versalis

Technical Data Sheet

PHARMALENE®
FL 45 PH BCA

Medical grade EVA

Ethylene vinyl acetate copolymer bio circular attributed

SUSTAINABILITY

The product Pharmalene FL 45 PH BCA 'Bio circular attributed' is a highly sustainable medical grade EVA 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 FL 45 PH BCA 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 FL 45 PH BCA is an ethylene vinyl acetate copolymer (EVA) for blown film extrusion, extrusion & injection moulding, manufactured using high pressure tubular technology. It is produced according to good manufacturing practices (GMP).
The production of Pharmalene FL 45 PH BCA allows to contribute to the circular economy, since the bionaphtha used derives from waste from industrial processing of organic substances (e.g. used cooking oils). Pharmalene FL 45 PH BCA will be bio circular attributed for 86%. The exact amount of "bio circular 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)	2,5	g/10min	ISO 1133
Vinyl acetate content	14	%	Internal Method
Density	0,935	g/cm^3	ISO 1183
Melting Point	91	°C	Internal Method
Brittleness temperature	<- 80	°C	ASTM D 746
Vicat softening point (1 kg)	67	°C	ISO 306/A
Film Properties *	**Value**	**Unit**	**Test method**
Tensile stress at yield MD	5,5	MPa	ISO 527 - 3
Tensile stress at yield TD	5	MPa	ISO 527 - 3
Tensile stress at break MD	28	MPa	ISO 527 - 3
Tensile stress at break TD	26	MPa	ISO 527 - 3
Elongation at break MD	500	%	ISO 527 - 3
Elongation at break TD	700	%	ISO 527 - 3
1% Secant modulus MD	65	MPa	ISO 527 - 3
1% Secant modulus TD	70	MPa	ISO 527 - 3
Elmendorf tear resistance MD	26	N/mm	ISO 6383 - 2
Elmendorf tear resistance TD	50	N/mm	ISO 6383 - 2
Impact Resistance F50 (Dart Drop Test)	400	g	ISO 7765 - 1/A
Dynamic coefficient of friction (COF)	> 0,5	-	ISO 8295
Haze	2	%	ISO 14782
Gloss, 45°	85	%	ASTM D 2457
Recommended film thickness	25 ÷ 80	micron	-
Molded Specimen Properties *	**Value**	**Unit**	**Test method**
Hardness Shore A	92	-	ISO 868 A
Hardness Shore D	40	-	ISO 868 A
Flexural Modulus	60	MPa	ISO 178

(*) Film properties are typical of a blown film extruded at 160 °C. Molded specimen properties are referred to Injection Molding specimens. Actual properties may vary depending upon operating conditions and additive package.

PHARMALENE® EVA / Ethylene vinyl acetate copolymer bio circular attributed **FL 45 PH BCA**

MAIN APPLICATIONS

Pharmalene FL 45 PH BCA is intended for the use within pharmaceutical sector and is characterized by good optical properties and by good elasticity and sealability. Pharmalene FL 45 PH BCA is suitable for the production of flexible medical packaging, gaskets for medical applications or can be used for medical tubing applications.

PROCESSING NOTES

Pharmalene FL 45 PH BCA can be processed by conventional blown film extrusion equipments. Operation temperature from 150 °C to 170 °C is recommended. Depending on extrusion conditions, the suggested film thickness is 25÷80 µm.

STORAGE AND HANDLING

Pharmalene FL 45 PH BCA 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 FL 45 PH BCA 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

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