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.

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