

Masterbatches



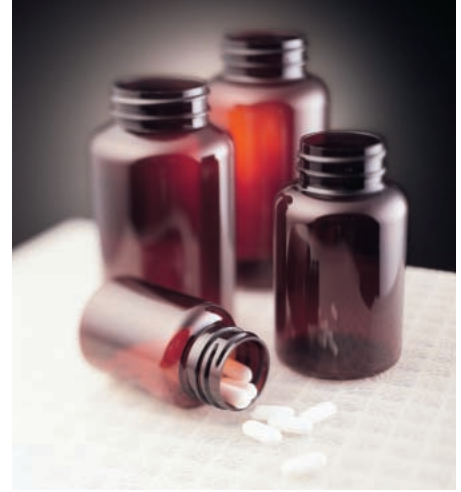
Exactly your chemistry.

*REMAFIN<sup>®</sup>-med Color Masterbatches  
for the Medical Industry*  
**Stock Color Chart**

# REMAFIN<sup>®</sup>-med Color Masterbatches for the Medical Industry – USP Class VI Series



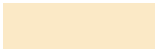






Now, selecting biocompatible and vibrant color that differentiates and defines unique style for your medical device is easy and reliable. Both standard and custom REMAFIN-med color masterbatches contain ingredients that meet the requirements for biological reactivity under United States Pharmacopeia Class VI (part 87, 88) <sup>1,2</sup>. REMAFIN-med masterbatches are available in a wide range of solid, opaque colors, translucent and transparent tints, and are suitable

for both injection molded and extrusion processes. We recommend REMAFIN-med products for evaluation <sup>1,2,6</sup> in medical devices, pharmaceutical and medical packaging as well as other healthcare products made with polyolefins and olefin-based thermoplastic elastomers (TPEs) <sup>4</sup>. These applications are typically designed for skin contact, short-term drug, body or body fluid contact where exposure time is limited to no more than 30 days <sup>3</sup>.



We recommend evaluation of these masterbatches in the following resins:

- HDPE
- LLDPE
- TPV <sup>4</sup>
- TPE
- IONOMER
- LDPE
- PP
- TPO
- EVA

	Color	PE Base	PP Base	Recommended Let-Down Ratio <sup>9</sup>	USP Class VI components <sup>1</sup>
	White	PE0SAA17700	PP0SAB17700	2%	Yes
	Marigold	PE13664975	PP13665005	2%	Yes
	Linen	PE82664957	PP82665090	2%	Yes
	Earth	PE83664958	PP83665091	2%	Yes
	Poppy	PE23664901	PP23665071	2%	Yes
	Lipstick	PE33665080	PP33665353	2%	Yes
	Carnation	PE32665081	PP32665354	2%	Yes
	Sky	PE52665218	PP52665373	2%	Yes
	Sailor Blue	PE53665219	PP53665374	2%	Yes

Combining REMAFIN-med color masterbatches with USP Class VI or ISO 10993 compliant polymers allows you to confidently select appropriate raw materials for device production. Clariant's REMAFIN-med masterbatches can help you:

- meet performance standards required by your company, your customers and regulatory agencies
- achieve polymer compatibility and end-use performance
- avoid the time and expense of testing unknown colorants
- reduce the chance of errors that could require reformulation and costly duplication of product tests and analysis – by using ingredients already tested for biocompatibility <sup>1</sup>
- accelerate your product to market by minimizing product development issues
- reduce demands on engineering resources

This translates into both financial as well as significant time savings, while delivering competitive advantages at reduced costs.

Clariant offers you support from design to production – ranging from material selection, provision of development samples, Drug Master Files (DMFs), certification and processing support.










Masterbatches for medical devices are manufactured by Clariant at specialized

sites <sup>5,8</sup>; Clariant also provides local support from a global network of over 50 locations.

**Custom colors available**

Clariant creates custom color masterbatches utilizing USP Class VI tested components <sup>1</sup> to fulfill your specific and

unique styling needs. In addition to the REMAFIN-med range, we offer a range of masterbatches specifically formulated for use in rigid and flexible plastics, in many engineering resins and in engineering elastomer applications. Contact Clariant for more information.

	Color	PE Base	PP Base	Recommended Let-Down Ratio <sup>9</sup>	USP Class VI components <sup>1</sup>
	Sapphire	PE54665220	PP54665375	2%	Yes
	Caribbean	PE63665104	PP63665301	2%	Yes
	Sea Glass	PE62665105	PP62665302	2%	Yes
	Fern	PE64665106	PP64665303	2%	Yes
	Jelly Bean	PE43664922	PP43665065	2%	Yes
	Pebble	PE72664959	PP72664969	2%	Yes
	Storm	PE74664960	PP74664971	2%	Yes
	Black	PE9SAA17700	PP9SAB17700	2%	Yes
	Custom	Custom colors can be provided.			

*Other Useful Clariant Products for the Medical Device Industry*

Custom compounds can be created in all thermoplastics, elastomers and engineering resins.

- Radiopaque compounds for x-ray visualization
- Pre-colored compounds and resins
- Static dissipative (ESD)
- Laser marking and laser welding formulas

- Custom compounds to your specifications
- High-slip, low-friction compounds
- Antimicrobial compounds and concentrates
- Performance additive masterbatches
- Custom and stock color masterbatches for every thermoplastic polymer, from ABS to PEEK



# ColorWorks™ Accelerated Product Development Services

ColorWorks supports your new product development efforts by combining compound and color selection with product performance and productivity analysis in enhanced Moldflow® programs, accelerating your path to market. ColorWorks brings together the elements of design, material performance, processing and function analyses to help you achieve your total product design objectives. Solid modeling can provide

sample parts within hours. ColorWorks support centers are located in Holden, MA; McHenry, IL; and other Clariant sites around the globe.

Clariant Masterbatches is one of the world's largest custom color and additive concentrate producers and can help you with any specific coloring or additive need. Contact your local service representative for further information.

Clariant Masterbatches products are marketed under six global brand names: REMAFIN® masterbatches for olefins; RENOL® masterbatches for engineering resins, styrenics and PVC; CESA® additive masterbatches; HYDROCEROL® chemical foaming and nucleating agents; OMNIColor® universal color masterbatches; and ENIGMA™ special effects.

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## TECHNICAL NOTES

- **Note 1** Ingredients have been tested under parts 87 and 88 of USP Class VI, Biological Reactivity Tests. Test certificates are available on request. However, because of the wide variety of medical device applications, sterilization regimen, etc., it is the responsibility of the device manufacturer to perform further appropriate tests ensuring compliance for the intended end-use application.
- **Note 2** All stock products have been added to Clariant's FDA Drug Master File (DMF) to facilitate your device submission. Contact us for access to this data.
- **Note 3** Clariant does not recommend use of REMAFIN-med products in implants or applications defined as "permanent" or "long-term," i.e., where the exposure to tissue or body fluids is greater than 30 days.
- **Note 4** TPV (Thermoplastic Elastomer Vulcanized) is a class of TPE typically made from olefinic components, but which may use other base resins. The ability to mix a polyolefin-based masterbatch in these alternative resins may be impaired.
- **Note 5** All REMAFIN-med products are manufactured under strict controls to ensure product purity and consistency.
- **Note 6** Sterilization techniques: Products were tested and found to be color stable following

ETO sterilization. Gamma, beta, dry heat and other sterilization techniques may cause some base polymers to discolor.

- **Note 7** REMAFIN-med masterbatches do not use materials that are known to be tallow-containing (animal-derived) or heavy-metal-containing as described under RoHS directives.
- **Note 8** Certificates are provided with all shipments. Your specific regulatory and documentation requests can also be discussed.
- **Note 9** REMAFIN-med products offer high color strength and are designed to give good mixing with polyolefin-type resins.



Exactly your chemistry.

Clariant's sole warranty is that our products meet their published specifications. The information in this publication corresponds to the present state of our knowledge and is intended to generally describe our products and their possible applications. Because processing conditions and end uses are outside our control, Clariant makes no warranties, express or implied, and assumes no liability in connection with any use of this information. Any existing intellectual/industrial property rights must be observed. For additional information, please contact your Clariant representative.

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