

MED50-4900-6

Color masterbatch for liquid silicone elastomers

DESCRIPTION

- A translucent green, single component masterbatch, with the consistency of a low viscosity paste
- 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 liquid silicone rubbers and low consistency elastomers suitable for injection molding
- Reduces production time and eliminates use of powders that may contaminate clean room environments
- Strict quality controls ensure color consistency

NuSil™ MED50-4900-6 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 | Translucent Green | 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. Can be combined manually or by third stream when using a dosing system. 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. 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 Technology for further information.

FDA MASTER FILE

A Master File for MED50-4900-6 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

Packaging

50 Gram
1 Pint (455 g)
1 Gallon (3.64 kg)
5 Gallon (18.2 kg)

Warranty

12 Months

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.

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 |
| 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-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 |