

> APPLICATION BULLETIN

Mevopur™ Healthcare 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 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







Healthcare use limitations apply—see below.

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Avient is committed to the needs of our healthcare customers. As part of our commitment, we publish Avient's Mevopur* product policy and use limitations to assist customers in their product selection.

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 with all applicable laws and regulations, including the suitability of all raw materials and components used for its manufacture.

Please be aware that there are certain applications Avient's Mevopur products have not been designed for, nor are they promoted or intended for use in: including, but not limited to long-term or permanent implants, birth control devices, or plastic surgery.

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