HEALTHCARE POLYMER SOLUTIONS

Mevopur[™] Healthcare Colorants & Formulations Mevopur[™] Healthcare Functional Additives

Sustainability Spotlight



Human Health & Safety



MITIGATING RISK AT EVERY STAGE OF DESIGN AND PRODUCTION

Mevopur[™] polymer solutions are trusted products and services developed to help medical device, diagnostics and pharmaceutical packaging sectors meet the growing challenges of product consistency, compliance and reliability.

DEDICATED HEALTHCARE EXPERTS

Our global and regional team of technical specialists provide support for multiple projects including global transfers, troubleshooting, and developing the right solution for each need.

GLOBAL ISO 13485 MANUFACTURING FOOTPRINT

Avient's certified sites are located on three continents and offer manufacturing support, project transfer and back-up supply to reduce supply chain risk.

COMPREHENSIVE REGULATORY TESTING AND DOCUMENTATION

Raw materials tested to:

- ISO 10993-1 and USP <87>, <88> (biological evaluation)
- European Pharmacopeia 3.1.3/3.1.5 (polyolefin —materials used for the manufacture of containers)
- USP <661.1> (polyethylene—plastic materials of construction)
- ICH Q3D (elemental impurities)

We provide Drug Master File (Type III) documentation and other supporting regulatory declarations that are relevant for the application.

MINIMIZING RISK OF CHANGES

Incoming batch-to-batch control of ingredients versus a fingerprint to monitor changes, and documented change control beyond CAS number reduce the risk of changes.



ADDING VALUE TO A WIDE RANGE OF HEALTHCARE APPLICATIONS

Our expertise and market understanding are based on numerous years of working in these highly demanding sectors. The result: an ever-expanding portfolio of colorants and additives that are compatible with all thermoplastic processes utilized by the industry, and that combine creativity with production efficiency for our customers.

Mevopur color and performance concentrates as well as ready-to-use formulations add value to a wide range of applications:

MEDICAL DEVICES

- Drug delivery
- Catheters
- Renal care/dialysis
- Surgical instruments
- Dental instruments
- Medical device packaging
- Electronic instruments and accessories for monitoring

PHARMACEUTICAL PACKAGING

- Vials, ampoules
- Bottles for pills, liquid medicines
- Blister packaging

IN VITRO DIAGNOSTICS (IVD)

- Blood analysis
- IVD devices
- IVD disposables (e.g., pipette tips)
- Point-of-Care

To meet various manufacturing processes, colorants and functional additives are provided as concentrates for dilution into the polymer or as ready-to-use formulations. Mevopur products cover the wide range of polymers and thermoplastic elastomers (TPEs) used in the medical and pharmaceutical sectors. These include PE, PP, ABS, SAN, PC/ABS, PC, PA6, 66 and 12, cyclic olefins (COP), high performance polymers, and elastomers such as EVA, SEBS, TPU and PEBA.



PROVIDING STANDARD AND CUSTOM COLORANTS & ADDITIVES

STANDARD COLOR RANGES

To speed up time to market, Avient offers a standard range of colorants using pre-tested raw materials suitable for a wide range of polymers including PE, PP, PEBA, PC, and others. Additionally, other standard portfolios, such as colors for ophthalmic closures or white for pharmaceutical packaging, help fast-track the coloration of specific healthcare applications. Custom color concentrates and ready-to-use pre-colored formulations are available on request.

APPLICATION	PORTFOLIO DESCRIPTION
General use	Opaque and transparent colors in PP, PE, COC, ABS, POM, PC, TPU, PEEK, and more
Needle hubs and cannulae	Opaque and translucent colors evaluated to ISO 6009
Ophthalmic caps and closures	13 standard colors in PE matched to American Academy of Ophthalmology; biologically evaluated to USP standard
White pharmaceutical packaging	White colorants for PE, HDPE, PP covering solid dose to nasal packaging needs
Amber pharmaceutical packaging	Pre-tested amber colorants
LSR silicones	For LSR silicones and transparent color PET/PP (e.g. amber)

FUNCTIONAL ADDITIVES

Materials can also be enhanced with functional additives to meet stringent product performance requirements. The table below shows a non-exhaustive list of additives used in healthcare applications. Contact us to discuss the additive solution most adapted to your healthcare product.

FUNCTIONALITY	ADDITIVE PERFORMANCE
UV protection in transparent packaging	Blocks UV in 290–450nm for PP, PE, PETG, COP
Processing aid/friction reduction	Optimizes processing for PE, PP, ABS, POM—non-migrating
Nucleation for reduced material consumption/cycle time	Improves thermal and mechanical properties of PE and PP and allows wall thinning to support sustainability
Clarifying	Improves clarity of transparent PP applications with reduced migration and improved thermal stability—sorbitol-free
Laser marking/welding	Activates the polymer to absorb Nd-YAG laser for fast reliable marking/assembly
Gamma/e-beam sterilization	Preserves the properties of PP and COP, reduces yellowing and compensates for discoloration
Anti-static	Reduces static buildup in applications such as films in API handling and inhaler spacers/nebulizers
Antioxidant	Provides thermal protection during converting/ downstream sterilization
Anti-counterfeit/brand protection	Covert and non-covert systems

SUPPORTING SUSTAINABILITY TARGETS

As the need to integrate sustainability in the design of healthcare products is growing, manufacturers of medical devices, diagnostic products and pharmaceutical packaging are looking for materials with a more environmentally friendly profile. Avient takes a multi-faceted approach to support sustainability in healthcare applications. This includes offering bio-based solutions where possible, helping reduce material use, and providing custom formulations to reduce fossil fuel-based usage and achieve higher sustainability.

BIO-BASED SOLUTIONS

Bio-polymers are already used with success in different plastic products, notably in packaging, but to be used in healthcare applications, they need to be risk-assessed. Avient provides color and functional additive concentrates based on bio-polymers that follow the concept of consistency and compliance of our Mevopur portfolio. They are manufactured at ISO 13485 certified sites with bio-compatible raw materials and documented change control.

REDUCED MATERIAL USE Chemical Foaming Agents (CFA)

Mevopur CFA products are the result of Avient's combined experiences in the development of chemical foaming agents for automotive plastic components and of polymer solutions for healthcare applications. These additive concentrates help reduce material use by up to 20% depending on part geometry and wall thickness and are specially formulated and risk-assessed for healthcare applications. They also improve the visual appearance of plastic components by reducing sink marks.

Nucleating solutions

Mevopur nucleating agents help produce thinner walls in polyolefin applications while maintaining main mechanical properties and stability of the end article. This is particularly interesting for larger scale production, where the impact of material use reduction will be more important. The cycle time in injection molding can be reduced (10–15% in PP) to support higher output and less energy consumption. Nucleating solutions can also help reduce MVTR (Moisture Vapor Transmission Rate) in HDPE and eliminate potential warpage influence of certain pigments.

CUSTOM FORMULATIONS

Our experts work with customers to select custom polymer solutions that fulfill specific technical and regulatory requirements, and sustainability targets. Custom formulations are provided as ready-to-use products that do not require further dilution into the polymer. Examples of custom formulations that help achieve a more sustainable product profile are a nucleating agent combined with color in a ready-to-use formulation or a desired color offered in a bio-polymer based ready-to-use product.



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.