

Eastman Ecdel™ elastomer delivers The Material Difference™

Eastman Ecdel™ elastomer is a copolyester elastomer (COPE) in the thermoplastic elastomer family of polymers (TPE). It can be extruded or molded into articles that are clear and tough with elastomeric-like properties. Ecdel™ elastomer is ideal for applications in flexible medical or pharmaceutical packaging and tubing where low extractables, toughness, flex crack resistance, high creep resistance, and utility in harsh environments are required.

Ecdel™ elastomer imparts strength and durability, and resists puncturing. It remains remarkably clear and free of the blush or haze that can occur in high-temperature autoclaving for medical applications. It combines chemical resistance, toughness, sterilization flexibility (irradiation, ethylene oxide, or autoclave), and inertness of polyesters with flexibility over a broad temperature range.

Compared to other thermoplastic materials, Eastman Ecdel™ provides many unique extruded film properties.

Key features and benefits

- High flexibility and toughness without the use of modifiers
- Free of ortho-phthalate plasticizers
- Very high clarity without blushing
- Excellent puncture resistance
- Low temperature strength
- Outstanding flex crack and creep resistance
- Temperature resistance
 - Autoclavable
 - Dimensionally stable, low shrink
 - Enables excellent sealing in multilayer films
- Meets selected USP Class VI / ISO 10993 testing requirements
- Solvent, RF, laser, and impulse bondable
- Low extractables
- Resistance to most medical chemicals



Figure 1
Creep data — Ecdel™ elastomer vs. PVC
150 psi (1.03 mPa) stress, 40°C (104°F)

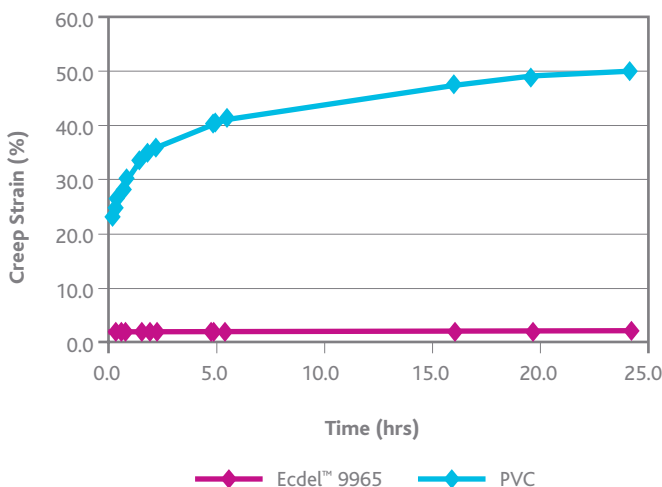
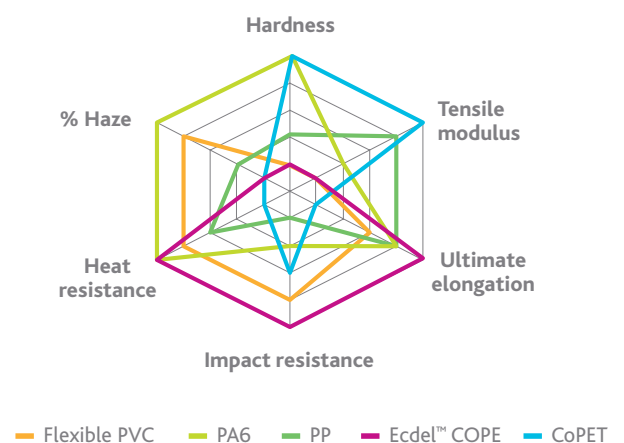
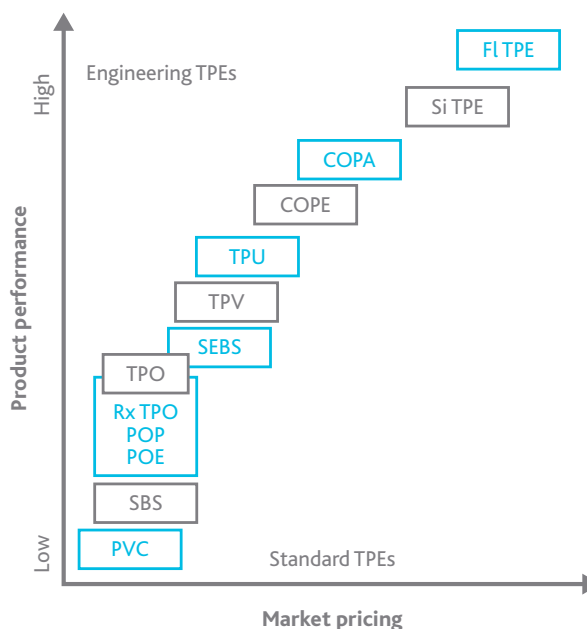


Figure 2
Monolayer film properties



Acronym	Definition
Fl Type	Fluorinated TPEs
Si Type	Silicone-based TPEs
COPA	Copolyamide
COPE	Copolyester elastomer
TPU	Thermoplastic polyurethane
TPV	Thermoplastic vulcanizates
SBS, SEBS, SEPS	Styrene block copolymers
TPO	Thermoplastic polyolefins
Rx TPO	Reactor grade TPO
POP	Polyolefin plastomer
POE	Polyolefin elastomer
PVC	Polyvinyl chloride alloys

Figure 3
Product performance matrix



EASTMAN

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Material Safety Data Sheets providing safety precautions, that should be observed when handling and storing 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.

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Committed, Knowledgeable, and Enabling

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 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 (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.