

APPLICATION BULLETIN

MEVOPUR™ Chemical Foaming Agents (CFA)
for Medical Devices and Pharmaceutical Packaging

As the need to integrate sustainability in the design of healthcare products is growing, manufacturers of medical devices and pharmaceutical packaging are looking for materials with a more environmentally-friendly profile.

Avient takes a multi-angle approach to support sustainability in healthcare applications. One angle is to offer chemical foaming agents that help reduce plastic material use. MEVOPUR CFA is the result of Avient's combined experiences in the development of chemical foaming agents for automotive plastic components and polymer solutions for healthcare applications. The products help reduce material use by up to 20% depending on part geometry and wall thickness. They are specially formulated for healthcare applications and manufactured under controlled conditions. They also improve the visual appearance of plastic components by reducing sink marks.

KEY CHARACTERISTICS

- Manufactured under ISO 13485 procedures
- Documented change control beyond CAS number reducing risk of change
- Can be used on common injection molding and extrusion machines—set-up support by a technical assistance team
- Available for use in polyolefins, styrenics and copolymers
- Can be combined with colorants

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 USA FDA and EU norms

Sustainability Spotlight

Lightweighting

AVIENT™

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.