LIFE SCIENCES IMPLANT LINE



DESCRIPTION

- One-part, solvent-free silicone
- Cures at room temperature upon exposure to atmospheric moisture

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

NuSil Technology's MED-2000 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
Extrusion Rate**	2.5 g/min.	ASTM C603	033
Tack-Free Time	13 minutes	ASTM C679	005
Cured: 72 hours minimum at ambient temperature	and humidity		
Specific Gravity	1.08	ASTM D792	003
Durometer, Type A	25	ASTM D2240	006
Tensile Strength	1,375 psi (9.5 MPa)	ASTM D412	007
Elongation	800%	ASTM D412	007
Tear Strength	80 ppi (14.1 kN/m)	ASTM D624	009
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87>	061
		ISO 10993-5	
Elemental Analysis of Trace Metals	Pass	ASTM E305	131



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. ** Performed using a Semco model 250-A pneumatic gun with a 14 gauge nozzle orifice and 90 +/- 5 psi air pressure.

INSTRUCTIONS FOR USE

Apply MED-2000, supplied in cartridges, with the use of appropriate dispensing equipment. Do not store alcohol near the worksite as traces of alcohol inhibit the catalytic system of the adhesive.

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.

Packaging

8 Gram Tube

2 Ounce Tube (59 mL)

5 Ounce Tube (148 mL)

6 Ounce Semco® Tube

12 Ounce Semco® Tube

Warranty

12 Months

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

Curing Time

Curing or vulcanization time depends upon the thickness of the silicone adhesive layer, relative humidity, and accessibility of atmospheric moisture to the curing adhesive. For sections of typical thickness, a relative humidity level between 20-60% is recommended to cure the adhesive at room temperature.

Generally the adhesive forms a thick, tack-free outer skin for thick section films within a few minutes after application. The vulcanization rate slows when exposing very thin films to excessive humidity (\geq 80% relative air humidity). For films below 80 microns, the relative air humidity should be within 30% - 50%.

Because MED-2000 cures upon exposure to atmospheric moisture, keep tubes tightly closed when not in use. A plug of cured material may form in the tip of the tube. Remove or dispense the plug from the tube before using.

Non-Sterile Packaged Units

The acidic nature of MED-2000 provides a natural bactericidal effect. While containers may be relatively free of microorganisms, they can not be considered sterile unless subjected to a validated sterilization process. When the adhesive is fully cured it can withstand sterilization with ethylene oxide, dry heat, or steam autoclaving. The size and shape of fabricated articles must be considered when establishing the conditions of sterilization. Larger quantities and larger parts may require longer periods of heating and may retain ethylene oxide longer than small parts. It is the user's responsibility to determine the out-gassing time required for a particular application if ethylene oxide sterilization methods are used.



Caution

Do not use MED-2000 in its uncured state to repair or encapsulate living tissue in the body. During curing, approximately 4-5% acetic acid (vinegar-like odor) is generated in vapor form. Avoid contact with eyes and skin, as uncured adhesive irritates. Take appropriate precautions if wearing contact lenses. In case of contact, flush eyes with water, use a dry towel to remove from skin and contact a physician. Keep out of REACh of children.

FDA MASTER FILE

A Master File for MED-2000 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

MED-2000 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACh) regulation (European Union 1907/2006). MED-2000 does not contain any of the chemicals or substances identified as Substances of Very High Concern (SVHC) by the European Chemicals Agency (ECHA), which oversees REACh compliance.

Please contact 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.

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.

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.

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