

MED1-1356

Pressure sensitive silicone adhesive

DESCRIPTION

— One-part, non-curing, pressure sensitive adhesive

APPLICATION

- Well suited for use as an adhesive for bonding and sealing silicone materials
- For applications requiring the bonding of silicone to metals, urethanes and various other substrates
- Non-irritating to skin
- Use for medical tapes and fasteners, external incontinence devices, transdermal skin patches, hair replacement adhesives, and special effect adhesives

NuSil™ MED1-1356 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:		·	·
Appearance	Translucent	ASTM D2090	002
Viscosity	245 cP (245 mPas)	ASTM D1084, D2196	001
Non-Volatile Content	50 %	ASTM D2288	004
FT-IR Spectroscopy	Pass	-	057
Cured: 24 hours minimum at ambient tempe	rature and humidity		
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061
Cured: 90 minutes at 150°C (302°F)	•		·
Release Force of PSA	11 ppi (1.9 kN/m)	ASTM D1876	085
PSA Blunt Probe Test	1.5 lbs (0.7 kg)	ASTM D2979	122

The above properties are tested on a lot-to-lot basis. Do not use as a basis for preparing specifications. Please <u>contact</u> NuSil Technology for assistance and recommendations in establishing particular specifications.



BIOCOMPATIBILITY

MED1-1356 passes testing for the following (after solvent evaporation): Cytotoxicity, In Vitro Hemolysis, Systemic Toxicity, Intracutaneous Study, and 1 week Muscle Implantation.

INSTRUCTIONS FOR USE

Surface Preparation

Thoroughly clean surfaces being bonded or built-up with silicone adhesive using a non-oily cleaner or mild soap to remove any surface contaminants. Do not use synthetic detergents or oil-based soaps, as they may be absorbed and subsequently leach out. Rinse first with hot water, followed by a thorough rinse using distilled water. Use compatible degreasers to clean metal surfaces.

Bonding Applications

Spread a layer of silicone adhesive on one of the surfaces. Squeeze both surfaces together to bond. Apply sufficient pressure to ensure full contact without forcing the silicone adhesive from between the pieces.

Note: Some bonding applications may require the use of a primer. NuSil Technology's MED-160 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-1000 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 <u>contact</u> 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 <u>contact</u> NuSil Technology for assistance and recommendations in establishing particular specifications.

Packaging

2 Ounce (45 g)

1 Pint (400 g)

1 Gallon (3.4 kg) 5 Gallon (17.0 kg)

1 Drum (180 kg)

Warranty

12 Months

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 <u>contact</u> 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 <u>contact</u> NuSil Technology with any questions about product safety information.

BIOMATERIALS PREMIUM CARE LINE



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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