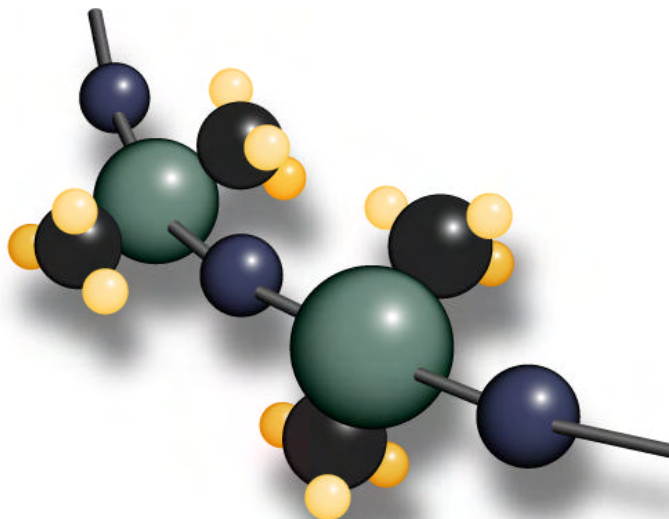


Polymer Systems Technology Limited

UK & Ireland Distributor



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Product Profile



MED-6321

Silicone Gel

NuSil Technology LLC
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www.nusil.com • silicone@nusil.com

An ISO 9001
Certified Company

Description

- An optically clear silicone gel manufactured under controlled conditions
- A two-component system of low viscosity liquids that blend easily
- NuSil Technology LLC can formulate custom materials to meet specific penetration requirements
- 1:1 Mix Ratio (Part A: Part B)

NuSil Technology's MED-6321 is a restricted product. It shall not be considered for use in human implantation for a period of greater than 29 days.

Typical Properties	Result	TEST REFERENCE	NT-TM
Uncured:			
Appearance	Transparent	D2090	002
Viscosity	1,000 cP (1,000 mPas)	D1084, D2196	001
Volatile Content	2.0% maximum	D2288	004
Specific Gravity	0.98	D891, D1475	022
Cured: 5 hours @ 140°C (284°F)			
Penetration (Lab Line Penetrometer, 12g shaft, 1" diameter foot, 15 seconds)	5 mm (0.20 inches)	-	011
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061
Elemental Analysis of Trace Metals	Pass	ASTM E 305	131

Properties tested on a lot-to-lot basis. Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please contact NuSil Technology LLC for assistance and recommendations in establishing particular specifications.

Instructions for Use

Mixing

Thoroughly mix prior to use in a ratio of 1:1 (Part A: Part B) by weight or volume. Airless mixing, metering and dispensing is recommended for production processing.

Vacuum Deaeration

Remove air entrapped during mixing by common vacuum deaeration procedures, observing all applicable safety precautions. Slowly apply full vacuum to a container rated for use and at least four times the volume of material being deaerated. Hold vacuum until bulk deaeration is complete.

Substrate Considerations

Cures in contact with most materials. Exceptions include sulfur cured organic rubbers and chlorinated rubbers, some RTV silicones and unreacted residues of some curing agents.

FDA Master File

Customers interested in authorization to reference U.S. Food and Drug Administration Master Files must contact NuSil Technology LLC.

Packaging

2 Pint Kit (910 g)
2 Gallon Kit (7.28 kg)
10 Gallon Kit (36.4 kg)
2 Drum Kit (340 kg)

Warranty

12 Months

Specifications

Do not use the typical 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.