

> APPLICATION BULLETIN

Mevopur[™] Healthcare Functional Additives Nucleating Agents

Colors are used in the medical industry for brand recognition, the coding of different pharmaceuticals, or visual appeal. However, pigments used to color plastic parts can cause warping or shrinking, leading to dosing inaccuracy or even malfunctioning healthcare devices.

The Mevopur[™] Healthcare Functional Additives portfolio includes nucleating agents that neutralize the negative effect pigments can have on the mechanical properties of the finished plastic part. The additives reduce production variability, warping, and shrinking. By improving mechanical properties, wall-thinning and reduced material usage can be achieved, without compromising the performance of the plastic part.

The nucleating agents also foster constant process settings throughout part manufacturing with a higher crystallization temperature for improved crystallization speed. This can lead to a cycle time reduction of 5–15%.

REGULATORY SUPPORT

- Drug delivery devices
- Pharmaceutical packaging
- Medical equipment

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 the risk of change
- Allows crystallization in semi-crystalline
 polymers to begin faster and complete earlier

REGULATORY SUPPORT

- Raw materials tested to:
 - ISO 10993-1 and USP <87> <88> biological evaluation
 - European Pharmacopeia 3.1.3/3.1.5 (polyolefin)
 - USP <661.1> (polyethylene)
 - ICH Q3D elemental impurities
- Registered Drug Master File (Type III) and/or Device Master File
- Food contact established with FDA/EU*





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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