

Technical Data Sheet DX Material

Applications

- · Rigid medical packaging
- · Orthodontic aligners and retainers

Product Description

DX Material is a higher heat polymer than Eastar'" copolyester 6763, used for rigid medical packaging applications only. Plastic sheet and film can be purchased through Tru-Tain.

Requests for DX Material should be directed to Ryan Truax of Tru-Tain (507) 288-3067.

This product has received a Platinum level Material Health Certificate from the Cradle to Cradle Products Innovation Institute. A Material Health Certificate is awarded to products that meet the Material Health requirements of the multi-attribute *Cradle to Cradle Certified™* Product Standard. The Cradle to Cradle Products Innovation Institute is 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 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 www.c2ccertified.org. Search for Eastman Chemical Company in the Material Health Certificate Registry.

Typical Properties

Property•	Test Methodb	Typical Value, Unitsc
Film Properties		
Thickness of Film Tested		0.01 in.
Inherent Viscosityd	EMN-A-AC-G-V-1	0.71
Glass Transition Temperature (Tglf	DSC	87 OC (189 Of)
Tensile Strength @ Yield		_
M.D.	D 882	44 MPa (6400 psi)
Tensile Strength @ Break		
M.D.	D 882	66 MPa (9600 psi)
Elongation @ Yield		
MD	D 000	407
M.D.	D 882	4%
Elongation @ Break•		
M.D.	D 882	250 %
Tensile Modulus, 1% Secant		_
M.D.	D 882	1600 MPa (2.4 x 10 ⁵ psi)
Tensile Modulus, Tangent		
M.D.	D 882	1700 MPa (2.5 x 10 ⁵ psi)
Dart Impact	 D 1709A	466 g
Impact Resistance (Puncture). Energy @ Max. Load	D 3763	3.3 J (2.4 <u>ft·lbf)</u>
Color		
a*	D 2244	0.01

b*	D 2244	0.3
L*	D 2244	96.25
Gloss		
@45°	D 2457	106
Transparency	D 1746	100 %
Regular Transmittance	D 1003	90 %
Total Transmittance	D 1003	93 %
Hazee	D 1003	0.96%
Injection Molded Properties		
Specific Gravity	D 792	1.23
Water Absorption, 24 h Immersion	D 570	0.14%
Mold Shrinkage•	D 955	-0.0036 mm/mm (-0.0036 in.fin.)
Deflection Temperature		
@ 0.455 MPa (66 psi)	D 648	72 oc (162 Of)
@ 1.82 MPa (264 psi)	D 648	66 oc (151 Of)
Vicat Softening Temperature	D 1525	87 oc <u>(189 Of)</u>
Tensile Stress @ Yield	D 638	46 MPa (6700 psi)
Tensile Stress @ Break	D 638	44 MPa (<u>6400 psi)</u>
Elongation @ Yield	D 638	5%
Elongation @ Break	D 638	270 %
Flexural Strength	D 790	66 MPa (9600 psi)
Flexural Modulus	D 790	1900 MPa (2.8 x 10 ⁵ psi)
Rockwell Hardness, R Scale	D 785	108
Izod Impact Strength, Notched		
@ 23°c (73°FJ	D 256	NB
@ -40°C (-40°F)	D 256	67 J/m (1.3 ft-lbf/in.)
Impact Strength, Unnotched		
@ 23°c (73°F)	D 4812	NB
@ -40°C (-40°F)	D 4812	NB
Color ⁹		
a*	D 2244	-0.11
b*	D 2244	0.3
L*	D 2244	95.83
Total Transmittance	D 1003	93 %
Hazee		

⁸Unless noted otherwise, all tests are run at 23°G (73°F) and 50% relative humidity. bUnless noted otherwise, the test method is ASTM. cunits are in SI or US customary units.

ecoefficient of variance >10%.

f2nd heating cycle.

9Transmitted, molded plaque.

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.

a 10-mil film, in PM 95

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 150-10993, 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.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified 150-10993, Part 1 "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (sub-acute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available upon request. The Manufacturer of the medical device 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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