EASTMAN

Technical Data Sheet

Ecdel™ Elastomer 9965

Applications

- Iv bags packaging
- Medical tubing & bags - not iv
- 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 medical grade copolyester ethers (COPE) that offer the clarity, toughness, and chemical resistance needed in a variety of flexible packaging including medical and pharmaceutical applications. Ecdel™ elastomer 9965 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 film for later fabrication into bags. Ecdel™ elastomers are radiation, electron beam, ethylene oxide, and autoclave sterilization stable. 9965's low inherent viscosity may be helpful for extrusion coating or cast film extrusion applications.

This product has been *CRADLE TO CRADLE CERTIFIED*™ 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*™ Product Standard which provides designers and manufacturers with criteria and requirements for continually improving product materials and manufacturing processes. The *Cradle to Cradle Certified*™ 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.

Typical Properties

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	80
Regular Transmittance	D 1003	90 %
Total Transmittance	D 1003	93 %
Tensile Strength @ Yield		
M.D.	D 882	13.7 MPa (2000 psi)
T.D.	D 882	13.5 MPa (2000 psi)
Tensile Strength @ Break		
		23.7 MPa (3400 psi)

M.D.	D 882	
T.D.	D 882	22.6 MPa (3300 psi)
Elongation @ Yield		
M.D.	D 882	26 %
T.D.	D 882	26 %
Elongation @ Break		
M.D.	D 882	550 %
T.D.	D 882	550 %
Tensile Modulus, Tangent		
M.D.	D 882	185 MPa (26800 psi)
T.D.	D 882	179 MPa (26000 psi)
Water Vapor Transmission Rate[g]	F 372	132 g/m^2·24h (8.5 g/100$in.^2$·24h)
Gas Permeability, O_2		
@ 30°C (86°F)	D 1434	841 cm^3/m^2*24h*atm (54 cm^3/100$in.^2$·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	20 MPa (2900 psi)
Tensile Stress @ Yield[e]	D 638	14 MPa (2030 psi)
Elongation @ Yield	D 638	30 %
Elongation @ Break	D 638	300 %
Tensile Modulus	D 638	170 MPa (24650 psi)
Flexural Modulus	D 790	150 MPa (21750 psi)
Tear Strength	D 1004	370 N (84 lbf)
Izod Impact Strength, Notched		
@ -40°C (-40°F)	D 256	50 J/m (0.94 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	0.35 %
Thermal Properties		
Inherent Viscosity	EMN-A-AC-G-V-1	1.05
Flow Rate		
(Condition 215°C/2.16 kg)	D 1238	25 g/10 min
(Condition 230°C/2.16 kg)	D 1238	39 g/10 min
Crystalline Peak Melting Point (T_m)	D 3418	207 °C (405 °F)
Crystallization Temperature on Cooling (T_cc)	DSC	140 °C (284 °F)
Glass Transition Temperature (T_g)	DSC	-40 °C (-40 °F)
Specific Heat[f]		
@ 100°C (212°F) - solid	DSC	1.8 kJ/kg·K (0.43 Btu/lb·°F)
@ 150°C (302°F) - solid	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)
Heat of Fusion	E 793	27 kJ/kg (11.6 Btu/lb)
Thermal Conductivity	C 177	0.19 W/m·K (1.3 Btu·in./h·ft^2·°F)
Coefficient of Linear Thermal Expansion	D 696	15 x 10^{-5} /°C (mm/mm·°C) (8 x 10^{-5} /°F (in./in.·°F))
Brittleness Temperature	D 746	<-75 °C (<-103 °F)

Vicat Softening Temperature @ 1 kg load	D 1525	170 °C (338 °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.*
[d]*D 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.*
[e]*Injection 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.*
[f]*For 200°C (392°F) - transition, apparent specific heat, including the effects of the heat of fusion.*
[g]*Test 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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