MED2-4102-6

Color masterbatch for high consistency silicone elastomer

DESCRIPTION

- A green, 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
- Supported by USP Class VI and ISO 10993 Biological testing (reference Biological Testing Data Table)

APPLICATION

- For easy and more precise pigmentation of high consistency silicone materials, suitable for molding, calendering or extrusion
- Reduces production time and eliminates use of powders that may contaminate clean room environments
- Strict quality controls ensure color consistency
- Homogeneity of masterbatch minimizes agglomerates

NuSil® MED2-4102-6 shall not 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	Green	ASTM D2090	002
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061

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 contact NuSil for assistance and recommendations in establishing limits for product specifications.

INSTRUCTIONS FOR USE

The color masterbatch is supplied as a single component material. Easily combine in desired proportions with other high consistency materials on a two-roll mill. Suggested concentration is 2 pph masterbatch by weight. The biological testing performed in support of these products does not cover masterbatch concentration in excess of 4 pph. Combine and cross-blend components until thoroughly mixed. Take the usual precautions to avoid contamination of the materials.

CUSTOM COLORS

Custom colors, obtained through the blending of qualified base colors, are available upon request. Please contact NuSil for further information.

FDA MASTER FILE

A Master File for MED1-4102-2 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must contact NuSil.

REACH COMPLIANCE

Please contact NuSil's 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 contact NuSil for assistance and recommendations in establishing limits for product specifications.

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC is 12 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.

Packaging	Warranty
1 Pound (0.45 kg) 5 Pound (2.27 kg) 25 Pound (11.34 kg)	12 Months

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 contact NuSil 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 contact NuSil 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 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.

BIOLOGICAL TESTING DATA TABLE

Test	Standard/Method	Test Results
Cytotoxicity Study Using The ISO Elution Method - 1X MEM Extract	ISO 10993-5 USP <87>	A-Noncytotoxic B-Noncytotoxic C-Noncytotoxic
In Vitro Hemolysis Study (Modified ASTM-Extraction Method)	ISO 10993-4	A-Nonhemolytic
USP and ISO Systemic Toxicity Study Extract*	ISO 10993-11 USP <88>	A-Nontoxic
Sub Chronic Systemic Toxicity (4 Week)	ISO 10993-11 ISO 10993-6	A-Nontoxic
ISO Intracutaneous Study Extract*	ISO 10993-10 USP <88>	A-Nonirritant
ISO Muscle Implantation Study (1 Week)*	ISO 10993-6 USP <88>	A-Slight irritant
Genotoxicity: Bacterial Reverse Mutation Study (DMSO and Saline Extract)	ISO 10993-3	A-Nonmutagenic
USP Pyrogen Study Material Mediated	ISO 10993-11 USP <151>	A-Nonpyrogenic
ISO Maximization Sensitization Study	ISO 10993-10	A-Nonsensitization
Mammalian Mutagenesis Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance for Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Corning Silastic Materials.' "	-------	----------
Cytogenic Damage Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance For Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Corning Silastic Materials.' "	-------	----------

* Product meets USP Class VI test requirements.

Note: The biological testing performed in support of these products does not cover masterbatch concentration in excess of 4 pph.

TEST ARTICLE CONDITIONING

Sample	Condition
A	Per NuSil Product Specification
B	Condition A + Hot Air Oven 12 Hours at 200°C
C	Condition A + Autoclave 2 Hours at 15 psi