



» APPLICATION BULLETIN

REMAFIN™ EP White Colorants for Pharmaceutical Packaging

REMAFIN™ EP is a range of PE and PP based masterbatches designed for protecting oral, topical, parenteral, ophthalmic and nasal pharmaceuticals by opacifying primary and secondary pharmaceutical packaging. High loading and optimized dispersion of pigments provide a cost-effective way to safeguard light transmission requirements while supporting regulatory requirements for pharmaceutical packaging materials.

KEY CHARACTERISTICS

- Manufactured under change control principles beyond CAS number (similar level as MEVOPUR concentrates), reducing risk of change
- Free from animal-derived substances and phthalates
- Suitable for blown film, injection molding, blow molding and extrusion

REGULATORY SUPPORT

- Raw materials tested to:
 - ISO 10993-1
 - USP chapters <87>, <88> including Class VI, a requirement for ophthalmic and nasal drugs
 - European Pharmacopeia 3.1.3/3.1.5 (polyolefin)
 - USP <661.1> (polyethylene)
 - ICH Q3D elemental impurities
 - USP <671> and USP <661.2> light transmission
- Registered Drug Master File (Type III)
- Food contact compliance established with FDA/EU*



* FDA/EU compliance information available upon request

REMAFIN™ EP WHITE PORTFOLIO

CARRIER MATERIAL	PIGMENT CONTENT/TYPE	LIGHT FASTNESS	THERMAL STABILITY	PRODUCT CODE
HDPE	50% TiO ₂	8	300°C	PH00075525
LLDPE	60% TiO ₂	8	300°C	PL00075542
LLDPE	70% TiO ₂	8	300°C	PL00075545
PP	50% TiO ₂	8	300°C	PP00075717



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.