High purity silicone gel

DESCRIPTION

— A high purity, clear silicone gel manufactured under controlled conditions
— Resists fracturing under stress
— Easy mixing, two-component, low viscosity system
— 3:1 Mix Ratio (Part A: Part B)
— Alternate mix ratios may be considered to adjust penetration

APPLICATION

— Ideal for backfilling and dampening
— Suitable for applications requiring a high purity, clear silicone gel that resists fracturing under stressed conditions.
— NuSil Technology can formulate custom materials to meet specific penetration requirements

NuSil™ MED3-6311 may be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

<table>
<thead>
<tr>
<th>Typical Properties</th>
<th>Average Result</th>
<th>Standard</th>
<th>NT-TM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncured:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appearance</td>
<td>Translucent</td>
<td>ASTM D2090</td>
<td>002</td>
</tr>
<tr>
<td>Viscosity</td>
<td>500 cP (500 mPas)</td>
<td>ASTM D1084, D2196</td>
<td>001</td>
</tr>
<tr>
<td>Volatile Content</td>
<td>0.10 %</td>
<td>ASTM D2288</td>
<td>004</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>0.97</td>
<td>ASTM D891/D1475</td>
<td>022</td>
</tr>
</tbody>
</table>

Cured: 3.5 hours at 160°C (320°F)

<table>
<thead>
<tr>
<th>Property</th>
<th>Result</th>
<th>Standard</th>
<th>NT-TM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penetration (Lab Line Penetrometer, 12g shaft, 1” diameter foot, 5 seconds)</td>
<td>2.6 mm</td>
<td>-</td>
<td>011</td>
</tr>
<tr>
<td>Tissue Culture (Cytotoxicity Testing)</td>
<td>Pass</td>
<td>USP &lt;87&gt;</td>
<td>061</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ISO 10993-5</td>
<td></td>
</tr>
<tr>
<td>Elemental Analysis of Trace Metals</td>
<td>Pass</td>
<td>ASTM E305</td>
<td>131</td>
</tr>
</tbody>
</table>

The above properties are tested on a lot-to-lot basis. Do not use as a basis for preparing specifications. Please contact NuSil Technology for assistance and recommendations in establishing particular specifications.
INSTRUCTIONS FOR USE

Mixing
Combine Part A and Part B in a 3 : 1 mix ratio prior to use. 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.

Substrate Considerations
Cures in contact with most materials common to biomedical assemblies. Exceptions include: sulfur-cured organic rubbers, latex, chlorinated rubbers, some RTV silicones and unreacted residues of some curing agents.

Note: Some bonding applications may require the use of a primer. NuSil Technology’s MED1-161 is 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 MED3-6311 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
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 contact 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 contact 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 contact 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.

Packaging Warranty
- 4 Pint Kit (1.82 kg) 12 Months
- 4 Gallon Kit (14.77 kg)
- 20 Gallon Kit (74.1 kg)
- 4 Drum Kit (695 kg)
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.