

CLARIANT



Healthcare Polymer
Solutions



**Ethicon
Medical Grade Resin Mini-Conference**

Cincinnati, OH
August 8, 2019 1:40pm – 2:00pm

what is precious to you?

Clariant HPS portfolio of offerings

Enhancing polymer performance and appearance

Materials:

- A. Masterbatches (functional additive & color concentrates)
- B. Fully formulated compounds

Capabilities / services:

- Technical services & support
- Fully formulated specialty solutions
- Regulatory & quality systems and practices that are consistent with today's requirements for materials used for the manufacture of medical products
- Toll compounding



Global medical footprint

CLARIANT'S ISO-13485-CERTIFIED MEVOPUR® PRODUCTION SITES



3 dedicated manufacturing facilities
for the global healthcare sector

Clariant Medical Grade Materials

MEVOPUR®

- Functional additive and color concentrates (masterbatches)
- Fully formulated compounds
- MEVOPUR®-LQ for liquid silicone resin and transparent medical packaging

REMAFIN®-EP

- Portfolio of polyolefin-based white masterbatches
- Designed primarily for use in pharmaceutical packaging applications

**Drug Master Files (DMF) and/or
Device Master Files (MAF) available**

Controlled, Consistent, Compliant

MEVOPUR® & REMAFIN®-EP

Controlled

- Common QMS
- ISO13485 certified since 2010
- Segregation / line clearance
- Cleaning validation
- Change control policy & procedures



Consistent

- Globally harmonized product formulations available
- Security of supply – processes validated across 3 global sites
- Lot-to-lot fingerprinting of raw materials & routine batch testing

Controlled, Consistent, Compliant

MEVOPUR® & REMAFIN®-EP

Compliant

- Library of pre-tested raw materials:
 - ✓ ISO10993 parts 4, 5, 10, 11 & 18
 - ✓ USP Class VI: USP<87>, USP<88>
 - ✓ EuPh <3.1>
 - ✓ ICHQ3D extractable metals
 - ✓ USP <661.1>



Medical material design considerations

- Application regulatory classification
- Regulatory requirements
- End use application
- Processing conditions
- Supply region/s and forecasted demand
- Material information:
 - ✓ color target (match accuracy)
 - ✓ transparent/opaque/translucent
 - ✓ finish (matte, gloss, textured)
 - ✓ resin

The image shows a 'Medical Application Design Form' (MADF) from CLARIANT. The form is a comprehensive checklist for medical material design, organized into several key sections:

- Customer Information:** Fields for Attention, Location, Project Name, Project Leader, OFVA #, and Email.
- Application Classification:** Checkboxes for Pharmaceutical Packaging, Parenteral, and FDA Class 1 (Emergency critical).
- Application Information:** Details on 'End Use of the Material', including drug delivery, laser address, surface friction, and post-treatment.
- Regulatory Requirements:** Checkboxes for ISO 10993, ISO 10873, USP, FDA 21 CFR, and EU Directive 90/269.
- Process Information:** Options for 'Clear Processing' (Injection Molding, Blow Molding) and 'Continuous Process' (Extrusion, Sheet Extrusion).
- Sample Requirements:** Fields for Order Type, Quantity, and Material Name.
- Match Accuracy:** Checkboxes for 'Consistent/Good' and 'Critical'.

The form also includes a 'Product Information' section with fields for Customer Application Name, Address, and Phone. A yellow callout box states: 'Yellow background denotes required fields; see page 1 of the form for details.' The CLARIANT logo is prominently displayed in the top right corner.

Selecting the optimal solution for your application

Clariant Medical Policy - Restrictions

Clariant products have not been designed for nor are they promoted or intended for use in:

- (a) medical devices categorized by either the United States Food and Drug Administration or the International Standards Organization (ISO) as an “implant” device; or “Permanent” as defined under US Pharmacopoeia (USP) or ISO standards; or
- (b) active implantable medical devices as defined in EU Directive 90/385/EEC as amended; or
- (c) medical devices for “Long Term” use as defined in EU Directive 93/42/EEC as amended.

Without limiting the generality of this statement, Clariant products shall not be used in any medical device application intended for:

- (1) exposure to human tissue or body fluids for 30 days or greater;
- (2) “plastic” (cosmetic or reconstructive) surgery use;
- (3) reproductive implants or any birth control device; or
- (4) any critical component in a permanently (greater than 30 days) implanted medical device that supports or sustains human life.

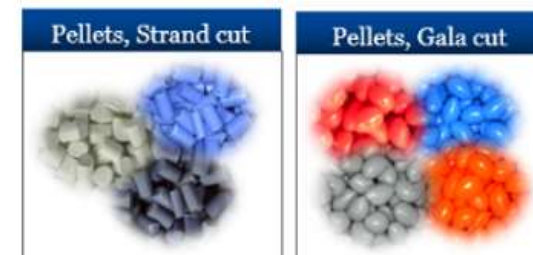
It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, with all applicable laws and regulations.

CLARIANT MAKES NO REPRESENTATION, PROMISE, OR EXPRESS OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OR LAWFULNESS OF CLARIANT’S PRODUCTS FOR USE IN ANY MEDICAL DEVICE UNLESS EXPRESSLY STATED IN A WRITTEN AGREEMENT SIGNED BY A DULY AUTHORIZED CLARIANT REPRESENTATIVE.

Version January 18, 2010

Mevopur[®] Masterbatches

standard colors



	Color	Pantone Reference	PE Base	PP Base	Transparent PP Base	PEBA Base	PC Base	Transparent PC Base	ABS Base
	White		PE0M176031	PP0M176045		AH0M415001	NC0M176058		SB0M665206
	Yellow	102C	PE1M176076	PP1M176060	PP1M176062	AH1M415002	NC1M176058	NC1M176059	SB1M664958
	Orange	158C	PE2M176044	PP2M176046			NC2M176044	NC2M664912	SB2M664939
	Red	199C	PE3M176131	PP3M176111	PP3M176113	AH3M415002	NC3M176116	NC3M176122	SB3M665037
	Pink	196C	PE3M176130	PP3M176109		AH3M415001	NC3M176117	NC3M665052	SB3M665039
	Violet	2593C	PE4M176023	PP4M176036	PP4M176039	AH4M415001	NC4M176038	NC4M176044	SB4M664978
	Light Blue	292C	PE5M176155	PP5M176169		AH5M415003	NC5M176142		SB5M665402
	Mid Blue	285C	PE5M176154	PP5M176171	PP5M176175	AH5M415002	NC5M176143	NC5M176146	SB5M665404
	Dark Blue	288C	PE5M176153	PP5M176173			NC5M176144		SB5M665406
	Light Green	346C	PE6M176128	PP6M176111			NC6M176118		SB6M665070
	Bluish Green	3145C	PE6M176126	PP6M176115			NC6M176119		SB6M665068
	Medium Green	348C	PE6M176127	PP6M176113	PP6M176118	AH6M415001	NC6M176120	NC6M176121	SB6M665072
	Dark Gray	425C	PE7M176066	PP7M176091	PP7M176094		NC7M176124		SB7M665297
	Mid Gray	Cool Grey 5C	PE7M176067	PP7M176089		AH7M415001	NC7M176125	NC7M665175	SB7M665295
	Beige	7502C	PE8M176048	PP8M176058			NC8M176058		SB8M664871
	Brown	463C / 731C	PE8M176049	PP8M176060			NC8M176059		SB8M664869
	Black	Black C	PL9M176008	PP9M176017			NC9M176008	NC9M176009	SB9M664896

custom and special effect colors
available upon request