



» APPLICATION BULLETIN

MEVOPUR™ Laser Marking Additives for Medical Devices and Pharmaceutical Packaging

Laser marking offers several advantages compared to other marking technologies. It yields precise markings without the use of solvents or inks or the need of any pre-treatment, making it a more environmentally friendly process. The marking is abrasion resistant and long-lasting. Laser marking also achieves fast writing speeds at low operating costs. In some cases, additives are required to achieve the desired marking quality by enabling the plastic to absorb laser energy and/or improve the laser marking contrast. Additives can also be used to increase laser marking speed and reduce the needed laser energy.

MEVOPUR laser marking products are additive concentrates or ready-to-use additive formulations specially designed for use in healthcare applications. They are formulated with a non-migratory additive system and yield durable and highly resistant markings that can survive repeated sterilization cycles, regardless of sterilization method. Potential applications include graduation markings for dose-dials, syringes and droppers, and serialization/coding (e.g. UDI) for medical devices and pharmaceutical packaging. Our team of experts provides guidance on the masterbatch or ready-to-use formulation which is suitable to the specific laser marking methodology, regulatory requirements, application and processing settings.

KEY CHARACTERISTICS

- Designed for Nd:YAG lasers operating between 1060-1070 nm
- Available for different polymers including PP, PE, PC, PBT, POM, ABS, MABS
- Manufactured at four ISO 13485 certified sites, providing global consistency and increased security of supply
- Documented change control beyond CAS number reducing risk of change
- Can be designed for dark marking on natural or white/light colored background or light marking on black/dark background

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*

* FDA/EU compliance information available upon request; exceptions may occur



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

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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.