

MED3-4502

Titanium dioxide healthcare silicone color masterbatch

DESCRIPTION

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

APPLICATION

- For easy and more precise pigmentation of 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™ MED3-4502 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 | 87 mils (2.2 mm) | ASTM D926 | 058 |
| Non-Volatile Content | 99% | ASTM D2288 | 004 |
| Specific Gravity | 2.28 | 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 Titanium Dioxide 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.

FDA MASTER FILE

A Master File for MED3-4502 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

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

Packaging

1 Pound (450 g)
5 Pound (2.27 kg)
25 Pound (11.34 kg)

Warranty

12 Months

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.

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.



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