Eltex[®] MED PH23H630

Product Technical Information

Low Density Polyethylene for Pharmaceutical Blow-Fill-Seal

Benefits & Features

Eltex[®] MED PH23H630 is a LD-polyethylene produced in a high-pressure process intended for blow moulding of soft and flexible packages for pharmaceutical products.

Eltex[®] MED PH23H630 is produced according to good manufacturing practice and is additive-free. Eltex[®] MED PH23H630 is available in granular form.

Applications

Eltex® MED PH23H630 can be used in "blow-fill and seal" machines for the production of ampoules and bottles. The product can also be used for pharmaceutical products manufactured with other conversion techniques such as blow moulding or injection moulding. The product is not intended for heat sterilization.

Properties	Conditions	Test Methods	Values	Units
Physical				
Density		ISO1183-1 & ISO 1872-1	923	kg/m³
Melt Flow Rate	190°C/2.16 kg	ISO 1133-1	2.0	g/10 min
Mechanical				
Tensile Stress at Yield	50 mm/min	ISO 527-1,-2	11	MPa
Hardness Shore D		ISO 868	50	-
Thermal				
Heat Deflection Temperature	0.45 MPa	ISO 75-2	50	°C
Data should not be used for specification work				

Compliance to Regulations on Medical use

Eltex® MED PH23H630 complies with the European Pharmacopoeia – Monograph 3.1.4 and meets the requirements of the USP29, <88> guideline concerning the biological reactivity test in vivo (so-called USP Class VI)

Processing guidelines

Eltex[®] MED PH23H630 is easy to extrude. Recommended melt temperature is 165-190°C

Storage

The product should be stored in a dry and dust free environment at temperature below 50°C. Exposure to direct sunlight should be avoided as this may lead to product deterioration. It is advised to process the product within maximum one year after delivery.

Regulatory Information

The product and uses described herein may be subject to specific requirements or limitations for use in certain applications like food contact, drinking water or medical devices. Further information may be obtained from the website <u>www.ineos.com</u> where a specific Regulatory Certificate is available for each grade under the heading "SDS & Regulatory Certificate".

Unless specifically indicated, the product mentioned herein is not suitable for applications in the medical or pharmaceutical sectors.

Health and Safety Information

The product described herein may require precautions in handling. The available product health and safety information for this material is contained in the Safety Data Sheet (SDS) that may be obtained from the website <u>www.ineos.com</u>. Before using any material, a customer is advised to consult the SDS for the product under consideration for use.

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