



» APPLICATION BULLETIN

MEVOPUR™ Colorants for Ophthalmic Closures

The MEVOPUR range of standard masterbatches for closures used with ocular (ophthalmic) medicines matches the color standards from the American Academy of Ophthalmology (AAO). This portfolio is based on a PE carrier, but can be provided in a PP carrier on request. Custom pre-color formulations can be developed in other resins upon customer request.

KEY CHARACTERISTICS

- Manufactured at three ISO 13485 certified manufacturing sites, providing global consistency and increased security of supply
- Documented change control beyond CAS number, reducing risk of change
- Free from animal-derived substances and phthalates
- Standard masterbatches in a PE carrier and on request in PP
- Pre-colored formulation can be supplied in specific resins selected for the application

REGULATORY SUPPORT

- Raw materials tested to:
 - ISO 10993-1 and USP <87> <88> biological evaluation
 - European Pharmacopeia 3.1.3/3.1.5 (polyolefin)
 - USP <661.1> (polyethylene)
 - ICH Q3D elemental impurities
- Registered Drug Master File (Type III)
- Food contact established with FDA/EU*



* FDA/EU compliance information available upon request

DRUG TYPE	COLOR DESCRIPTION	PANTONE REFERENCE	AVIENT PRODUCT CODE PE BASED
Adrenergic agonist combinations	Light Green	373 C	PE6M176349
Adrenergic agonists	Purple	2583 C	PE4M176057
Anti-infectives	Tan	467 C	PE8M176130
Anti-inflammatory, nonsteroidal	Grey	Cool Grey 4 C	PE7M176184
Anti-inflammatory, steroids	Pink	197 C	PE3M176237
Anti-inflammatory, immunomodulators	Olive Green	5763 C	On request
Beta-blockers	Yellow	Yellow C	PE1M176160
Beta-blocker combinations	Dark Blue	281 C	PE5M176272
Carbonic anhydrase inhibitors	Orange	1585 C	PE2M176089
Cytotoxic	Black	6 C	PL9M176008
Miotics	Dark Green	348 C	PE6M176267
Mydriatics and cycloplegics	Red	1797 C	PE3M176236
Prostaglandin analogues	Turquoise	326 C	PE5M176273

For containers/bottles, Avient also offers REMAFIN™ EP white pre-colored formulations and concentrates, available in low density and high density PE and PP resins.

Healthcare use limitations apply—see below. Contact Avient for more information.

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Avient 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 (FDA) 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, Avient 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, and with all applicable laws and regulations.