MED1-6300

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)

APPLICATION

- Ideal for backfilling and dampening
- Suitable for applications requiring a high purity, very soft, clear, low viscosity silicone gel
- NuSil Technology can formulate custom materials to meet specific penetration requirements

NuSil™ MED1-6300 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:			
Appearance	Translucent	ASTM D2090	002
Viscosity	1,000 cP (1,000 mPas)	ASTM D1084, D2196	001
Volatile Content	0.10 %	ASTM D2288	004
Specific Gravity	0.98	ASTM D891/D1475	022
Cured: 5 hours at 140°C (284°F)			
Penetration (Lab Line Penetrometer, 12g shaft, 1" diameter foot, 15 seconds)	5 mm	-	011
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061
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.

Version uploaded 24/12/2019

INSTRUCTIONS FOR USE

Mixing

Combine Part A: 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.

Note: Some bonding applications may require the use of a primer. NuSil Technology's MED1-161 is recommended. 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 MED1-6300 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must contact NuSil Technology.

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.

Packaging	Warranty
2 Pint Kit (910 g) 2 Gallon Kit (7.28 kg) 10 Gallon Kit (36.4 kg) 2 Drum Kit (340 kg)	12 Months

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.

Version uploaded 24/12/2019

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.

Version uploaded 24/12/2019

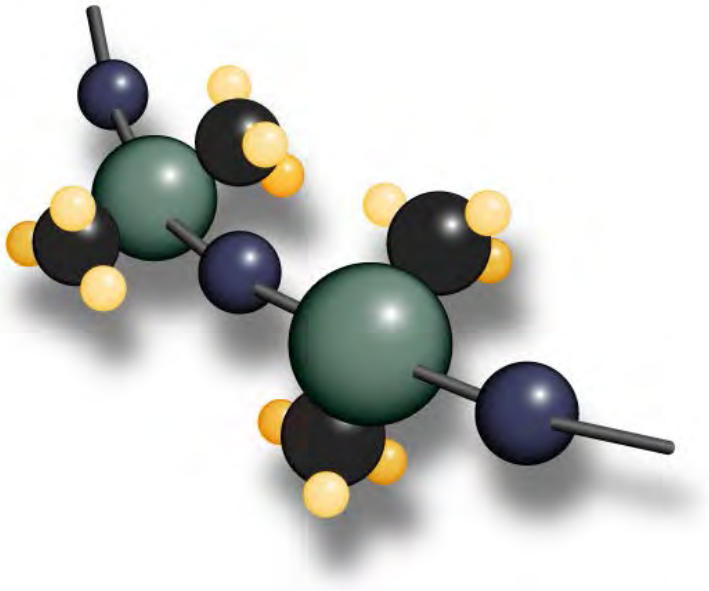
Silicone Sales & Services
UK - Ireland - Benelux

Unit 2. Network 4. Cressex Business Park,
Lincoln Road, High Wycombe, Bucks. HP12 3RF

tel: +44 (0) 1494 446610

web: https://www.silicone-polymers.com

email: sales@silicone-polymers.co.uk



Version uploaded 24/12/2019