Technical Data Sheet

# PHARMALENE®
## FL 20 PH BA

Medical grade LDPE
Low density polyethylene bio attributed

## SUSTAINABILITY

The "bio attributed" product Pharmalene FL 20 PH BA is a highly sustainable medical grade LDPE 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 20 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 FL 20 PH BA is a low density polyethylene (LDPE) without additives obtained by high pressure autoclave process. It is produced according to good manufacturing practices (GMP) and is mainly used for blown film extrusion, extrusion and extrusion blow moulding. The production of Pharmalene FL 20 PH BA allows to contribute to the circular economy, since the bionaphtha used derives from renewable sources (e.g. vegetable oils). Pharmalene FL 20 PH BA will be bio attributed for 100%. 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) | 2,2 | 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 | 0,921 | g/cm$^3$ | ISO 1183 |
| Melting Point | 109 | °C | Internal Method |
| Brittleness temperature | <- 75 | °C | ASTM D 746 |
| Vicat softening point (1 kg) | 90 | °C | ISO 306/A |

| Film Properties * | Value | Unit | Test method |
|---|---|---|---|
| Tensile stress at yield MD | 10 | MPa | ISO 527 - 3 |
| Tensile stress at yield TD | 10 | MPa | ISO 527 - 3 |
| Tensile stress at break MD | 25 | MPa | ISO 527 - 3 |
| Tensile stress at break TD | 19 | MPa | ISO 527 - 3 |
| Elongation at break MD | 300 | % | ISO 527 - 3 |
| Elongation at break TD | 550 | % | ISO 527 - 3 |
| 1% Secant modulus MD | 160 | MPa | ISO 527 - 3 |
| 1% Secant modulus TD | 180 | MPa | ISO 527 - 3 |
| Elmendorf tear resistance MD | 70 | N/mm | ISO 6383 - 2 |
| Elmendorf tear resistance TD | 45 | N/mm | ISO 6383 - 2 |
| Impact Resistance F50 (Dart Drop Test) | 190 | g | ISO 7765 - 1/A |
| Dynamic coefficient of friction (COF) | > 0,5 | - | ISO 8295 |
| Haze | 9 | % | ISO 14782 |
| Gloss, 45° | 54 | % | ASTM D 2457 |
| Recommended film thickness | 25 ÷ 80 | micron | - |

(*) Typical value for a film extruded with BUR 1:3, thickness 40 µm. Actual properties are typical and may vary depending upon operating conditions and additive package.

Manufacturer website: https://www.versalis.eni.com/

**PHARMALENE®** LDPE / Low density polyethylene bio attributed

**FL 20 PH BA**

## MAIN APPLICATIONS

Pharmalene FL 20 PH BA is intended for the use within pharmaceutical sector and is characterized by an optimal balance between processability and mechanical properties.
Pharmalene FL 20 PH BA is suitable for the production of multilayer films for blisters and for pharmaceutical monodoses or small bottles.

## PROCESSING NOTES

Pharmalene FL 20 PH BA can be processed by conventional blown film extrusion equipments. Melt temperature from 160 °C to 190°C is recommended. Depending on extrusion conditions, the suggested film thickness is 25÷80 µm.

## STORAGE AND HANDLING

Pharmalene FL 20 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 FL 20 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

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**IMPORTANT:** please consult the relevant safety data sheet for more detailed information. The information and data presented herein are to the best of our knowledge true and accurate but no warranty or guarantee, expressed or implied, is made nor is any liability accepted with respect to the use of such information and data. Versalis is available to provide the guaranteed values for each product on demand.

**DISCLAIMER:** It is the responsibility of the user to verify the technical suitability and the safe and regulatory compliant usage of this product in all medical and pharmaceutical applications. If a usage of this product in applications of the pharmaceutical and medical sector, such as Class I, IIa, IIb or III Medical Devices (U.S. FDA, Health Canada and/or EU Directive 2007/47/EC) and in applications involving permanent implantation into the human body, is intended, user must consult Versalis to receive prior written approval for each specific product and applications.

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Manufacturer website: https://www.versalis.eni.com/