

Product Data Sheet

Eastar™ Copolyester MN021 Natural

Application/Uses

- Drug Delivery
- Labware
- Medical

Key Attributes

- Chemical resistance to most medical solvents including lipids and IPA
- Gamma and E-beam color stability

Product Description

Eastar™ Copolyester MN021 Natural has been tested for FDA/ISO 10993 and USP Class VI Biological Evaluation testing after Gamma and EtO sterilization. It is a thermoplastic condensation copolymer produced by a continuous melt-phase polymerization process followed by a solid-state polymerization process. It has been crystallized.

This product has been GREENGUARD INDOOR AIR QUALITY CERTIFIED®.

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Typical Properties

Property ^a	Test ^b Method	Typical Value, Units ^c
General Properties		
Specific Gravity	D 792	1.33
Mechanical Properties		
Tensile Stress @ Yield	D 638	58 MPa (8400 psi)
Tensile Stress @ Break	D 638	25 MPa (3600 psi)
Elongation @ Break	D 638	120%
Tensile Modulus	D 638	2400 MPa (3.5 x 10 ⁵ psi)
Flexural Yield Strength	D 790	84 MPa (12200 psi)
Flexural Modulus	D 790	2500 MPa (3.6 x 10 ⁵ psi)
Rockwell Hardness, R Scale	D 785	112
Izod Impact Strength, Notched @ 23°C (73°F)	D 256	40 J/m (0.75 ft·lbf/in.)

@ -40°C (-40°F)	D 256	27 J/m (0.51 ft·lbf/in.)
Impact Strength, Unnotched		
@ 23°C (73°F)	D 4812	NB
@ -20°C (-4°F)	D 4812	NB
@ -30°C (-22°F)	D 4812	NB
@ -40°C (-40°F)	D 4812	NB

Impact Resistance (Puncture), Energy @ Max. Load		
2.5-mm (0.100-in.) Thick Plaques, @ 23°C (73°F)	D 3763	26 J (19 ft·lbf)
2.5-mm (0.100-in.) Thick Plaques, @ -40°C (-40°F)	D 3763	1.6 J (1.2 ft·lbf)
3.2-mm (0.125-in.) Thick Plaques @ 23°C (73°F)	D 3763	31 J (23 ft·lbf)
3.2-mm (0.125-in.) Thick Plaques @ -40°C (-40°F)	D 3763	2.1 J (1.6 ft·lbf)

Thermal Properties

Deflection Temperature		
@ 0.455 MPa (66 psi)	D 648	69°C (156°F)
@ 1.82 MPa (264 psi)	D 648	65°C (149°F)

Optical Properties

Haze	D 1003	1.0%
Total Transmittance	D 1003	84%

Typical Processing Conditions

Drying Temperature	150-160°C (300-320°F)
Drying Time	4-6 hrs
Processing Melt Temperature	275-295°C (530-565°F)
Mold Temperature	10-30°C (50-90°F)

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

^b Unless noted otherwise, the test method is ASTM.

^c Units are in SI or US customary units.

Comments

Properties reported here are typical of average lots. Eastman makes no representation that the material in any particular shipment will conform exactly to the values given.

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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.

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