

Technical Data Sheet Ecdel™ Elastomer 9967

Applications

- Iv bags packaging
- Pharmaceutical packaging

Key Attributes

- Chemical resistant with low extractables
- Excellent clarity
- Excellent toughness & flexibility without plasticizers
- Heat & sterilization stability

Product Description

Meets ISO 10993 and/or USP Class VI biocompatibility requirement.

Ecdel[™] elastomers are plasticizer free copolyester elastomers (COPE) that offer clarity, toughness, flexibility, and chemical resistance for flexible packaging including medical and pharmaceutical applications. Ecdel[™] elastomer 9967 may be processed on standard injection molding, extrusion blow molding, profile extrusion, extrusion coating, or film extrusion equipment. Ecdel[™] elastomers may be extrusion blow molded directly into bags or extruded into blown or cast film for later fabrication into bags. Ecdel[™] elastomers are radiation, electron beam, ethylene oxide, and autoclave sterilization stable. 9967's high inherent viscosity may be helpful where good melt strength is required (blown film or profile extrusion).

This product has been *CRADLE TO CRADLE CERTIFIED*TM Bronze, with Material Health Certificate, Platinum. The *CRADLE TO CRADLE CERTIFIED* mark is a registered certification mark used under license through the Cradle to Cradle Products Innovation Institute, a nonprofit organization that administers the publicly available *Cradle to Cradle Certified*TM Product Standard which provides designers and manufacturers with criteria and requirements for continually improving product materials and manufacturing processes. The *Cradle to Cradle Certified*TM Product Standard guides designers and manufacturers through a continual improvement process that looks at a product through five quality categories—material health, material reutilization, renewable energy and carbon management, water stewardship, and social fairness. A product receives an achievement level in each category—Basic, Bronze, Silver, Gold, or Platinum—with the lowest achievement level representing the product's overall mark.

The Material Health Certificate provides manufacturers with a trusted way to communicate their efforts to identify and replace chemicals of concern in their products. For more information about Cradle to Cradle certification and to obtain printable certificates for Eastman copolyesters, visit . Search for Eastman Chemical Company in *Cradle to Cradle Certified* Products Registry.

Property ^a	Test Method ^b	Typical Value, Units ^c
Film Properties		
Thickness of Film Tested		0.13 mm (5 mils)
Refractive Index, n _D	D 542	1.51
Haze	D 1003	1 %
Gloss		
@ 45°	D 2457	73
Regular Transmittance	D 1003	91 %
Total Transmittance	D 1003	94 %
Tensile Stress @ Yield		
T.D.	D 882	11.2 MPa (1600 psi)
Tensile Strength @ Break		
M.D.	D 882	41.5 MPa (6000 psi)
		18.1 MPa (2600 psi)

Typical Properties



T.D.	D 882	
Elongation @ Yield		
M.D.	D 882	46 %
T.D.	D 882	20 %
Elongation @ Break		
M.D.	D 882	330 %
T.D.	D 882	>550 %
Tensile Modulus, Tangent		
M.D.	D 882	197 MPa (28600 psi)
T.D.	D 882	221 MPa (32000 psi)
Water Vapor Transmission Rate ^g	F 372	146 g/m ² ·24h (9.5 g/100in. ² ·24h)
Gas Permeability, O ₂		
@ 30°C (86°F)	D 1434	940 cm ³ /m ² *24h*atm (61
		cm ³ /100in. ² ·24h∙atm)
Coefficient of Friction	D 1894	>1
Mechanical Properties		
Specific Gravity	D 792	1.13
Durometer Hardness		
Shore A Scale	D 2240	95
Shore D Scale	D 2240	55
Tensile Stress @ Break ^d	D 638	23 MPa (3300 psi)
Tensile Stress @ Yield ^e	D 638	13 MPa (1900 psi)
Elongation @ Yield	D 638	38 %
Elongation @ Break	D 638	400 %
Tensile Modulus	D 638	170 MPa (24650 psi)
Flexural Modulus	D 790	150 MPa (21750 psi)
Tear Strength	D 1004	350 N (79 lbf)
Izod Impact Strength, Notched		
@ -40°C (-40°F)	D 256	40 J/m (0.75 ft·lbf/in.)
Torsional Modulus Temperature		
@ 240 MPa (35,000 psi)	D 1043	-28 °C (-18 °F)
@ 930 MPa (135,000 psi)	D 1043	<-70 °C (<-94 °F)
Water Absorption, 24 h immersion	D 570	0.4 %
Thermal Properties	0 0 0 0	
Inherent Viscosity	EMN-A-AC-G-V-1	1.23
Flow Rate		
(Condition 215°C/2.16 kg)	D 1238	8 g/10 min
(Condition 230°C/2.16 kg)	D 1238	12 g/10 min
Crystalline Peak Melting Point (T _m)	D 3418	205 °C (400 °F)
Crystallization Temperature on	DSC	140 °C (284 °F)
Cooling (T_cc)	030	
Glass Transition Temperature (T_{d})	DSC	-40 °C (-40 °F)
Specific Heat ^f		
•	DSC	1.8 kJ/kg·K (0.43 Btu/lb·°F)
@ 100°C (212°F) - solid @ 150°C (302°F) - solid	DSC DSC	2.0 kJ/kg·K (0.48 Btu/lb·°F)
@ 175°C (347°F) - solid	DSC	2.3 kJ/kg·K (0.55 Btu/lb·°F)
@ 200°C (392°F) - transition	DSC	3.1 kJ/kg·K (0.74 Btu/lb·°F)
@ 225°C (437°F) - melt	DSC	2.3 kJ/kg·K (0.55 Btu/lb·°F)
@ 25°C (77°F) - solid	DSC	1.6 kJ/kg·K (0.38 Btu/lb·°F)
		27 kJ/kg (11.6 Btu/lb)
Heat of Euclop		
Heat of Fusion	E 793	
Thermal Conductivity	C 177	0.19 W/m·K (1.3 Btu·in./h·ft ² ·°F)
Thermal Conductivity Coefficient of Linear Thermal		0.19 W/m·K (1.3 Btu·in./h·ft ² ·°F) 15 x 10 ⁻⁵ /°C (mm/mm·°C) (8 x 10
Thermal Conductivity	C 177	0.19 W/m·K (1.3 Btu·in./h·ft ² ·°F)

Vicat Softening Temperature

^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.

^dD 412, Die C specimens, which are equivalent to ASTM D 638, Type IV specimens. Specimens were 2.0 mm (0.075 in.) thick and were tested using a crosshead speed of 500 mm (20 in.) per min.

^eInjection molded ASTM D 638 Type I specimens, about 3 mm (1/8 in.) thick, were tested using a crosshead speed of 500 mm (20 in.) per min. ^fFor 200°C (392°F) - transition, apparent specific heat, including the effects of the heat of fusion.

^gTest conducted at 38°C (100°F) and 100% relative humidity.

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

Properties reported here are based on limited testing. Eastman makes no representation that the material in any particular shipment will conform exactly to the values given.

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