Technical Data Sheet

PHARMALENE®
MR 50 PH BA

Medical grade LLDPE
Linear low density polyethylene bio attributed

SUSTAINABILITY

The "bio attributed" product Pharmalene MR 50 PH BA is a highly sustainable medical grade LLDPE produced using bionaphtha from renewable raw materials together with traditional raw materials. In order to attribute the sustainable feedstock component to the final product, Versalis applies the Mass Balance approach, a recognized methodology that allows to trace the flow of materials along the value chain and to assign the sustainability characteristic of the raw material to the final product on a documentary basis. Pharmalene MR 50 PH BA provides the same chemical composition and physical-mechanical performance of the traditional grade, in addition is accompanied by a sustainability declaration that certifies the share of bio attributed product.
Pharmalene MR 50 PH BA is a linear low density polyethylene (LLDPE) with antioxidants, obtained by medium pressure autoclave technology. It is produced in conformity to the good manufacturing practices (GMP) and is mainly used for injection moulding.
The production of Pharmalene MR 50 PH BA allows to contribute to the circular economy, since the bionaphtha used derives from renewable sources (e.g. vegetable oils). Pharmalene MR 50 PH BA will be bio attributed for 90%. The exact amount of "bio attributed" product will be reported in the sustainability certificate issued upon delivery of the product.

MAIN PROPERTIES

Resin Properties	Value	Unit	Test method
Melt Flow Rate (190 °C/2,16 kg)	22	g/10min	ISO 1133
Melt Flow Rate (190 °C/5 kg)	-	g/10min	ISO 1133
Melt Flow Rate (190 °C/21,6 kg)	-	g/10min	ISO 1133
Density	0,939	g/cm^3	ISO 1183
Melting Point	126	°C	Internal Method
Brittleness temperature	<- 70	°C	ASTM D 746
Vicat softening point (1 kg)	113	°C	ISO 306/A

Mechanical Properties *	Value	Unit	Test method
Tensile stress at yield	15	MPa	ISO 527
Tensile stress at break	15	MPa	ISO 527
Elongation at break	> 450	%	ISO 527
Flexural modulus	500	MPa	ISO 178
Hardness Shore D	56	-	ISO 868 A

(*) Values are referred to injection moulded specimens. Actual properties are typical and may vary depending upon operating conditions.

PHARMALENE® LLDPE / Linear low density polyethylene bio attributed **MR 50 PH BA**

MAIN APPLICATIONS

Pharmalene MR 50 PH BA is intended for the use within pharmaceutical sector and is characterized by a high rigidity.
Pharmalene MR 50 PH BA is suitable for the production thin walled pharmaceutical containers as well as closures.

PROCESSING NOTES

Pharmalene MR 50 PH BA can be processed by conventional injection moulding equipments.

Typical processing conditions (*):
Temperature profile of the barrel (°C) 170 - 230
Temperature of the mould (°C) 10 - 40

(*) Processing conditions depend on several parameters: the shape of the part to be manufactured, the localisation of the injection point, the injection moulding machine and the cooling of the mould.

STORAGE AND HANDLING

Pharmalene MR 50 PH BA is supplied in pellet form. This material may readily be conveyed and bulk fed through equipment designed for conventional pelletised polyethylene resin, provided the equipment is designed to prevent accumulation of fines and dust particles that are contained in all polyethylene resins. These fines and dust particles can, under certain conditions, pose an explosion hazard. We recommend that the conveying system used, is equipped with filters of adequate size, operated and maintained in such a manner to ensure that no leaks develop and earthed adequately. We further recommend, that good housekeeping should be practised throughout your facility.

Shelf Life: Polyethylene can be stored over a long period of time, as long as it is stored protected from solar irradiation, in a ventilated, dry and cool place, with a temperature kept below 50°C. Any exposure of the material to solar irradiation, reinforced by higher temperatures, has a detrimental impact on the product quality and can induce a degradation, which goes on subsequently.
We guarantee that Versalis Pharmalene® products keep complying with Versalis sales specification for 2 years after date of delivery under the recommended storage conditions. This statement does not prevent user performing MFR and density tests on the incoming material and every year for quality evaluation.

Ensuring a consistent material quality, we strongly recommend to follow the above mentioned handling and storage conditions for all Pharmalene® products. In case of non-respect of these storage precautions, Versalis cannot be held liable to any quality problem related to inappropriate handling and storage of the material and shelf-life can be altered.

Before using this product it is recommended to refer to the relevant Safety Data Sheet (SDS) for more detailed information.

AVAILABILITY

Contact the Versalis sales office nearest to you regarding availability and your specific application requirements.

FOOD CONTACT AND PHARMACOPOEIA STATUS

Pharmalene MR 50 PH BA complies with the European Union (Reg. 10/2011) and the USA (FDA) rules, related to the use of plastic materials intended for contact with foodstuffs. The composition of our product is compliant to the relevant sections of the European Pharmacopoeia (10th ed.) and those of the U.S. Pharmacopoeia (USP 42). Certificates of compliance are available upon request.

TECHNICAL MANAGEMENT POLYETHYLENE PHARMALENE

Versalis S.p.A.

Head Office
Piazza Boldrini, 1
20097 San Donato Milanese (MI) - Italy
tel. +39 02 52032998

Versalis Int. SA - Zweigniederlassung Deutschland

Duesseldorfer Str. 13
65760 Eschborn - Deutschland
tel. +49 15140260561

January 2023