
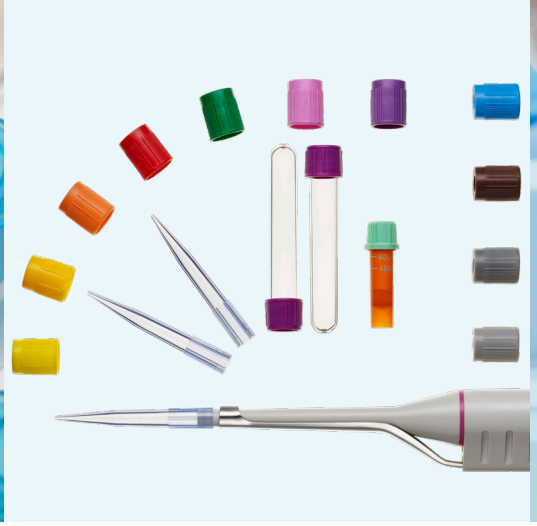


APPLICATION BULLETIN

MEVOPUR™ Colors and Functional Additives for In Vitro Diagnostic Devices

Diagnostic devices and consumables, now more than ever, play a vital role in delivery of safe treatements. Fast, accurate and reliable results aid medical professionals to understand the illness and develop the strategy for an effective treatment. New innovations in diagnostic equipment such as improvement in laboratory automation and self-testing devices/POCT (Point-of-Care Testing) diagnostics require increased reliability.

Plastic materials offer opportunities and play an increasingly vital role: colors aid identification and automated laboratory processes whilst functional additives expand the usable property window of the polymer in areas such as surface chemistry or oxygen protection. Furthermore, designers, quality and regulatory specialists face new compliance challenges as regulations such as the In-Vitro Diagnostics Regulation (IVDR) EU2017/746 are tightened and impact of reclassifications come into force.

KEY CHARACTERISTICS

- Manufactured at four 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
- Available as masterbatches or ready-to-use formulations in a wide range of polymers
- Functionality and color can be combined in one product for convenience

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
- Documentation support for approval or transition to comply with (new) regulations such as IVDR

AVIENT™

FUNCTIONALITY	TARGET APPLICATIONS	BLOOD COLLECTION	REAGENT CONTAINERS/ KITS	PIPETTE/ LABWARE	SELF-TESTING/ POCT	INSTRUMENT/ ACCESSORIES
Colorants for coding for lab automation/ identification	Wide range of colors in various polymers, available in ready-to-use formulation or masterbatch adapted to your process	✓	✓		✓	✓
Colors – low migration/ interference	Ready-to-use formulation to avoid interference with analytical tests; extractable metal data	✓	✓		✓	
Colors – biologically evaluated	Reduced risk of non compliance to current and proposed regulations such as IVDR	✓	✓	✓	✓	
Color in PP, ABS, PC and high temperature polymers with UL listings	Ready-to-use solutions/masterbatch supporting Underwriters Laboratory requirements of electric enclosures				✓	✓
Antistatic for PP, ABS, PC/ABS	Permanent/non-migrating ready-to-use formulation; fast decay time independent of % relative humidity				✓	✓
Clarifying PP	Sorbitol-free, minimizing potential migration	✓		✓		
Laser marking for UDI replacing ink printing/labels	Activation of the polymer to laser energy give high contrast solvent-free, high speed identification	✓	✓		✓	✓
Laser welding for fast, reliable assembly of a range of polymers	Custom masterbatches and ready-to-use formulations for optically transparent and opaque colors while allowing laser transmission/absorption		✓		✓	✓
Nucleation of semicrystalline polymers e.g. HDPE, PP, POM	Fast acting new generation nucleant for PE and PP; improved dimensional stability, thermal and mechanical properties	✓				
Protection from moisture for improved barrier	Reduced Moisture Vapor Transmission Rate (MVTR) HDPE ready-to-use formulation; moisture absorbing masterbatch		✓		✓	
Protection from oxygen scavenging in PET	Reduced transmission of oxygen vacuum loss in BCT (blood collection tubes) and protect reagents from oxygen degradation	✓	✓			
Protection from UV in transparent containers (PP, PE, PETG, COP)	UV blocking in 290–450nm with no impact on clarity; protection of light sensitive reagents		✓	✓	✓	✓

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

1.844.4AVIENT
www.avient.com

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.