



BIOMATERIALS IMPLANT LINE

MED-6613-2

Black silicone coating and marking ink

DESCRIPTION

- Two-part, addition –cure black silicone ink dispersed in xylene
- Cures via addition-cure chemistry
- 1:1 Mix Ratio (Part A: Part B)

APPLICATION

- Ideal for use as a marking ink for silicone parts and other components on which the coating must maintain long-term stability
- Use in applications requiring a rapid cure schedule
- For use in pad and transfer printing applications
- Provides high opacity for single print applications

NuSil™ MED-6613-2 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	Black	ASTM D2090	002
Non-Volatile Content, Part A	60%	ASTM D2288	004
Non-Volatile Content, Part B	60%	ASTM D2288	004
Viscosity, Part A	900 cP (800 mPas)	ASTM D1084, D2196	001
Viscosity, Part B	800 cP (11,500 mPas)	ASTM D1084, D2196	001
Cured: 5 minutes at 150°C (302°F)			•
Adhesion	Pass	ASTM D3359	039
Cured: 30 minutes minimum at ambient ter	nperature and humidity		
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87>	061
		ISO 10993-5	

The test data shown for this material is the average value for typical properties. All of these properties may not be tested on a lot to lot basis and cannot be used to draft specifications. Please <u>contact</u> us for assistance and recommendations in establishing limits for product specifications.

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INSTRUCTIONS FOR USE

To ensure homogeneity, stirring Part A and Part B individually prior to use is recommended. Although material cures rapidly at elevated temperatures, adhesion may be significantly improved by utilizing a post-curing period. Contact us for material-specific post-curing instructions.

Note: Some bonding applications may require the use of a primer. NuSil's MED1-161 is recommended. For more information on primer selection, <u>contact</u> us.

Mixing

Thoroughly stir individual components prior to addition to ensure homogeneity. Mix in a 1:1 ratio by weight or volume. Exercise care to prevent solvent loss during deairing. Accomplish additional dilution for thin film applications by adding appropriate solvent.

Warning: Consult the MSDS for MED-6613-2 prior to use, as its solvent carrier is hazardous.

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.

FDA MASTER FILE

A Master File for MED-6613-2 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must <u>contact</u> us.

REACH COMPLIANCE

Please <u>contact</u> our Regulatory Compliance department with any questions or for further assistance.

SPECIFICATIONS

Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please <u>contact</u> us for assistance and recommendations in establishing limits for product specifications.

Packaging

2 Pint Kit (0.91 kg) 2 Gallon Kit (6.8 kg)

Warranty

6 Months

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC is 6 months from the date of shipment when stored below 40°C in original unopened containers. Unless NuSil provides a specific written warranty of fitness for a particular use, NuSil's sole warranty is that the product will meet NuSil's then current specification. NuSil 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'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 expressly disclaims any liability for incidental or consequential damages.

WARNINGS ABOUT PRODUCT SAFETY

NuSil 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 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 makes no warranty concerning fitness for any use or purpose. NuSil has completed no testing to establish safety of use in any medical application.

NuSil has tested this material only to determine if the product meets the applicable specifications. (Please <u>contact</u> us for assistance and recommendations when establishing specifications.) When considering the use of NuSil products in a particular application, review the latest Material Safety Data Sheet and <u>contact</u> us 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

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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 disclaims any expressed or implied warranty against the infringement of any domestic or international patent/intellectual property right. NuSil 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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NO Bubbles



NO Blades



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Contact us today to discuss your options: sales@silicone-polymers.co.uk



Silicone Cleaning & Removal

To ensure a safe and clean environment and to prevent contamination that could impact your silicone in the future, we recommend using the following products on the link below:

PST- Silicone Cleaning and Removal

Polymer Systems Technology Limited

Unit 2, Network 4, Lincoln Road, Cressex Business Park, High Wycombe, Buckinghamshire, HP12 3RF www.silicone-polymers.com