Product Data Sheet

DuraStar™ Polymer MN631, Natural

Application/Uses

- Blood Contact
- Drug Delivery
- IV Components
- Medical
- Surgical Instruments

Key Attributes

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

Product Description

DuraStar™ Polymer MN631 has been tested for FDA/ISO 10993 and USP Class VI Biological Evaluation testing after Gamma and EtO sterilization. It contains a mold release. It has excellent appearance and is nearly water-clear. Its most outstanding features are toughness, chemical resistance, and excellent processing characteristics. MN631 has very good toughness. Easy to process with minimal drying time, it flows readily and fills the most intricate tools.

Typical Properties

Property[a]	Test[b] Method	Typical Value, Units[c]
General Properties		
Specific Gravity	D 792	1.19
Mold Shrinkage	D 955	0.003 mm/mm (0.003 in./in.)
Water Absorption, 24 h immersion	D 570	0.15%
Mechanical Properties		
Tensile Stress @ Yield	D 638	50 MPa (7200 psi)
Tensile Stress @ Break	D 638	43 MPa (6300 psi)
Elongation @ Yield	D 638	5%
Elongation @ Break	D 638	270%
Flexural Yield Strength	D 790	68 MPa (9800 psi)
Flexural Modulus	D 790	1900 MPa (2.7 x 10^5 psi)
Rockwell Hardness, R Scale	D 785	107
Izod Impact Strength, Notched		
@ 23°C (73°F)	D 256	80 J/m (1.5 ft·lbf/in.)
@ -40°C (-40°F)	D 256	44 J/m (0.8 ft·lbf/in.)

Impact Strength, Unnotched		
@ 23°C (73°F)	D 4812	NB
@ -40°C (-40°F)	D 4812	NB
Impact Resistance (Puncture), Energy @ Max. Load		
@ 23°C (73°F)	D 3763	40 J (30 ft·lbf)
@ -40°C (-40°F)	D 3763	38 J (28 ft·lbf)
Thermal Properties		
Deflection Temperature		
@ 0.455 MPa (66 psi)	D 648	73°C (163°F)
@ 1.82 MPa (264 psi)	D 648	66°C (150°F)
Vicat Softening Temperature @ 1 kg load	D 1525	86°C (186°F)
Optical Properties		
Total Transmittance	D 1003	92%
Haze	D 1003	< 1%
Typical Processing Conditions		
Drying Temperature		70°C (160°F)
Drying Time		4 hrs
Processing Melt Temperature		230-280°C (450-530°F)
Mold Temperature		15-30°C (60-80°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.

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.

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