MED-4102-2

Color masterbatch for high consistency silicone elastomer

DESCRIPTION

- A black, 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™ MED-4102-2 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	Black	ASTM D2090	002
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

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 eight base colors, are available upon request. Please contact NuSil Technology for further information.

FDA MASTER FILE

A Master File for MED-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 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.

Packaging	Warranty
50 Gram 1 Pound (455 g) 5 Pound (3.64 kg) 25 Pound (18.2 kg)	12 Months

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.

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.

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
ISO Intracutaneous Study Extract*	ISO 10993-10 USP <88>	A-Nonirritant
ISO Muscle Implantation Study (1 Week)*	ISO 10993-6 USP <88>	A-Nonirritant
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

* 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%.

TEST ARTICLE CONDITIONING

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