


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 secondarypharmaceutical 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

AVIENT™

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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