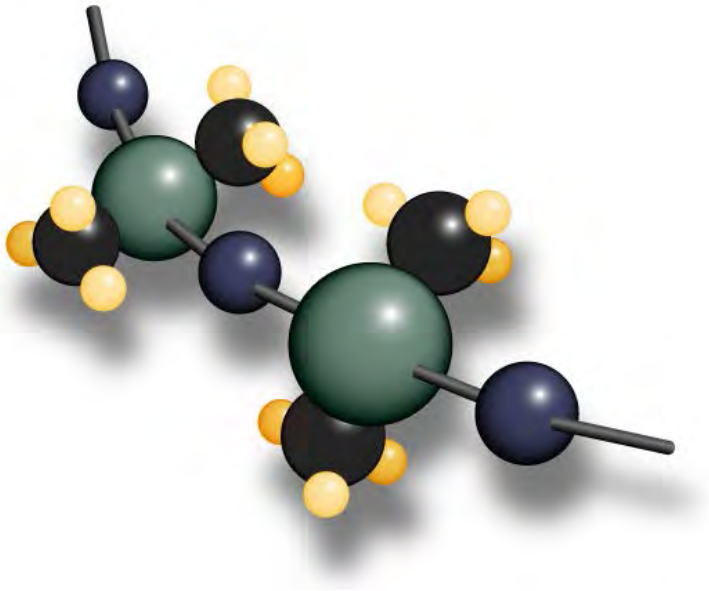

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