



➤ APPLICATION BULLETIN

MEVOPUR™ Functional Additives For Medical Devices, Diagnostics and More

MEVOPUR functional additives help protect and enhance the performance of polymers used in healthcare applications, such as medical housings, drug delivery devices, syringes and needles, diagnostics, and catheters. The portfolio includes formulations for UV protection, friction reduction, protection against oxidation, improved clarity, gamma/e-beam sterilization protection, reduction of static electricity buildup, laser marking/welding, and more. These functional additives are available as “ready-to-use” additive formulations, additive masterbatches, or a “combi,” where the additive functionality is included with the desired color in a formulation or concentrate for convenience.

KEY CHARACTERISTICS

- Manufactured at three ISO 13485 certified 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
- Available for use in a wide range of polymers including polyolefins, styrenics, polycarbonate and alloys, polyester, POM
- Functionality can be combined with colorants

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) and/or Device Master File
- Food contact established with FDA/EU*

* FDA/EU compliance information available upon request

FUNCTIONALITY	TARGET APPLICATIONS	DRUG DELIVERY DEVICES	SYRINGES & NEEDLES	DIAGNOSTICS	CATHETERS
Clarifying PP	Sorbitol-free for transparent applications with reduced migration and improved thermal stability	✓	✓	✓	✓
Lubricant—permanent/non-migrating	Fast acting reduction in friction for wide variety of polymers such as PP, ABS, POM, PC	✓	✓		✓
Protection from UV in transparent applications for PP, PE, PETG, COP	UV blocking in 290-450nm with no impact on clarity; can be combined with colors (e.g., amber)	✓	✓		
Antistatic ready-to-use solution for PP, ABS, PC/ABS	Permanent/non-migrating; fast decay time independent of % relative humidity	✓			
Gamma/e-beam sterilization protection of the polymer	Preserving the properties of PP and COC/COP; reduction in yellowing using Color Compensation Technology (CCT)	✓	✓		✓
Reduced material consumption/cycle time—nucleation	Fast acting new generation nucleant for PE and PP; improved thermal and mechanical properties allows wall thinning; reduction of tolerance/dimensional problems between different colors	✓	✓	✓	
Laser marking replacing ink printing/labels	Solvent-free, high speed identification for Nd/YAG laser for PE,PP, ABS, PC, POM	✓	✓	✓	✓
Antioxidants for PE, PP, TPE	Thermal protection during converting/downstream sterilization	✓	✓	✓	
Brand protection/ anticounterfeit	Covert and non-covert systems	✓			✓

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.