

Proper sterilization of packaging made with Eastman Tritan™ copolyester MP100, MP150, and MP200

Medical devices must be free from bacteria to ensure patient safety and health. Sterilization, a rigorous process of eliminating these microorganisms, can subject the device—package combination to extreme temperatures, gases, radiation, and other elements that may alter the performance of certain materials. Prior to designing a medical device package, packaging engineers should first consider the method by which the packaged product will be sterilized. Engineers, therefore, need to fully understand the effects of the chosen sterilization method on packaging materials. This technical tip contains guidelines for the proper method of ethylene oxide (EtO), gamma irradiation, and electron beam sterilization of copolyesters as these are the most common forms of sterilization used in the industry today. These guidelines should be followed to optimize the performance of packaging made with Eastman Tritan™ copolyester MP100, MP150, and MP200.

Sterilization methods

Ethylene oxide

- Bacteria are eliminated by penetration of EtO gas mixture into the sealed package.
- Efficiency is boosted by the use of moderately high temperature and humidity.
- Chamber gas can either be 100% EtO or EtO blends with other inert gasses.
- Typical cycle includes 18–24 hours preconditioning (43°C [110°F], 60% relative humidity), 8 hours total cycle (with the average gas dwell of 3–4 hours) all at 52°C (125°F), and a 24-hour aeration at 46°–49°C (115°–120°F).

- Thermoformed packages made with Tritan can withstand temperatures up to 85°C (185°F) without distortion. This may allow higher EtO sterilization chamber temperatures to be used with reduced risk of warping and sticking. Moreover, this high heat resistance may allow faster EtO cycle times and lower sterilization cost.

Gamma irradiation

- Bacteria are eliminated by penetration of gamma irradiation from a cobalt-60 source.
- Gamma irradiation provides a high level of penetration at a relatively low dosage rate without the generation of heat. Tritan is highly resistant to gamma radiation in that the polymer's molecular weight and outstanding physical, optical, and color properties are not significantly affected by relatively high doses of radiation.
- Typical dose is 25 to 50 kGy (2.5 to 5 M Rads). Tritan has been sterilized up to 100 kGy without any significant physical property loss.

Electron beam radiation

- An electron beam is focused on the product. The beam scans the product to ensure uniform treatment.
- Bacteria are eliminated by penetration of high-energy electrons without heat.
- Typically, the electron beam does not penetrate deeply into large dense substrates without increasing exposure time, changing the actuator location relative to the package—device combination, or increasing the radiation dose.
- Typical dose is 25 to 50 kGy (2.5 to 5 M Rads). Tritan has been sterilized up to 50 kGy without any significant physical property loss.

Table 1. Radiation device specifications

| Property | Gamma irradiation | E-beam |
|--------------------|-------------------|-----------|
| Energy spectrum | 1.17 and 1.33 MeV | 3–10 MeV |
| Useful power range | 15–100 kW | 10–200 kW |
| Typical dose rate | 25–50 kGy | 25–50 kGy |

Conclusion

Gamma, e-beam, and EtO are the gentlest and most common methods for sterilizing Tritan. However, the polymer can be successfully and safely sterilized by hydrogen peroxide vapor, peracetic acid vapor, and plasma. Proper processing conditions and controls should always be used during sterilization of any polymer. If excessive high humidity, high temperature, high energy levels, and/or long dwell times are used, increased physical aging or other degrading issues may occur. This may cause brittleness in the package material and could lead to package integrity failure.



The results of insight[™]

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

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.

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.

© 2016 Eastman Chemical Company. Eastman brands referenced herein are trademarks of Eastman Chemical Company or one of its subsidiaries or are being used under license. The ® symbol denotes registered trademark status in the U.S.; marks may also be registered internationally. Non-Eastman brands referenced herein are trademarks of their respective owners.