



» APPLICATION BULLETIN

MEVOPUR™ Functional Additives for Pharmaceutical Packaging

MEVOPUR functional additives help protect and enhance the performance of polymers used in pharmaceutical packaging products such as vials, bottles, closure systems, films and combination devices. The portfolio includes formulations for UV protection, slip/torque reduction, protection against oxidation, improved clarity, gamma/e-beam sterilization protection, 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 four 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

- Pre-tested raw materials:
 - 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

FUNCTIONALITY	TARGET APPLICATIONS	EBM/IBM CONTAINERS	CLOSURES	FILM	COMBINATION DEVICES
Clarifying PP	Sorbitol-free—possibilities in packaging ocular solutions	✓	✓		✓
Slip/torque reduction	Slip for PE, PP films, processing aid, torque reduction for closures		✓	✓	
Protection from UV in transparent packaging for PP, PE, PETG, COP	UV blocking in 290–450nm with no impact on clarity	✓		✓	✓
Antistatic ready-to-use solution for PE films e.g. for API handling	Permanent/non-migrating; fast decay time independent of % relative humidity			✓	
Antistatic masterbatch for PE films	Cost effective, long-lasting, migrating type but with biological evaluation			✓	
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/improved properties—nucleation	Fast acting new generation nucleant for PE and PP; improved dimensional stability, thermal and mechanical properties	✓	✓		✓
Laser marking replacing ink printing/labels	Solvent-free, high speed identification for Nd/YAG laser	✓	✓		✓
Antiblock for PE/PP film	Non-migrating additive system maintaining high gloss and printability			✓	
Antioxidants for PE, PP, TPE	Thermal protection during converting/downstream sterilization	✓	✓	✓	✓
Brand protection/ anticounterfeit	Range of covert and non-covert systems	✓	✓		✓
Volatiles/odor absorber for PE/PP	Physical absorption of a wide range of molecules responsible for odor, VOC and potential extractables/leachables in plastics	✓			✓

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:

- 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
- active implantable medical devices as defined in EU Directive 90/385/EEC as amended; or
- medical devices for “Long Term” use as defined in EU Directive 93/42/EEC as amended.

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- exposure to human tissue or body fluids for 30 days or greater;
- “plastic” (cosmetic or reconstructive) surgery use;
- reproductive implants or any birth control device; or
- 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.