

MED-6345

Soft silicone adhesive

DESCRIPTION

- A clear silicone gel adhesive
- A medium viscosity liquid that cures to a soft, low tack silicone gel
- 1:1 Mix Ratio (Part A: Part B)
- Solventless

APPLICATION

- Can be considered for wound care applications, scar care products, wearable monitoring devices and medical tape
- Can be used to coat various substrates

NuSil® MED-6345 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
Uncured:			
Viscosity	16,000 cP (16,000 mPas)	ASTM D1084, D2196	001
Appearance	Translucent	ASTM D2090	002
Work Time	30 minutes	-	008
Cured: 3 hours at 60°C (140°F)			
Penetration (62.4g cone, 60 seconds)	16.5 mm	-	011
Surface-Tack	5.0 psi	ASTM D429	103
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.

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.

Note: Some bonding applications may require the use of a primer. NuSil'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 MED-6345 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

Packaging

2 Pint Kit (0.910 kg)
2 Gallon Kit (7.28 kg)
10 Gallon Kit (36.4 kg)
2 Drum Kit (340 kg)

Warranty

12 Months

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 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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