



» APPLICATION BULLETIN

Mevopur™ Healthcare Colorants and Formulations Amber Colorants for Pharmaceutical Packaging

Amber shades are used in pharmaceutical packaging to offer effective protection from certain wavelengths. However, some amber polymer solutions on the market don't offer regulatory support to comply with pharmaceutical packaging regulations. The Mevopur™ Healthcare Colorants and Formulations portfolio includes pre-tested amber masterbatches specially developed to protect and prolong the shelf-life of pharmaceuticals and nutraceuticals in amber PET packaging. The amber tone can be customized to be more/less red or yellow and to be lighter or darker.

KEY CHARACTERISTICS

- Manufactured at several ISO 13485 certified sites across the globe, providing consistency and increased security of supply
- Documented change control beyond CAS number level, reducing risk of change
- Different tones of amber available on request
- Also available in liquid form

REGULATORY SUPPORT

- Pre-tested raw materials:
 - ISO 10993-1 and USP <87> <88> biological evaluation
 - European Pharmacopeia 3.1.15 (polyester)
 - USP <661.1> (polyester)
 - USP <661.2> appearance of solution (polyester)
 - ICH Q3D elemental impurities
- Registered Drug Master File (Type III) by the FDA
- Food contact declaration according to US FDA/EU*
- YBB00102002-2015 (oral liquid pharmaceutical PET bottles) compliance support



* US FDA/EU compliance information available upon request



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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