ProVital+ White 209

Healthcare Segment

Medical Grade White Polyolefin Masterbatch for Pharmaceutical & Medical Applications

Issue date: October 2021

Background

In today's healthcare environment, medical plastics play a crucial role allowing health care providers to diagnose sickness or disease, treat cases and help to improve patient's quality of life during or after the recovery period.

White plastics are the most commonly employed by the healthcare industry and are widely used in pharmaceutical and medical applications. Complete consistency of performance, traceability and control of raw materials used for fabrication of these plastics are crucial for manufacturers of medical devices, immediate pharmaceutical packaging and in-vitro diagnostic equipment's.

Ampacet **ProVital+ White 209** is a medical grade white masterbatch solution characterised by outstanding quality, reliability and consistency to meet the standards of the healthcare industry.

Benefits

Making part of Ampacet ProVital+ product range, Ampacet **ProVital+ White 209** is a medical white masterbatch grade specially designed for the opacification and coloration of primary & secondary pharmaceutical packaging, medical and in-vitro diagnostic devices. It meets stringent quality and performance requirements of the healthcare industry to ensure compliancy with strict medical regulations.

ProVital+ White 209 has been designed with selected high quality raw materials pretested for biocompatibility according to ISO 10993 and European Pharmacopeia section 3.1.3 standards.

ProVital+ White 209 offers full consistency of formulation with stringent manufacturing process and rigorous control of raw materials.

AMPACET is offering full supporting documentation on customer demand.

End Products

ProVital+ White 209 is suitable for:

- Blow molding
- Injection molding
- Extrusion
- Blown films









Performance

ProVital+ White 209 has been formulated with high quality raw materials pre-evaluated for:

- Biocompatibility according to ISO 10993 part 5, 10 and 23 (cytotoxicity, sensitization and irritation)
- European Pharmacopeia (Ph. Eur.) monograph 3.1.3 polyolefin for containers

ProVital+ White 209 offers full consistency of formulation through:

- no-change policy for raw materials at CAS and commercial level
- manufacturing under consistent process parameters
- production under HACCP principles to minimize risks of cross contamination

Value Proposition

Specially developed for the healthcare industry with the unique characteristics, **ProVital+ White MB 209** is an ideal coloration and opacifying solution for pharmaceutical packaging and medical devices including drug delivery devices, disposables, diagnostic equipment and surgical instruments.

Engineered with premium quality raw materials, **ProVital+ White MB 209** demonstrates safety, reliability and full consistency.

Produced under strict hygienic conditions and consistent process parameter windows, **ProVital+ White MB 209** meets high regulatory standards and requirements of the healthcare market thus delivering peace of mind to manufacturers of medical equipment and pharmaceutical packaging.

Technical Specifications

		ProVital+ White 209 - 1101209-EM
Carrier Resin		Low-density polyethylene
Specific Gravity		1.55
TiO2	%	50%
Melt Flow Index	g/10min	35*(nominal) ASTM D1238, 190°C 2.16Kg
Bulk Density	(g/l):	ND* (nominal)
*Final specifications have to be determined after several industrial productions.		

To support our customers in product design, documentation such as Safety Datasheet, Technical Datasheet and supporting data are available upon request.

Handling & Storage

- Store in dry and cool conditions
- It should not be stored outside
- Shelf life after production: 18 months in appropriate conditions

Regulatory Compliance

ProVital+ White 209 has been assigned a FDA Drug Master File.

This masterbatch has been tested according to the European Pharmacopoeia Monographs 3.1.3 and ISO10993 parts 5 (Cytotoxicity), 10 (in vitro Skin Sensitization) and 23 (in vitro Skin Irritation).

These tests have been performed for informational purposes only, in the aim to support our customers in their developments. These results cannot be used to ensure the suitability of final or intermediate products made from the masterbatch 1101209-EM in any medical or pharmaceutical applications

For more information on Ampacet ***ProVital+ White 209*** and its uses contact your Ampacet Sales Representative or visit ***www.ampacet.com***. A complete Regulatory Status is available upon request.

Ampacet Disclaimer

Ampacet general disclaimer

Unless otherwise expressly agreed in a written agreement signed by duly authorised representative of Ampacet, the choice of our products for any specific intended use is the sole and exclusive responsibility of the customer; Ampacet shall not, under no circumstances, be held liable for any specific use nor application of its products by a customer in the absence of such agreement.

Medical devices

More particularly and without prejudice to Ampacet's general disclaimer, Ampacet products are not intended for use, nor to be incorporated in the manufacture of medical devices which are categorised or classified as:

- United States' Food and Drug Administration Class III, Canadian Classes III and IV and European Union Classes IIb and III or any equivalent within another country's regulatory classification.
- "Invasive devices", devices for "Long Term" (i.e., in principle longer than 30 days) use or devices involved in a " Vital physiological process" as defined by the International Medical Device Regulators Forum - IMDRF (formerly Global Harmonization Task Force) as well as by the applicable regulations on medical devices.

The natural or legal person in charge of the placing on the market, making available on the market or putting into service of medical devices and/or their accessories shall be the sole and exclusive responsible to ensure compliance of such devices or accessories with applicable laws and regulations. This also includes compliance in relation to any material or component which is used for their manufacture or the manufacture of their packaging.

Global Regional Headquarters:
Ampacet North America: 660 White Plains Road, Tarrytown, NY 10591-5130, ***marketing.northamerica@ampacet.com***
Ampacet South America, S.A.: Dardo Rocha 2454 – 2o Piso, (B1640FTH) San Isidro, Buenos, Aires, Argentina, ***marketingALA@ampacet.com***
Ampacet Europe, S.A.: Z.A.E. Wolser H, 130, L-3451 Dudelange, Luxembourg, Phone : +352.29.20.99.1, ***marketing.europe@ampacet.com***
Ampacet Asia: ESIE (Rayong),64/19 Moo 4, Highway 331, Pluakdaeng, Rayong 21140, ***AsiaMarketing2@ampacet.com***