

APPLICATION BULLETIN

MEVOPUR™ Amber Colorants for Pharmaceutical Packaging

Avient constantly monitors the evolution of regulations in the healthcare industry, and develops compliant products well before those regulations go into effect. An addition to the MEVOPUR portfolio is a pre-tested amber masterbatch for PET vials, bottles and other packaging products. Amber shades are known to offer effective protection from certain wavelengths, but the technologies of most amber polymer solutions on the market do not have regulatory support to comply with the pharmaceutical packaging regulations. MEVOPUR amber provides the safety of pre-tested raw materials while protecting and prolonging the shelf life of pharmaceuticals and nutraceuticals in amber PET packaging products.

KEY CHARACTERISTICS

- Manufactured at three ISO 13485 certified sites, providing global consistency and increased security of supply availability
- Documented change control beyond CAS number level reducing risk of change
- Free from animal-derived substances and phthalates
- Different tones of amber available on request — more or less red or yellow and/or lighter or darker

REGULATORY SUPPORT

- Pre-tested raw materials:
  - ISO 10993-1 and USP parts <87>, <88> (Class VI)
  - European Pharmacopoeia, monograph 3.1.15, USP <661.1> and elemental analysis as per ICH Q3D
  - USP <661.2> criteria appearance of solution, color
- Registered Drug Master File (Type III) by the FDA (DMF 27630)
- Food contact compliance established with FDA/EU*

* FDA/EU compliance information available upon request

AVIENT™

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

1.844.4AVIENT
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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.