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Sterilization of Polyolefins

A Methodological Overview

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Sterilization

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Introduction

The process of sterilization refers to any action used to eliminate or kill any form of life present on a surface or contained in a liquid. Currently, a variety of sterilization methods can be used to reduce microbial load on medical devices and pharmaceutical products in order to minimize risk for patients.

Backed by more than 30 years of industry experience, LyondellBasell offers a range of polyethylene and polypropylene resins selected by customers for healthcare applications. Experience has shown that while several different methods of sterilization can be employed and ultimately considered suitable, each method can also have an impact on the polyolefin material selected, depending upon conditions.

This quick reference guide provides an overview of the sterilization methods available and their effects on polyolefin performance.

General Overview

Sterilization can be achieved through a combination of heat, chemicals, irradiation, high pressure and filtration. See Table 1 for more details.

Heat Sterilization

Vapor (steam) sterilization using an autoclave is one of the most widely used methods for heat sterilization of polypropylene and polyethylene packaging in pharmaceutical applications. Standard conditions typically use saturated steam at a constant temperature of 121 °C (250 °F). At this temperature, a holding time of at least 15 minutes is required to achieve sterility. Fast autoclaving uses temperatures of 134 °C (273 °F). Polypropylene can typically withstand all of these sterilization temperatures when correctly molded.

Sensitive pharmaceutical substances such as dextrose (D-glucose) and packaging materials such as LDPE cannot withstand sterilization temperatures of 121 °C. When they are used, 'equivalence' methods can be applied to calculate the holding time required at the lower temperature required.

The most widely known equivalence method used for steam sterilization is the F_0 method; referred to in both European Pharmacopeia* and US Pharmacopeia** as an alternative to standard sterilization conditions.

In Figure 1, *Purell* PE 3420F under $F_0 = 8$ conditions can be sterilized in an autoclave 97 minutes faster than *Purell* PE 3020D. Under $F_0 = 12$ conditions, also shown in figure 1, the time saving is nearly 150 minutes.

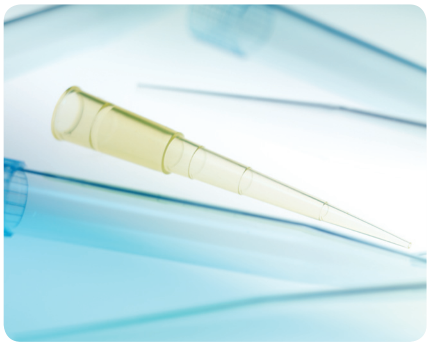
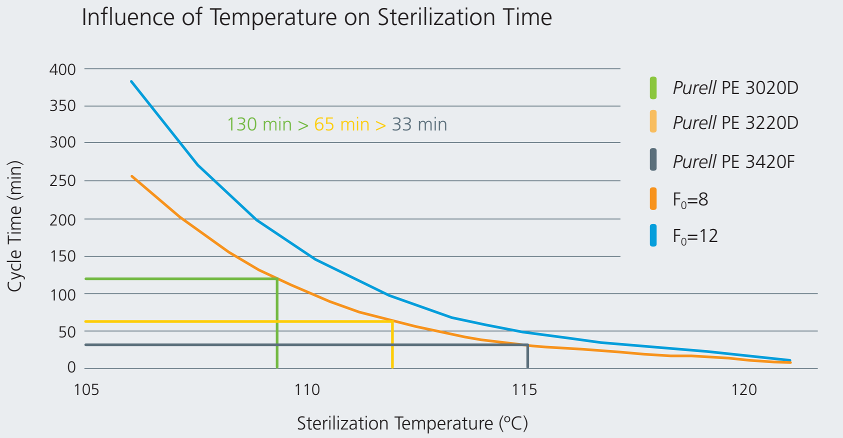


Table 1: Types of Sterilization

Method	Description	Resin Requirement	Remark
Heat sterilization	Temperature and time needed dependent upon choice of material; typically uses steam autoclave or equivalent.	Sufficient heat resistance	
Gas sterilization, ethylene oxide (EO/EtO)	Ethylene oxide gas kills the organism by reacting with its cellular constituents in a three-stage process: 1. Preconditioning 2. Sterilization 3. Degassing	None	Relatively easy handling for mass-produced articles. Special safety measures and waste management required.
Radiation (Gamma)	Cobalt 60 radioactive source delivering variable dose, measured in kGy.	Good impact strength and resistance to yellowing	Packed products can be sterilized.
Radiation (E beam)	A heated cathode generates a focused beam of electrons at a frequency of 50 to 100 Hz.	As above	Short treatment time and higher dosage rate. Packed products can be sterilised but penetration less than gamma.
Radiation (other)	Beta, X-ray and UV available, but not commonly used	As above	X-ray has higher penetration than gamma. Packed products can be sterilized.

Figure 1 – Example of Holding Time and Sterilization Temperature Using an Autoclave



*Ph. Eur. 5.1.5: Application of the F_0 concept on steam sterilization of aequeous preparations **USP 24, NF19, p. 2144: Steam sterilization: "Apart from the description of the sterilization cycle, using a temperature of 121°C, the F_0 concept may be appropriate."

Gas Sterilization

Ethylene oxide (EO or EtO) gas is the most common sterilization method used in more than 70 percent of all sterilizations, and in 50 percent of all disposable medical devices. Treatment is generally carried out between 30 °C and 60 °C with relative humidity above 30 percent; and a gas concentration between 200 and 800 mg/l for a duration of at least three hours. EtO can kill all known viruses, bacteria and fungi, including bacterial spores, and is compatible with most materials even when applied repeatedly. EtO can be used in polypropylene and polyethylene sterilization.

Radiation Sterilization

Methods of sterilization exist using radiation such as gamma rays, electron beams, X-rays, ultraviolet light and subatomic particles.

Gamma rays have high penetration and are frequently used for sterilization of disposable medical equipment, such as syringes, needles, cannulas and IV sets in their final packaging. Gamma irradiation requires bulky shielding for the safety of the operators and safe storage of the radioisotope from which the gamma radiation is emitted.

Polyolefin resins used in applications requiring gamma irradiation must be correctly additivated to mitigate the effects of radiation on the polymer structure. Certain additives typically used in polyolefin resins and masterbatches are not compatible with gamma irradiation; without correct modification, these resins may turn yellow and become brittle. Additionally, the actual delivered dosage of radiation (rather than the dose emitted) should be carefully considered. *Purell* HP371P and HM671T can be considered for this type of sterilization.

Besides electromagnetic irradiation with gamma rays, particle radiation can also be used for sterilization. The best known form is radioactive beta radiation, which results in the release of energy-rich electrons. Compared to gamma, it has less penetration and a reduced detrimental effect on material properties. However, specialty materials are regularly used.

While beta-radiation needs a radioactive source (typically Sr-90), the electron-beam process creates free electrons by cathode discharge and subsequent particle acceleration. These sterilization facilities offer the advantage of on/off technology without the risk of handling radioactive sources, and provide a much higher dosing rate than gamma or X-rays. Due to the higher dosing rate, less exposure time is needed, thereby reducing potential degradation of polymers. One limitation is that electron beams are less penetrating than either gamma or X-rays.

High-energy X-rays are a form of ionizing energy that irradiates large packages and pallet loads of medical devices. Their penetration is sufficient to treat multiple pallet loads of low-density packages with very good dose uniformity ratios. X-ray sterilization is an electricity-based process which does not require chemical or radioactive material.

Ultraviolet (UV) light irradiation is useful only for sterilization of surfaces and some transparent objects, and is not typically used for polyolefins. UV irradiation is routinely used to sterilize the interiors of biological safety cabinets between uses, but is ineffective in shaded areas, including areas under dirt (which may become polymerized after prolonged irradiation, making it very difficult to remove). If exposed for prolonged periods of time, it damages some plastics such as polystyrene foam.

Conclusion

When considering a sterilization method to use for a specific *Purell* resin, many factors must be taken into account, such as the application, filling substance, when the sterilization will be conducted (i.e., in-line, after packaging, etc.), the *Purell* grade selected and the effects of sterilization on the specific material. Table 2 provides an overview of polyolefin performance under different sterilization methods.

Table 2 – Sterilization Resistance of Polyolefins

	Steam Sterilization	Gas Sterilization	Radiation Sterilization	Remarks
PP	Resistant, including fast autoclaving for homopolymers and block (heterophasic) copolymers	EtO resistant	Some speciality *Purell* PP grades available	Autoclaving temperatures of 121 °C possible for most *Purell* PP products. Radiation is critical for PP.
HDPE	Resistant, excluding fast autoclaving	EtO resistant	Used, but cross-linking can occur	Autoclaving temperatures of 121 °C possible. Radiation can be critical for HDPE.
LDPE	Resistant at lower temperatures	EtO resistant	Used, but cross-linking can occur	Equivalence methods used for steam sterilization. No additives used in most *Purell* PE products.

Note: Polyolefins are not recommended for repeated sterilization.

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