Sterilization of Polyolefins
A Methodological Overview
Sterilization

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

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
<th>Resin Requirement</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heat sterilization</td>
<td>Temperature and time needed dependent upon choice of material; typically uses steam autoclave or equivalent.</td>
<td>Sufficient heat resistance</td>
<td></td>
</tr>
<tr>
<td>Radiation (Gamma)</td>
<td>Cobalt 60 radioactive source delivering variable dose, measured in kGy.</td>
<td>Good impact strength and resistance to yellowing</td>
<td>Packed products can be sterilized.</td>
</tr>
<tr>
<td>Radiation (E beam)</td>
<td>A heated cathode generates a focused beam of electrons at a frequency of 50 to 100 Hz.</td>
<td>As above</td>
<td>Short treatment time and higher dosage rate. Packed products can be sterilized but penetration less than gamma.</td>
</tr>
<tr>
<td>Radiation (other)</td>
<td>Beta, X-ray and UV available, but not commonly used</td>
<td>As above</td>
<td>X-ray has higher penetration than gamma. Packed products can be sterilized.</td>
</tr>
</tbody>
</table>
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 radiisotope 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. These sterilization facilities can be used for sterilization. The best known form of this type of sterilization.

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

<table>
<thead>
<tr>
<th>Purell PE 3020D</th>
<th>Purell PE 3220D</th>
<th>Purell PE 3420F</th>
<th>F_p=8</th>
<th>F_p=12</th>
</tr>
</thead>
</table>

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

Influence of Temperature on Sterilization Time

- Purell PE 3020D
- Purell PE 3220D
- Purell PE 3420F
- F_p=8
- F_p=12

*Ph. Eur. 5.1.5: Application of the F_p concept on steam sterilization of aqueous preparations **USP 24, NF19, p. 2144: Steam sterilization. *Apart from the description of the sterilization cycle, using a temperature of 121°C, the F_p concept may be inappropriate.*
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Equistar Chemicals, LP
Lyondell Chemical Company
Newtown Square Center
3801 West Chester Pike
Newtown Square, PA 19073
1 Tel: +1 610 560 3300
2 Tel: +1 610 359 2000

European Sales Offices
Basell Deutschland GmbH
Industriepark Hoechst
Building B 852
65926 Frankfurt am Main
Germany
Tel: +49 69 305 85800
Fax: +49 69 305 85803

Basell Deutschland GmbH
Bruehler Strasse
50389 Wesseling
Germany
Tel: +49 2236 726000
Fax: +49 2236 726034

Basell Sales & Marketing Company B.V.
Groot Handelgebouw
Weena 737
3013 AM Rotterdam
The Netherlands
Tel: +31 10 71 36 010
Fax: +31 10 71 36 400

Basell UK Ltd.
Carrington Site
Urmston, M31 4AJ, UK
Tel: +44 161 776 3020
Fax: +44 161 776 3027

Basell France SAS
Chemin Départemental 54
Raffinerie de Berre
13130 Berre l’Etang
France
Tel: +33 (0) 4 42 74 42 74

Basell Italia S.r.l.
Piazza Montanelli 20
I-20099 Sesto San Giovanni (Milano),
Italy
Tel: +39 02 24 342 1
Fax: +39 02 24 342 600

Representative Office of Basell Sales & Marketing Company B.V.
Uspszewsky per., 10., bld 1
127006 Moscow, Russia
Tel: +7 (495) 641 33 22
Fax: +7 (495) 641 33 23

Basell Pololefinas
Comercial Española S.L.
Av. Diagonal, 615, 4th floor
E-08028 Barcelona, Spain
Tel: +34 93 365 2000
Fax: +34 93 365 2100

Basell Slovakia s.r.o
Prevoziska 4/A
821 09 Bratislava, Slovakia
Tel: +421 2 5827 5136
Fax: +421 2 5827 5150

Basell Polyolefin Istanbul Ticaret Limited Sirket,
Sahra Caddi Mahalles
Denya Sokak No. 14, Kat. 4 No. 9 Kadikoy,
Istanbul, Turkey
Tel: +90 216 468 6800
Fax: +90 216 302 0541

India Sales Office
Basell Polyolefins India Pvt. Ltd.
303/305, B wing
Delphi Building
Hiranandani Business Park
Powai, Mumbai-400076, India
Tel: +91 22 6706 1111
Fax: +91 22 6706 1100

South and Central American Regional Office
Petrooken Petroquimica Ensenada S.A.
Avda. Eduardo Madero 1020, 14/F
(C1106ACX) Buenos Aires, Argentina
Tel: +54 11 4393 3010
Fax: +54 11 4393 3085

Asia-Pacific Offices
Basell Asia Pacific Ltd.
12/F Caroline Centre
Lee Gardens Two
28 Yum Ping Road
Causeway Bay, Hong Kong
Tel: +852 2577 3855

Australia Sales Office
LyondellBasell Australia Pty. Ltd.
Level 2, 199 Toorak Road
South Yarra VIC 3141
Melbourne, Australia
Tel: +61 3 9829 9455
Fax: +61 3 9829 9531

Africa and the Middle East
Basell International Trading FZE
Regional Office
Dubai Airport Free Zone
P.O. Box 293611
Urmston, M31 4AJ, UK
Tel: +971 4 204 5970
Fax: +971 4 204 5969

You can find out more about us by visiting our website at: lyondellbasell.com

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