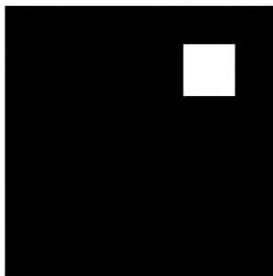




Creative Partners in a Material World

Color Masterbatch Selection Guide



COLOR MASTERBATCH SELECTION GUIDE

NuSil's color masterbatches offer off-the-shelf pigmenting options for silicone devices intended for the medical device market. NuSil Technology and GSDI co-developed a line of silicone masterbatches for coloring liquid silicone rubbers (LSRs) and high consistency silicone rubbers (HCRs). The color masterbatch can be used with NuSil's line of unrestricted (long-term implantable) and restricted (less than 30 day implant, or non-implant applications) silicone products.

The color masterbatches consist of pigments dispersed in vinyl functional silicone polymers that when used in conjunction with platinum systems will participate in the elastomer's curing process, becoming part of the polymer matrix.

Benefits of using color masterbatches:

PROCESSING

- » Eliminate dry pigment contamination in clean room environments
- » Reduce costly cleaning time
- » Provide a means to easily pigment silicone elastomer systems

PERFORMANCE

- » Unparalleled color consistency
- » Improved device aesthetics
- » No 'bleed' out will occur in the final cured state
- » Minimal effect on physical properties

REGULATORY SUPPORT

What differentiates NuSil's color masterbatches from other color options in the medical device market is the level of biological testing performed on these materials. NuSil color masterbatches are supported by the following biological test data and comprehensive Master Access Files (MAF) submitted to the FDA.

Section	Test	Tested per USP	Tested per ISO 10993	Test Results
1	In Vitro Hemolysis Study (Modified ASTM-Extraction Method)	Yes	Yes	Nonhemolytic
2	USP and ISO Systemic Toxicity Study Extract	Yes	Yes	Nontoxic
3	ISO Intracutaneous Study Extract	Yes	Yes	Nonirritant
4	ISO Muscle Implantation Study (1 Week)	Yes	Yes	Nonirritant
5	ISO Muscle Implantation (12 Week)*	Yes	Yes	Nonirritant
6	Genotoxicity: Bacterial Reverse Mutation Study (DMSO Extract) (Saline Extract)	Yes	Yes	Nonmutagenic Nonmutagenic
7	USP Pyrogen Study Material Mediated	Yes	Yes	Nonpyrogenic
8	ISO Maximization Sensitization Study	Yes	Yes	Nonsensitization

* Unrestricted Materials Only



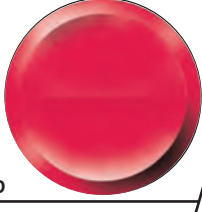
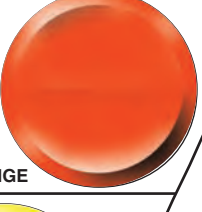
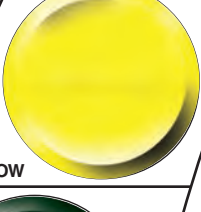
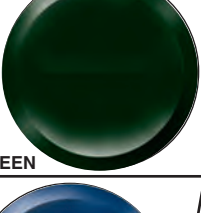
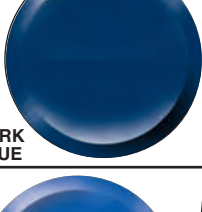

COLOR OPTIONS

- » Opaque Colors: black, white, red, orange, yellow, green, blue and dark blue
- » Translucent color palette is also available for coloring LSRs
- » Custom colors are available upon request
- » NuSil also has the capability to provide you with pre-colored versions of our LSRs, HCRs, and adhesives








For mixing instructions and further information please see Product Profiles located at www.nusil.com/colormasterbatch

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COLOR

LSR	HCR	
MED-4800-1	MED-4502-1	 WHITE
MED-4900-1	MED-4102-1	
MED-4800-2	MED-4502-2	 BLACK
MED-4900-2	MED-4102-2	
MED-4800-3	MED-4502-3	 RED
MED-4900-3	MED-4102-3	
MED-4800-4	MED-4502-4	 ORANGE
MED-4900-4	MED-4102-4	
MED-4800-5	MED-4502-5	 YELLOW
MED-4900-5	MED-4102-5	
MED-4800-6	MED-4502-6	 GREEN
MED-4900-6	MED-4102-6	
MED-4800-7	MED-4502-7	 DARK BLUE
MED-4900-7	MED-4102-7	
MED1-4800-7	MED1-4502-7	 BLUE
MED1-4900-7	MED1-4102-7	

TRANSLUCENT COLOR

	LSR
 WHITE	MED50-4800-1
	MED50-4900-1
 BLACK	MED50-4800-2
	MED50-4900-2
 RED	MED50-4800-3
	MED50-4900-3
 ORANGE	MED50-4800-4
	MED50-4900-4
 YELLOW	MED50-4800-5
	MED50-4900-5
 GREEN	MED50-4800-6
	MED50-4900-6
 DARK BLUE	MED50-4800-7
	MED50-4900-7
 BLUE	MED51-4800-7
	MED51-4900-7

UNRESTRICTED
 RESTRICTED

NuSil SILICONE TECHNOLOGY

gsdi

NuSil Technology's color masterbatches are comprised of pigments blended into vinyl functional polymers. The dispersion process and focus on pigment particle size ensures unparalleled lot to lot consistency. NuSil recommends adding these color and translucent color masterbatches at 2 parts per hundred. Customized colors are obtained by a process of blending the eight base colors and are available upon request.

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