

MED1-161

Silicone primer

DESCRIPTION

- One component primer supplied in VM&P Naphtha
- Easy to use, air-drying, one-part primer designed for use with platinum-cured systems
- Flash Point (TCC) of 17°C (63°F)
- Convenient container sizes yield less waste

APPLICATION

 Improves adhesion of silicones to various substrates including: metals (such as stainless steel, steel, copper and aluminum), ceramics, rigid plastics, and other silicone materials

NuSil® MED1-161 may be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

Typical Properties	Average Result	Standard	NT-TM
Appearance	Translucent	ASTM D2090	002
Specific Gravity, Pycnometer	0.77	ASTM D891, D1475	022
Percent Solids	4.0%	ASTM D2369	047
Devolatilized: 2 hours minimum at ambient	temperature and humidity		
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87>	061
		ISO 10993-5	

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

Storage and Handling

- 1. Decant the amount of primer needed from the original container into a secondary container.
- Containers should remain sealed when not in use. Silicone
 primers will react with atmospheric moisture and hydrolyze.
 Precautions should be taken to minimize exposure to
 moisture. Note: The formation of moderate amounts of
 precipitate as a result of hydrolyzation is inherent in this
 material and will not adversely affect its performance.
- 3. It is recommended to fill empty space in container with a dry gas, such as argon or nitrogen, before sealing.
- 4. Discard any primer remaining in secondary container when application is complete. Do not return primer from secondary container to the original container.

Instructions for Application

- 1. Using gloves and a lint-free wipe, clean the surface to be primed with a cleaning agent or solvent.
- 2. Apply primer to a lint free wipe and apply a thin uniform coat.
- 3. Remove excess primer by gently wiping with a clean lint-free wipe
- 4. Over-primed surfaces will decrease the effectiveness of the primer. A thick, chalky white appearance of the primed surface is indicative of over-use.
- Allow to dry for 30 minutes at room temperature and 50% relative humidity. This primer is activated by atmospheric moisture, therefore, lower levels of humidity require longer drying times.
- 6. Apply the appropriate NuSil adhesive/sealant.

Note: NuSil's primers are supplied in flammable hydrocarbon solvents. Keep away from heat and open flames. Use only with adequate ventilation.

FDA MASTER FILE

A Master File for MED1-161 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must <u>contact</u> NuSil.

REACH COMPLIANCE

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

Packaging

2 Ounce (0.045 kg)

4 Ounce (0.090 kg) 8 Ounce (0.180 kg)

16 Ounce (0.340 kg)

1 Gallon (2.88 kg)

Warranty

12 Months

SPECIFICATIONS

Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please <u>contact</u> 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 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 <u>contact</u> NuSil for assistance and recommendations when establishing

BIOMATERIALS IMPLANT LINE



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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