

Technical Data Sheet

Estar™ Copolyester MB002

Applications

- Blood contact and dialysis
- Fluid administration
- Medical devices
- Medical labware

Key Attributes

- Chemical resistance to most medical solvents including lipids and IPA
- Gamma and E-beam color stability
- Good melt strength for EBM processes

Product Description

Estar™ copolyester MB002 has been tested for FDA/ISO 10993 and USP Class VI Biological Evaluation testing after Gamma and EtO sterilization. It is a resin specifically developed for extrusion blow molding containers in medical applications where aesthetics such as high clarity and gloss, coupled with high toughness and chemical resistance, are desirable. Compared to many commonly used materials, Estar™ copolyester MB002 runs on most standard processing equipment with broader processing conditions, and its toughness and melt strength enable blow molding of larger containers with greater design flexibility. This product meets the biocompatibility requirements under FDA/ISO 10993 and USP Class 6, Plastics.

This product has been GREENGUARD INDOOR AIR QUALITY CERTIFIED®.

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Typical Properties

Property ^a	Test Method ^b	Typical Value, Units ^c
General Properties		
Density	D 792	1.25 g/cm ³
Mold Shrinkage	D 955	0.3 %
Mechanical Properties		
Tensile Stress @ Yield	D 638	47 MPa (6900 psi)
Tensile Stress @ Break	D 638	48 MPa (7000 psi)
Elongation @ Yield	D 638	5 %
Elongation @ Break	D 638	300 %
Tensile Modulus	D 638	1900 MPa (2.7 x 10 ⁵ psi)
Flexural Modulus	D 790	1900 MPa (2.7 x 10 ⁵ psi)
Flexural Strength	D 790	65 MPa (9400 psi)
Rockwell Hardness, R Scale	D 785	105
Izod Impact Strength, Notched ^d		
@ 23°C (73°F)	D 256	NB
@ -40°C (-40°F)	D 256	63C J/m (1.2C ft·lbf/in.)
Impact Strength, Unnotched ^e		
@ 23°C (73°F)	D 4812	NB
@ -40°C (-40°F)	D 4812	NB
Impact Resistance (Puncture), Energy @ Max. Load		
@ 0°C (32°F)	D 3763	41 J (30 ft·lbf)

@ 23°C (73°F)	D 3763	41 J (30 ft·lbf)
@ -40°C (-40°F)	D 3763	39 J (29 ft·lbf)
Optical Properties		
Haze	D 1003	1.3 %
Gloss		
@ 60°	D 2457	143
Regular Transmittance	D 1003	87 %
Total Transmittance	D 1003	91 %
Color		
a*	D 2244	-0.2
b*	D 2244	0.6
L*	D 2244	95.0
Thermal Properties		
Deflection Temperature		
@ 0.455 MPa (66 psi)	D 648	73 °C (163 °F)
@ 1.82 MPa (264 psi)	D 648	63 °C (145 °F)
Vicat Softening Temperature	D 1525	85 °C (185 °F)

^aUnless noted otherwise, all tests are run at 23°C (73°F) and 50% relative humidity.

^bUnless noted otherwise, the test method is ASTM.

^cUnits are in SI or US customary units.

^dC = Complete Break; Nonbreak as defined by ASTM D 256.

^eNonbreak as defined by ASTM D 4812.

Eastman Medical Disclaimer

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product in order to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman Chemical Company products have not been designed for nor are they promoted for end uses that would be categorized by either the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1 "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices, or (3) as any critical component in any medical device that supports or sustains human life.

Eastman Chemical Company products offered for the medical market have met selected FDA-Modified ISO-10993, Part 1 "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less. The tests include: cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (sub-acute), implantation, hemocompatibility. The Manufacturer is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman Product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

Comments

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