

MED2-4502

BARIUM SULFATE HEALTHCARE SILICONE MASTERBATCH

DESCRIPTION

- A white, single component masterbatch, with the consistency of
- a clay-like material
- Consists of Barium Sulfate dispersed in a vinyl-functional silicone polymer which covalently bonds into the matrix of platinum-cured silicone systems

APPLICATION

- For easy and more precise addition of Barium Sulfate to high consistency silicone elastomers, suitable for molding, calendaring or extrusion
- Reduces production time and eliminates use of powders that may contaminate clean room environments

NuSil Technology's MED2-4502 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	White	ASTM D2090	002
Plasticity	218 mils (5.5 mm)	ASTM D926	058
Non-Volatile Content	99%	ASTM D2288	004
Specific Gravity	2.31	ASTM D792	003
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061

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

Supplied as a single component material with a fixed Barium Sulfate concentration of 75%. Easily combine in desired proportions with other high consistency materials on a two-roll mill. Combine and cross-blend components until thoroughly mixed. Take the usual precautions to avoid contamination of the high consistency material with which the product is mixed. For further information, please see [Mixing Masterbatches - Guidelines for Mixing a Barium Sulfate Masterbatch into a Silicone Product](#).

Packaging

1 Pound (450 g)
5 Pound (2.27 kg)
25 Pound (11.38 kg)

Warranty

12 Months

FDA MASTER FILE

A Master File for MED2-4502 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

MED2-4502 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACH) regulation (European Union 1907/2006). MED2-4502 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 [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.

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