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MED1-161

Silicone primer

DESCRIPTION

- Specially formulated primer
- One component primer supplied in VM&P Naphtha requires no mixing
- Easy to use, air-drying, one-part primer designed for use with platinum-cured systems where conventional silicone primers are insufficient
- 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
Uncured:	·		
Appearance	Translucent	ASTM D2090	002
Percent Solids	4.5%	ASTM D2369	047
Specific Gravity, Pycnometer	0.77	ASTM D891, D1475	022
Cured: 2 hours minimum at ambient tempe	rature and humidity		
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87>	061
		ISO 10993-5	

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.





INSTRUCTIONS FOR USE

Storage and Handling

1. Decant the amount of primer needed, from the original container into a secondary container.

2. 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, clean the surface to be primed using a lint-free wipe with 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.

5. 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 Technology adhesive/sealant.

Note: NuSil Technology'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 Technology.

REACH COMPLIANCE

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

Packaging
1 Ounce (28g)
2 Ounce (45 g)
4 Ounce (90 g)
8 Ounce (180 g)
16 Ounce (340 g)
1 Gallon (2.88 kg)

Warranty 12 Months

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.

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

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BIOMATERIALS IMPLANT LINE





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.

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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