LIFE SCIENCES IMPLANT LINE

MED-6381 Firm RTV Silicone Gel

DESCRIPTION

- Pourable, three-component silicone gel
- 97: 2.50: 0.50 Mix Ratio (Base:Crosslinker:Catalyst)

APPLICATION

- Ideal for potting, encapsulating, casting, backfilling and dampening
- Suitable for applications requiring a firm, unfilled RTV silicone gel

NuSil Technology's MED-6381 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 |
| Viscosity | 10,000 cP (10,000 mPas) | ASTM D1084, D2196 | 001 |
| Cured: 24 hours minimum at ambient temperature and Specific Gravity | humidity .98 | ASTM D792 | 003 |
| Durometer, Type 00 | 75 | ASTM D2240 | 006 |
| Tissue Culture (Cytotoxicity Testing) | Pass | USP <87> ISO 10993-5 | 061 |
| 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

Mixing

Add 2.50% crosslinker and 0.50% catalyst by weight to the base material and mix thoroughly for two minutes. Airless mixing, metering, or dispensing equipment is recommended for production operations. If mixing by hand, take care to minimize air entrapment.

Vacuum Deaeration

Remove air entrapped during mixing by common vacuum deaeration procedure, observing all applicable safety precautions. Slowly apply full vacuum to a suitable container of at least four times the volume of material being de-aired. Hold vacuum until bulk deaeration is complete.

Packaging

1 Pint Kit (471 g)

Warranty

12 Months

Note: Some bonding applications may require the use of a primer. NuSil Technology's MED-160 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-6381 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

MED-6381 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACh) regulation (European Union 1907/2006). MED-6381 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.

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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.

PATENT / INTELLECTUAL PROPERTY WARNING

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