APPLICATION BULLETIN

MEVOPUR™ Special Effects

Effect Colorants for Healthcare Devices and Pharmaceutical Packaging

Self-administered medication, for example via pen devices and inhalers, has been the norm for many years. However, U.S. studies indicate only 28% patient-adherence to treatment programs. Designers are looking for ways to make their devices easier to use and more attractive—special effects can help this.

When added to plastics, special effect pigments create a distinctive impression like pearlescence, sparkle or a metallic look. These have been used successfully in personal care and consumer goods to enhance the look and feel of products and increase market appeal. However, these raw materials often lack the regulatory documentation to support their use in healthcare applications.

Avient brings deep knowledge gathered from use of these pigments in a wide range of applications and combines this with the dedicated experience of the healthcare team. Ingredients used in MEVOPUR have been tested to industry standards that support applications in both medical devices and pharmaceutical packaging.*

KEY CHARACTERISTICS

- Manufactured at three ISO 13485 certified manufacturing sites, providing global consistency and increased security of supply availability
- Documented change control beyond CAS Number reducing risk of change
- Free from animal-derived substances and phthalates
- Available as pre-colored formulation or masterbatch and for use in different polymers

REGULATORY SUPPORT

- Pre-tested raw materials:
  - ISO 10993-1
  - USP chapters <87>, <88> (Class VI)
  - USP <661.1> covering solid oral dose to injectables, ophthalmics and inhalation
  - ICHQ3D/USP <232> 2 extractable metals
  - European Pharmacopeia 3.1 polyolefins where applicable
- Registered Drug Master File (type III) by the FDA and/or Device Master File
- Food contact compliance established with FDA/EU**

* Design note: Effect colors require careful consideration of part design and polymer flow paths to minimize visible flow lines. It is important to consult your Avient technical representative during initial concept design.

** FDA/EU compliance information available upon request.

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.