CLARIANT

Enhancing and protecting healthcare products with polymer solutions

MEVOPUR®

what is precious to you?

Controlled, Consistent, Compliant.
MINIMIZING RISK AT EVERY STAGE OF DESIGN AND PRODUCTION

Designers and manufacturers of medical devices and pharmaceutical packaging invest significant time and money in meeting performance and regulatory standards to fulfill the increasingly stringent demands of these global markets. Materials that can help minimize the risks and costs of non-compliance in a product's development and lifecycle are vital to this process.

Clariant's package of dedicated service and expertise, product reliability and innovative material performance gives the industry the confidence it needs to address risk potential.

Our specialty formulated MEVOPUR® medical color and performance masterbatches and compounds recognize the high demands and standards of this industry, delivering consistent performance worldwide from our three sector-specific competence centers in North America, Europe and Asia.

Trusted formulation expertise, extensive medical market know-how from our global team of specialists, and exclusive development resources, combine to create a broad choice of standard and custom medical products for the medical industry. These are supported by change-control processes that ensure consistent quality for each customer.

From single-use disposables to reusable medical devices, trust Clariant's MEVOPUR® for color and performance.

Clariant
SUPPORTING RISK CONTROL AND REGULATORY COMPLIANCE

To help customers manage their risk potential, dedicated facilities and systems govern the production of Clariant's MEVOPUR® color and performance masterbatches and compounds.

Consistent performance, be it product or service-related, is a key priority at Clariant. Our customers can be confident that no matter what the application or location, they will receive the right materials and support to meet their exact specification or challenge: MEVOPUR®.

Three specialist centers of competence, one in Europe, one in Asia and one in North America, focus solely on developing and manufacturing materials for the medical and pharmaceutical sectors.

These production sites offer full manufacturing line segregation[1] to reduce risk of cross contamination between products, giving customers peace of mind regarding material purity.

Strict controls ensure the consistency and reliability of formulations and procedures around the world. Clariant implements a quality management system in line with the global harmonized standard ISO 13485 across all three plants. Common processes and standards across all three sites offer the reassurance of back-up supply facilities when required.

Our extensive experience in developing coloration and functional formulations to meet the regulatory requirements of these markets, such as USP, EuP, and DMF[2], underlines our capability to support risk reduction in device manufacturing.

A global team of specialists from R&D, production, sales and marketing, and customer service works closely with individual customers from the concept stage to develop targeted functionality for medical and pharmaceutical applications.

Tailored supply of our functional color and additive masterbatches, and pre-colored resin compounds is available in the production-ready format, quantity and turnaround time required by each customer. Consistency across the three production centers allows Clariant to deliver same product formulations to customers with operations in several continents.

Characterization of our raw materials and/or final masterbatches and compounds through careful selection, pre-testing and evaluation gives customers a clear picture of their material of choice. Our range of products includes those whose ingredients meet the requirements for biological reactivity under ISO10993-1 and United States Pharmacopeia part 87, 88 (Class VI)[3] standards.

Clariant is proud to develop material formulations that can help customers more easily comply with local regulatory requirements.

<
PRE-TESTED
Raw Materials

>
BATCH COMPARISON
to fingerprint

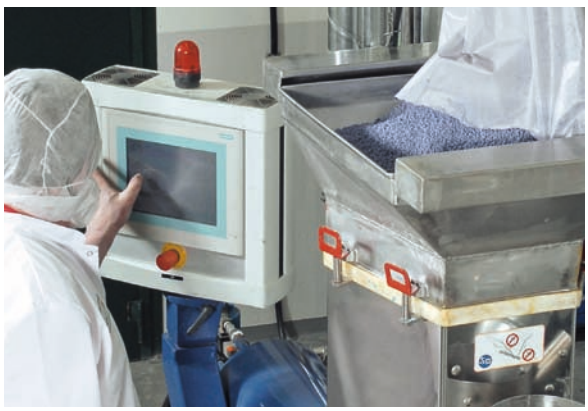
Our “open to audit” policy and controlled operations help meet FDA and other regulatory guidelines regarding fully traceable production. We strive constantly to improve our practices and reporting systems by working closely with partners in the supply chain.

Documentation support covering relevant product safety and compliance data is available to all customers, further encouraging transparency between Clariant and its customers.

Change-control processes [4] reduce the potential for product alterations, allowing customers to focus on the marketing of their product with the assurance of consistent quality and regulatory compliance in mind.

Clariant's innovative color and performance materials for medical and pharmaceutical applications [5,6] help customers respond quickly to rapidly changing preferences and demands. Products of the MEVOPUR® range meet the latest industry trends for surface functionality and aesthetics still taking into account safety and regulatory compliance.

Clariant
TRUSTED MATERIALS



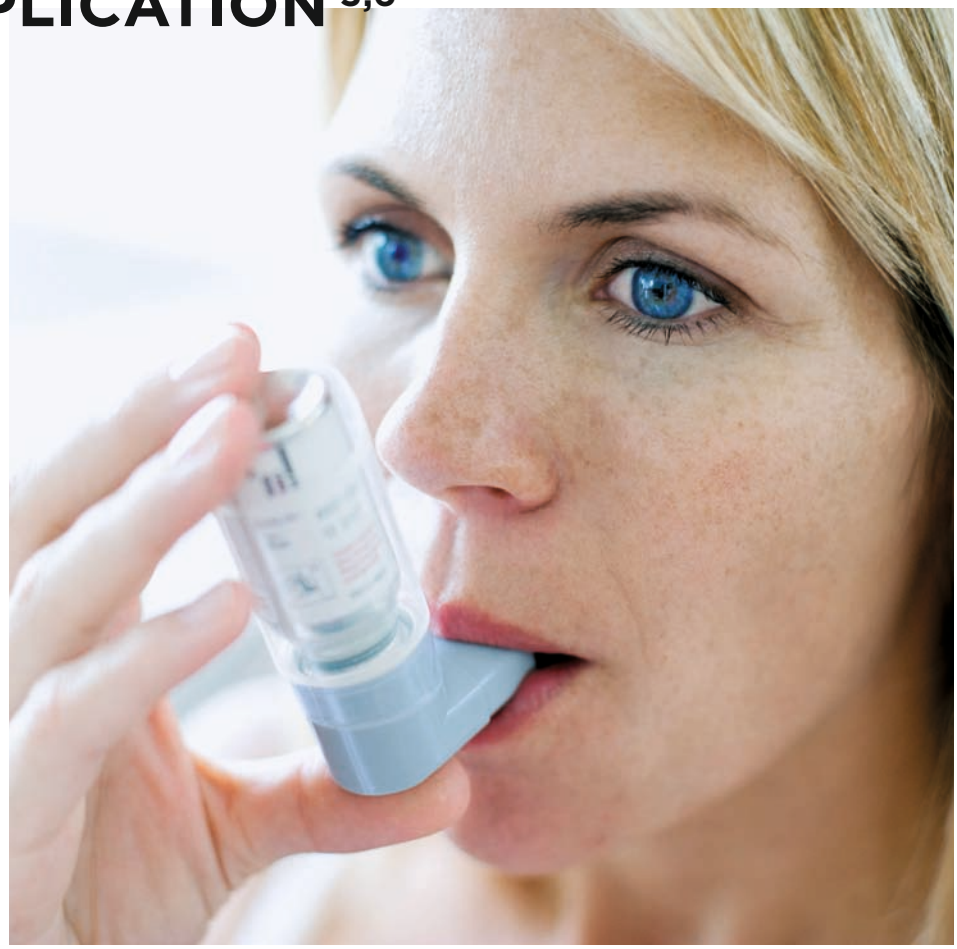
—
GLOBAL ISO 13485
Production sites.

Our expertise and market understanding is based on numerous years of working in these highly-demanding sectors. The result: an ever-expanding portfolio of compounds and masterbatches, compatible with all thermoplastic processes utilized by the industry, which combines creativity with production efficiency for our customers.

To meet preferred manufacturing processes, color is provided as color concentrate masterbatches for dilution into another polymer or as small lot pre-color compounds.

MEVOPUR® covers the wide range of polymers and thermoplastic elastomers (TPEs) used in the medical and pharmaceutical sectors. These include PE, PP, ABS, SAN, PC/ABS, PC, PA6, 66 and 12, cyclic olefins (COP), high performance polymers, and elastomers such as EVA, SEBS, TPU and PEBA.

Controlled, Consistent, Compliant and creative
FOR YOUR APPLICATION [5,6]



When it comes to boosting the functionality and brand appeal of medical and pharmaceutical applications, Clariant is at the cutting-edge of industry creativity.
Our MEVOPUR® color and performance-driven product solutions provide:

Product differentiation for your device or pharmaceutical packaging through the use of vibrant colors.
To enhance our normal color matching process, Clariant's specialist design team based at ColorWorks® Design Centers at seven strategic locations around the world works closely with customers from the early design stage to choose compliant but inspirational colors for the relevant polymer. Customers can create a distinctive style for a medical device still taking into account safety and regulatory compliance. This accelerates the design and regulatory approval processes.

Visualization of surgical devices [5].
Using the different options in radiopaque technology, even thin wall sections can be seen when in the body.

Surface engineering advantages that help to improve the ease of use and reliability of devices.
For example:

- Activation of the polymer for laser marking providing ink or solvent residue-free identification;
- Fluorine-free lubrication systems lowers friction between parts reducing force to rotate, slide and actuate helping the reliability of metered dose devices;
- Permanent antistatic agents help to ensure smooth delivery of powdered drugs;
- Addition of anti-microbial additives helps to reduce the transmission of bacteria and spread of infection;
- Covert and non-covert anti-counterfeit systems can be added to the polymer thereby contributing to your brand-protection strategy.

Enhancing and protecting healthcare products with polymer solutions ...

MEVOPUR® color and performance master batches and compounds add value to a wide range of applications.

Medical devices
- Drug delivery
- Catheters
- Renal care / dialysis
- Surgical instruments
- Dental instruments
- Medical device packaging
- Electronic instruments and accessories for monitoring

Pharmaceutical packaging
- Vials, ampoules
- Bottles for pills, liquid medicines
- Blister packaging

Diagnostics
- Blood analysis
- In Vitro Diagnostics (IVD) equipment

Mevopur® Standard
ISO10993 / USP COLORS

Colors for brand differentiation or for safe identification

Clariant has introduced a standard color range whose ingredients have been biologically evaluated to ISO10993-1 and USP parts 87 & 88 (Class VI)[3]. For more information see page 11.

The standard MEVOPUR® color range is available in polyolefins and a number of other polymers. Transluscent versions are also available on request[8].

Standard colors offer a faster and lower cost route versus development of a custom color and will be supported by Clariant's Drug Master File (DMF).

	COLOR	PANTONE REFERENCE[8]	EXAMPLE PRODUCTS – POLYOLEFINS & PEBA			
			PE Base	PP Base	PP transparent	PEBA Base
	WHITE		PE0M176031	PP0M176045		AH0M415001
	BLACK	Black C	PL9M176008	PP9M176017		
	YELLOW	102 C	PE1M176076	PP1M176060	PP1M176062	AH1M415002
	ORANGE	158 C	PE2M176044	PP2M176046		
	PINK	196 C	PE3M176130	PP3M176109		AH3M415001
	RED	199 C	PE3M176131	PP3M176111	PP3M176113	AH3M415002
	BEIGE	7502 C	PE8M176048	PP8M176058		
	BROWN	463 C / 731 C	PE8M176049	PP8M176060		
	MID GREY	Cool Grey 5 C	PE7M176067	PP7M176089		AH7M415001
	DARK GREY	425 C	PE7M176066	PP7M176091	PP7M176094	
	LIGHT BLUE	292 C	PE5M176155	PP5M176169		AH5M415003
	MID BLUE	285 C	PE5M176154	PP5M176171	PP5M176175	AH5M415002
	DARK BLUE	288 C	PE5M176153	PP5M176173		
	LIGHT GREEN	346 C	PE6M176128	PP6M176111		
	MID GREEN	348 C	PE6M176127	PP6M176113	PP6M176118	AH6M415001
	BLUISH GREEN	3145 C	PE6M176126	PP6M176115		
	VIOLET	2593 C	PE4M176023	PP4M176036	PP4M176039	AH4M415001
	AMBER (RED)				PP8M176062	
	AMBER (YELLOW)				PP8M176063	

Addition colors available on request.
In addition to the standard range, custom color based on the same biologically evaluated[3] ingredients can be designed to your requirements. This avoids the time and expense of testing unknown colors. Achieving a specific color may however depend on factors such as the resin and grade. Please contact Clariant for more details.

Technical Information for ISO10993 & USP Products / Biological Evaluation and Chemical Characterization

A defined range of MEVOPUR® products [3] are available where ingredients and/or finished masterbatches and compounds have been evaluated by Clariant or independent testing companies according to the following protocols. This helps to give customers a clear picture of their material of choice.

A standard range of colors using pretested ingredients are available in polyolefin masterbatches. Custom colors and other materials are available on request. We can offer an evaluation service for a product customized to your requirements, and also offer additional tests under ISO10993. Please contact us for more details and a specific quotation.

TESTING OF	PROTOCOL	TESTING STANDARD (FOR REFERENCE)	
		USP	ISO
STERILIZATION	Ethylene Oxide (ETO) 650mg / l 120		
IN-VITRO CYTOTOXICITY	Extraction 1% MEM (Minimal Essential Medium)	USP 87	ISO10993 part 5
HAEMOLYSIS [10]	Extraction: CMF-phosphate buffered saline. 37 degrees C 72 hours		ISO10993 part 4
INTRACUTANEOUS REACTIVITY – IRRITATION – RABBIT	Extraction: 70 degrees C 72 hours 4g/20ml 1. NaCl 0.9% 2. Sesame oil 3. Alcohol/saline mix 1:20 4. Polyethylene glycol (PEG400)	 USP 88 USP 88 USP 88 USP 88	 ISO10993 part 10 [3] ISO10993 part 10 [3] Additional tests stipulated by Clariant
SYSTEMIC TOXICITY – MICE	Extraction: 70 degrees C 72 hours 4g/20ml 1. NaCl 0.9% 2. Sesame oil 3. Alcohol/saline mix 1:20 4. Polyethylene glycol (PEG400)	 USP 88 USP 88 USP 88 USP 88	 ISO10993 part 11 ISO10993 part 11 Additional tests stipulated by Clariant
IMPLANTATION – RABBIT	Direct muscle implantation 7 days	USP 88 [9]	Please see [9]
CHEMICAL CHARACTERIZATION	Extraction: 70 degrees C 24 hours: polar, non-polar, mixed 1. Water 2. Hexane 3. Isopropanol Physical chemical analysis of extract to generate a 'fingerprint'		 ISO10993 part 18

Mevopur®
NOTES

- Note 1:
  To facilitate our manufacturing processes, different levels of segregation of lines are available at these facilities. Selection is based on detailed customer discussions on the product requirements and the risk assessment of the final application.

- Note 2:
  A number of 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:
  Ingredients for specific masterbatches and compounds have been tested either under ISO10993 parts 5, 10, and 11 or under USP parts 87 and 88 Biological Reactivity Tests (Class VI). More details and test certificates are available on request. However, because of the wide variety of medical device applications, sterilization regimes, etc, it is the responsibility of the device manufacturer to perform further appropriate tests for compliance with all requirements for the intended end-use application.

- Note 4:
  Change-control refers to Standard Operating Procedure (SOP) under Clariant's global quality system. It is possible to enter into individual change-control agreements covering aspects of our processes. Contact us for further discussion.

- Note 5:
  Clariant does not recommend use of any of its products in implants, active implantable medical devices or applications defined as "permanent" or "long-term" i.e. where the exposure to tissue or body fluids is greater than 30 days. Clariant products are not recommended for use in reproductive implants , birth control devices, or in cosmetic or reconstructive surgery applications.

- Note 6:
  Sterilization techniques: Products were tested and found to be color stable following ethylene oxide (ETO) sterilization. Gamma, beta, dry heat and other sterilization techniques may cause some base polymers to discolor. Please contact Clariant for further information. However, it is the responsibility of the device manufacturer to define the appropriate sterilization regime for its products.

Note 7:
Clariant products specifically developed for medical and pharmaceutical applications do not use materials that are known to be tallow-containing (animal-derived) or proscribed substances under RoHS directives.

- Note 8:
  Pantone references and printed representations of the colors are for guidance only. Exact shade may vary due to factors such as the resin type and base color.

- Note 9:
  Muscle implantation test is mainly used for evaluation of materials intended for use in United States Pharmacopeia (USP) for evaluation of Class VI devices, however it is more widely used as a "general" test. ISO10993-1 section 6 "Selection of Biological Evaluation Tests" follows a more selective approach that is device dependent mainly recommends implantation tests for devices classified as "permanent" or "long-term". Since these types of device are specifically excluded under Clariant policy [5], the ISO10993 muscle implantation test is not part of the standard test protocol. [ISO10993]

- Note 10:
  Haemolysis test was to the protocol in April 2011 for new materials. Previously evaluated materials will be included in a test programme to update the evaluation.
  Contact Clariant for more information.

- Note 11:
  ISO10993-1-2003 was revised during 2009. ISO10993 part 10 was revised in July 2010 and replaces previous versions by April 2011. As a result the recommended test protocol for part 10 was changed from 2 test animals to 3 test animals. Clariant test protocols were updated in April 2011.

Mevopur®
NOTES

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 Pharmacopeia (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, promis, or express or implied warranty concerning the suitability or lawfullness of Clariant‘s products for use in any medical device unless expressly stated in a written agreement signed by a duly authorized Clariant representative.

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