



» APPLICATION BULLETIN

Mevopur™ Healthcare Colorants and Formulations 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 concentrate 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 Healthcare Colorants and Formulations in amber tones provide 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 four ISO 13485 certified sites, providing global consistency and increased security of supply
- Documented change control beyond CAS number level, reducing risk of change
- Non-phthalate and formulated without animal-derived substances
- Different tones of amber available on request —more or less red or yellow and/or lighter or darker
- Also available in liquid form

REGULATORY SUPPORT

- Pre-tested raw materials:
 - ISO 10993-1 and USP parts <87> <88> (Class VI)
 - European Pharmacopeia, 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
- Food contact compliance established with FDA/EU*
- YBB00102002-2015 (oral liquid pharmaceutical PET bottles) compliance support



* 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.

For more detailed information on Mevopur uses and restrictions see www.avient.com/healthcare-use-limitations-mevopur-products or contact your Avient sales representative.