Eastman copolyesters—**Microbial barrier**

Eastman history

For more than 80 years, medical device manufacturers (MDMs) have benefited from using Eastman plastics in a wide range of medical device and packaging applications that meet performance demands and regulatory requirements. Eastman has enjoyed the trust of the industry's foremost innovators, and we continually assist customers throughout the value chain to develop medical devices and packaging on the cutting edge of science. Our copolyesters are substantially free of bisphenol A (BPA), halogens, and other common materials of concern.

Eastman understands the needs of the medical industry. Our products are used in devices as well as protective and functional packaging, giving us the ability to deliver a total solution to our customers. For medical grade resins, we offer characterization of our products, which may include technical data, ISO 10993 Part 1 biocompatibility test reports, USP Class VI test reports, and U.S. drug or device master file authorizations. MDMs can speed development time and bring applications to market with Eastman's comprehensive applications development and strong technical support.

Eastman has supplied Eastar™ copolyester 6763 to the medical industry for more than 40 years, and now we are offering Eastman Tritan™ copolyesters (MP100, MP150, MP200) and Eastman Eastalite™ copolyesters (MP005F, MP006F, MP007F, MP010F). Eastman works with extruding and thermoforming companies in supplying the global medical packaging industry. Eastar, Tritan, and Eastalite copolyesters are converted into film and sheet externally. Medical device manufacturers that are equipped with thermoforming or form-fill-seal capability receive the copolyester film and sheet from extruders for conversion into sterile barrier and/or packaging systems. Some medical device manufacturers prefer to purchase preformed sterile barrier packaging or packaging systems utilizing Eastman copolyesters from external thermoformers.

Rigid medical packaging made from Eastar or Tritan copolyesters will deliver functionality and performance. They maintain long-term clarity and do not yellow or stress whiten over time. Due to their inherent toughness, they provide puncture resistance which is critical in ensuring that the sterile barrier has not been breached. They have excellent thermoformability and cut cleanly, virtually eliminating the generation of particles in the packaging.

Eastman Eastalite™ copolyesters are typically extruded by external parties into sheeting between skins of Eastar™ copolyester 6763. On extrusion, the Eastalite containing core layer becomes foamed (closed cellular structure) and creates an article with increased yield or reduced density over unfoamed copolyesters. The final coextruded sheeting is also known as Eastalite. Sheet of Eastalite copolyester is becoming the new industry standard for use in opaque rigid medical packaging, delivering functionality with outstanding performance. It does not yellow or stress whiten over time. Due to its inherent toughness, it provides puncture and tear resistance, which is critical in ensuring that the sterile barrier has not been breached. It has excellent thermoformability and cuts cleanly, eliminating any possibility of generation of particles that can lead to contamination.

Microbial barrier properties

According to the ISO 11607 standard (Part 1 Section 5.2), a nonporous material, such as plastic sheeting or a preformed sterile barrier packaging system made from Eastman copolyesters, is considered impermeable if conditions in Annex C of the standard are met. Section 5.2.2 of ISO 11607 Part 1 indicates that the effective demonstration of a nonporous material that is impermeable to air shall satisfy the microbial barrier requirements specified elsewhere within the standard. Annex C states that a material is considered impermeable if there is no cylinder movement (+/–1 mm) for 1 hour when the material's porosity is evaluated using a Gurley porosity tester. This means that the plastic material is considered to be impermeable to air. Oxygen and nitrogen, which make up 99% of the composition of air, are around 3e–10 m in diameter, which is smaller than the diameter of viruses (~1e–7 m) and bacteria (~1e–6 m) when considering the smallest of microbes. If oxygen and nitrogen, which are smaller than bacteria and viruses, cannot pass through the substrate of a plastic material, then that material is considered an appropriate, satisfactory microbial barrier.

Films produced from Eastman copolyesters were subjected to Gurley Densometer testing conforming to TAPPI T-460, ASTM D726-58, APPITA/AS 1301-420, BS 5926, CPPA D-14, ISO 5636/5, D-202-77, SCAN R-19, and P-53. The test results are summarized in the table on the back page.

Gurley Densometer test results

Material	Sheet quality	Initial cylinder height, mm	Final cylinder height, mm	Cylinder movement, mm (in.)	Air lost, CC	Elapsed time, hr:min:sec	Air lost, cc	Pass, P or F
4-mil film of Eastar™ copolyester 6763	Good, no pinholes	—	—	0	0	01:31:02	—	—
4-mil film of Eastman Tritan™ copolyester MP100	Good, no pinholes	—	—	0	0	01:36:31	—	—
20-mil Eastman Eastalite™ copolyester MP006F with 2-mil Eastar 6763 skins	—	116	116	—	—	01:17:41	0	P
42-mil Eastman Eastalite™ copolyester MP007F with 2-mil Eastar 6763 skins oriented 5 × 5 to 2.25 mil	—	116	116	—	—	01:14:09	0	P
Same	—	116	116	—	—	15:22:25	0	P

This data indicates that Eastar copolyester 6763, Tritan copolyester, and Eastalite copolyester sheeting and preformed sterile packaging systems that are manufactured to be free of pinholes or other defects and per good manufacturing practices can be effective microbial barriers as defined by ISO 11607 Part 1 Section 5.2, 5.2.2, and Annex C.

Additional data

Films with a 0.9-mil thickness produced from Eastman copolyester GP001, a polymer providing a filmed porosity similar to that of Eastar and Tritan copolyester, were also subjected to the same Gurley Densometer testing. These films did not permeate any air for up to 17 hours, 50 minutes, and 54 seconds, which was the time of test termination. However, the same copolyester film with a 20-mil diameter pinhole permeated 400 cubic centimeters of air in 5 minutes and 48 seconds, indicating an inadequate microbial barrier. This underscores the importance that the sterile barrier film and packaging must be free of pinholes. Eastman does not produce extruded sheet or thermoformed packaging. Certification that the finished packaging is free of pinholes is the responsibility of the extruded film or sheet supplier, thermoformed package producer, and/or medical device manufacturer.

EASTMAN
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Eastman Chemical Company
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