ECDEL™
elastomers

EASTMAN

You have our
undivided attention.

Eastman is proud of its commitment to the healthcare industry. Supplying plastics and chemicals for medical products since 1935, Eastman has built its reputation on high quality materials, prompt and knowledgeable technical service, dependability, lot-to-lot consistency, and technological advancement and innovation with strict adherence to regulations around the world.

Eastman's portfolio of resins for the medical industry, as shown in the following list, represents a diverse range of chemistries and capabilities that enable our customers to develop new medical devices required in today's specialized medical fields. These resins are used in a wide variety of medical applications such as filters, syringes, tubing, connectors, pump housings, clamps, caps, blood tubes, IV and drainage bottles, and rigid and flexible packaging.

- DuraStar™ polymers
- Eastar™ copolyesters
- Ecdel™ elastomers
- Eastman Provista™ copolymer MP
- Tenite™ cellulosics
- Eastman Tritan™ copolyester

Ecdel elastomers

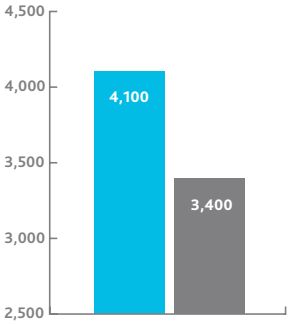
Ecdel elastomers are copolyester-ether (COPE) copolymers that are clear and tough with elastomeric-like properties that impart strength, durability, and puncture resistance to medical articles. Applications include extruded flexible film and tubing for the delivery of IV solutions. Ecdel elastomers retain physical properties and remarkable blush-free clarity even after high-temperature or steam autoclaving. Ecdel combines chemical resistance, toughness, sterilization stability, and flexibility over a broad temperature range.

Ecdel elastomers are ideal for applications in medical packaging and tubing where low extractables, toughness, flex-crack resistance, and utility in harsh environments are required.

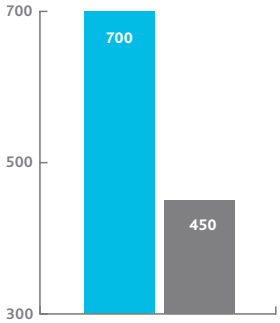
Features and benefits

- High flexibility without plasticizers
- Very high clarity
- Excellent toughness
  - Puncture resistance
  - Low-temperature strength
- No plasticizer additives
- Passes ISO 10993/USP Class VI biocompatibility testing
- Solvent bondable
- Low extractables
- Chemical resistance
- Thermal/autoclave stability
- Dimensional stability
- Radiation and ethylene oxide stability

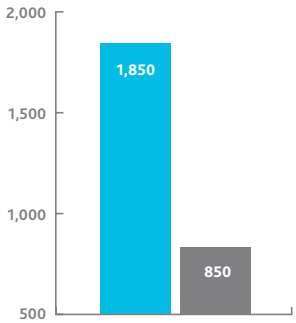
Tensile strength @ break, machine direction (psi) ASTM D882



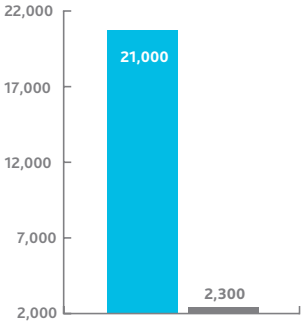
Elongation @ break, machine direction (%) ASTM D882



Trouser tear resistance, machine direction (g) ISO 6383



1% secant modulus, machine direction (psi) ASTM D882



Ecdel 9966—8 mils
PVC—14 mils

Mechanical properties of Ecdel™ 9966 elastomer

Property[a] units	ASTM method	Typical value
Specific gravity	D792	1.13
Durometer hardness, shore D/A scale	D2240	55/95
Tensile stress @ break, MPa (psi)	D638[b]	22 (3,200)
Tensile stress @ yield, MPa (psi)	D638[c]	14 (2,030)
Elongation @ yield, %	D638	38
Elongation @ break, %	D638	400
Tensile modulus, MPa (psi)	D638	170 (24,650)
Flexural modulus, MPa (psi)	D790	150 (21,750)
Tear strength, N (lbf)	D1004	350 (79)
Izod impact strength, notched, J/m (ft·lbf/in.) @ –40°C (–40°F)	D256	40 (0.75)
Torsional modulus temperature, °C (°F) @ 240 MPa (35,000 psi)	D1043	–28 (–18)
@ 930 MPa (135,000 psi)		<–70 (<–94)
Water absorption, 24h, %	D570	0.4

[a]*Unless noted otherwise, all tests are run @ 23°C (73°F) and 50% RH.*

[b]*D412, Die C specimens, which are equivalent to ASTM D638, 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.*

[c]*Injection molded ASTM D638 Type I specimens, about 3-mm (0.25-in.) thick, were tested using a crosshead speed of 500 mm (20.0 in.) per min.*

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.

Ecdel™ elastomers for film applications

Ecdel elastomers can be processed into film via cast or blown film processes. This film offers brilliant clarity and gloss as well as extreme toughness to packaging applications. In addition, Ecdel can be coextruded with other thermoplastic materials such as EVOH, PP, and PE when additional performance properties, such as oxygen or a water barrier, are required. When used as an outer skin layer, the elastomer provides softness, strength, clarity, and scuff resistance. It has excellent heat resistance as it does not begin to soften until 170°C (335°F).

Flexible tubing

Ecdel elastomers can be successfully extruded into both monolayer or coextruded medical tubing products. It is particularly suitable as the outer skin layer of flexible, coextruded tubing, offering excellent bonding to a variety of materials using solvent, adhesive, UV, heat, radio frequency, and laser methods.

Whether injection molded, blow molded, or extruded, Ecdel elastomers combine unique value-adding properties and good processing to enable solutions in very demanding medical applications.

Working with customers to bring innovative solutions to the marketplace

As the flexible tubing market seeks alternatives to PVC, medical OEMs are introducing tubing solutions containing Ecdel elastomers. OEMs are specifying Ecdel because it delivers the needed safety, cleanliness, toughness, autoclavability, clarity, and bondability they require for high-end applications. Ecdel may be safely incinerated.

Due to health and disposal concerns, many companies are looking to switch to non-PVC products. Ecdel elastomer can be readily disposed of in landfills or through incineration with minimal by-products.

Technical service and product development

Eastman is constantly innovating new medical products and services needed in the rapidly changing and demanding medical marketplace. We are committed to offering high quality heritage and new medical plastics to exceed customer requirements. Eastman opened its new thermoplastic elastomer (TPE) application development center in June 2009 to expand into exciting underserved elastomer applications. We also expanded our medical polymer portfolio in 2009, 2010, and 2011 by launching new grades of award-winning, top-performing, and application-winning Eastman Tritan™ copolyester.

In addition to resins, Eastman provides outstanding applications, sales, marketing, and technical support. Our Technical Service group is available to assist you during the design and production phases of your application. Eastman's highly trained technical staff can help reduce development and commercialization cycles critical to maintaining a competitive edge.

Eastman Technical Service centers offer a variety of tools to assist you:

- Processing bulletins
- Physical and analytical testing
- Prototype development
- Production start-up assistance

Our website, **www.eastman.com,** features e-commerce capabilities, making it easier to do business with Eastman. Also, the online medical technical center is full of information to help you research, troubleshoot, and develop rapid solutions.

You can readily order products, check order status, review order history, request COAs for Eastman products, track railcar shipments, and view open invoices online. Our Product Catalog features technical information such as data sheets, SDS, and application, health, safety, and environmental information. Also, browse our Solutions Area to use online wizards, view product documents, and access frequently asked questions relating to brands, markets, and processes.

For more information about Eastman's portfolio of resins for the medical industry or, specifically, Ecdel™ elastomers for medical packaging and tubing applications, call your Eastman representative today or visit **www.eastman.com/markets/medical.**

EASTMAN

The results of **insight**™

Eastman Corporate Headquarters
P.O. Box 431
Kingsport, TN 37662-5280 U.S.A.

U.S.A. and Canada, 800-EASTMAN (800-327-8626)
Other Locations, +(1) 423-229-2000

www.eastman.com/locations

Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman Chemical Company ("Eastman") products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

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 to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by 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.

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 ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on 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 on 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.

SP-MBS-5806 8/18