

DESCRIPTION

- One part, low slump, solvent-free translucent 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-1137 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: | | | |
| | Tropolicopat | | 000 |
| Appearance | Translucent | ASTM D2090 | 002 |
| Flow Rate | 0.2 inches | ASTM D2202 | 019 |
| Tack-Free Time | 9 minutes | ASTM C679 | 005 |
| Cured: 72 hours minimum at ambient temperature and humidity | | | |
| Specific Gravity | 1.07 | ASTM D792 | 003 |
| Durometer, Type A | 30 | ASTM D2240 | 006 |
| Tensile Strength | 700 psi (4.8 MPa) | ASTM D412 | 007 |
| Elongation | 560% | ASTM D412 | 007 |
| Stress at 200% Strain | 170 psi (1.2 MPa) | ASTM D412 | 007 |
| 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.

INSTRUCTIONS FOR USE

Apply MED-1137, supplied in cartridges, with the use of appropriate dispensing equipment. Do not store alcohols near the worksite as traces of alcohol inhibit the adhesive's catalytic system.

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 <u>www.nusil.com</u> and review <u>Choosing a Silicone Primer/Adhesive System</u>

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-1137 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-1137 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.

10 cc Syringe Packaging

Over time, MED-1137 may display small voids near the plunger of the 10 cc packaging configuration. This behavior is typical and has no impact on the quality or quantity of adhesive dispensed.



Packaging

100 x 10 cc Syringe 8 Gram Tube 2 Ounce Tube (59 mL) 5 Ounce Tube (148 mL) 6 Ounce Semco® Tube

Warranty

12 Months

Caution

Do not use MED-1137 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-1137 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-1137 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACh) regulation (European Union 1907/2006). MED-1137 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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