

APPLICATION BULLETIN

MEVOPUR™ Bio-Based Polymer Solutions
for Medical Devices and Pharmaceutical Packaging

Manufacturers of medical devices and pharmaceutical packaging are increasingly faced with the challenge of integrating sustainability into the design of their products. One way to achieve this is to switch to bio-polymers where possible. Bio-polymers are already used with success in different plastic products, notably in packaging, but to be used in healthcare applications, they need to be evaluated to the relevant protocols to support regulatory compliance of the end article.

Avient provides pre-tested color and additive concentrates (masterbatch) based on bio-polymers to minimize the risk of non-compliance and support a more sustainable profile for plastic products used in the healthcare industry.

KEY CHARACTERISTICS

- Available for polyethylene, polypropylene, ABS, polycarbonate and styrenics
- Bio-content of resin carrier varies from 70% to 100% depending on polymer—calculated to ASTM D6866 standard
- Manufactured at four ISO 13485 certified sites, providing global consistency and security of supply
- Documented change control beyond CAS number reducing risk of change
- Drop-in solutions that can be processed like fossil-based grades on common injection molding and extrusion machines
- Can be provided as ready-to-use pre-colored or additive formulation

REGULATORY SUPPORT

- Raw materials tested to:
  - ISO 10993-1
  - USP <87> and <88> (incl. class VI)
  - European Pharmacopeia, monograph 3.1.3/ 3.1.5 (polyolefin packaging materials)
  - USP <661.1> (polyethylene)
  - Elemental impurities as per ICH Q3D
- Registered Drug Master File (Type III) and/or Device Master File
- Food contact according to US FDA and

Sustainability Spotlight

Bio-polymers

AVIENT™

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

1.844.4AVIENT
www.avient.com

AVIENT™

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.