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SPECIAL REPORT

Compatibility of PETG with Low-Temperature Hydrogen Peroxide Gas Plasma Sterilization

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Sensing a potential benefit to medical device manufacturers, Advanced Sterilization Products (ASP; Irvine, CA), a division of Ethicon Inc., a Johnson & Johnson company, and Eastman Chemical Co. (Kingsport, TN) set out to determine the compatibility of packaging film made of Eastman's Eastar PETG copolyester 6763 with low-temperature hydrogen peroxide gas plasma (LTHPGP) sterilization, specifically ASP's relatively new Sterrad technology.

LTHPGP has a number of advantages compared to established sterilization technologies. These include a short (one to four hours) sterilization cycle, low temperature and humidity, no aeration requirement, no toxic chemical residues or environmental impact, and broad compatibility with materials. The five stages of the process consist of vacuum, hydrogen peroxide (H₂O₂) injection, diffusion, plasma, and vent. Disadvantages of the technology include its inability to process liquids, powders, or strong absorbers such as cellulose.

Recently, LTHPGP sterilization has been used for terminal sterilization applications of single-use and implantable medical devices. The technology has been shown to be especially beneficial for sterilizing temperature-sensitive polymeric materials, and it offers unique advantages to medical manufacturers in materials and device compatibility, rapid turnaround times, in-house control of the sterilization process, and lower inventory requirements.

PETG copolyester 6763 is predominantly used for medical device packaging because of its excellent clarity, toughness, and ease of forming intricate part designs. It is beneficial for medical device manufacturers to know whether this film is compatible with the LTHPGP sterilization technology.

PACKAGING CONSIDERATIONS

The compatibility of the packaging is critical to the sterilization process. The LTHPGP technology, like other sterilization processes, depends heavily on sterilant diffusion through the load and into the packaging. Packaging must be designed using LTHPGP-compatible materials with sufficient open area and vapor permeability to permit unimpeded diffusion of the sterilant.

Because LTHPGP is a gas-phase sterilant, the packaging must be vapor permeable. The permeable element must also provide a bacterial barrier to maintain sterility after processing. This vapor-permeable element can be incorporated by using a nonwoven spunbonded fibrous outlay such as Tyvek, available from DuPont Medical Packaging (Wilmington, DE). Paper products should not be used, as large quantities of these materials can absorb and immobilize excessive amounts of hydrogen peroxide sterilant. Packaging configurations that meet these requirements are currently commercially available, such as pouches, rollstock, and thermoformed trays with Tyvek.

EXPERIMENTAL METHODS

Eastman supplied samples of Eastar PETG copolyester 6763 at 25-mil film thickness. Eastman retained controls that were not exposed to any form of sterilization.

Exposure of the PETG film to LTHPGP sterilization was conducted in ASP's Sterrad 100 SI GMP Sterilization System.

Samples were exposed to moderate industrial full-cycle parameters consisting of a four-dose exposure at maximum volume (1800 ml) to hydrogen peroxide. This included a six-minute hydrogen peroxide injection, a five-minute diffusion, and a two-minute plasma stage.

Exposed samples were returned to Eastman for functionality evaluation. The functionality testing included the following tests on both control (unexposed) and sterilization-exposed samples: optics (haze, gloss, transmittance, transparency), tensile (mechanical properties), instrumented impact at 73°F and 0°F, Hunter color, and I_hV.

ASP retained samples for hydrogen peroxide residual analysis. This is used as a measure of materials compatibility, as non-hydrogen peroxide-absorbing materials do not compete with the sterilant. Residues of hydrogen peroxide were evaluated by extraction of the exposed sample materials in deionized water for four hours. Colorimetric liquid titration of the extract for

hydrogen peroxide was done. The extract was made acidic, and iodine was generated by adding excess potassium iodide. The free iodine was titrated with standardized sodium thiosulfate ($\text{Na}_2\text{S}_2\text{O}_3$) solution, using starch as an indicator. The method was verified for each study by evaluating unexposed controls along with the test samples. All titrants were standardized.

RESULTS

Eastman did the functionality assessment of the PETG copolyester after exposure to the Sterrad sterilization system. The results of the functionality testing are shown in Table I. The data show that the physical properties of the sterilization-exposed polymer are unchanged from the unexposed control samples.

Test Method		Control PETG 6763 ^a	PETG 6763 After Sterrad	
Haze, %	ASTM D1003	92	94	
Gloss at 45°, units	ASTM D2457/D523	106	107	
Gloss at 60°, units	ASTM D2457/D523	161	161	
Transparency, %	ASTM D1746	80	81	
Transmittance, %	ASTM D1003	91	91	
Tensile Strength, MD				
At yield, MPa	ASTM D882	49	50	
At break, MPa		54	53	
Elongation at yield, %		4	4	
Tensile Strength, TD				
At yield, MPa	ASTM D882	48	45	
At break, MPa		52	51	
Elongation at yield, %		4	4	
Tensile Modulus, MD				
Tan Mod., MPa	ASTM D882	1737	1674	
Tensile Modulus, TD				
Tan Mod., MPa	ASTM D882	1723	1741	
Impact at 23°C—all ductile				
Maximum load, kN	ASTM D3763	0.95	0.095	0.92
Energy at max load, J		7.3	7.	
Total energy, J		8.7	8.4	
Impact at -18°C—all ductile				
Maximum load, kN	ASTM D3763	1.1	1.1	
Energy at max load, J		7.3	7.8	
Total energy, J		10.7	11.3	
Color				
L*	ASTM D2244	95.48	95.49	
a*		0.04	0.02	
b*		0.72	0.72	
Na ² S ² O ³ Residuals, ^b ppm		N/D	279	
^a X26678-165-C, 25 mil, produced at Eastman Chemical Co.				
^b Tested at Advanced Sterilization Products.				

Table I. Comparison of selected physical properties of sheets of Eastar PETG copolyester 6763 before and after the Sterrad sterilization process.

ASP analyzed hydrogen peroxide residuals on the postexposure samples of PETG copolyester 6763, as described previously. The results are summarized in Table I and detailed in Table II.

Sample	Weight (g)	Extracting Volume (mL)	Aliquot Volume (mL)	$\text{Na}_2\text{S}_2\text{O}_3$ ^a	H_2O_2 (ppm)	Mean (ppm)	SD
Control	1.6713	100	100	0.00	0	—	—
1	1.1263	100	100	0.40	304	279	26

2	1.3710	100	100	0.45	281	—	—
3	1.7025	100	100	0.50	251	—	—

^aNormality of Na₂S₂O₃ = 0.0504

Table II. Hydrogen peroxide residuals on Eastar PETG copolyester 6763 after LTHPGP sterilization exposure.

The data also show that the hydrogen peroxide residuals on the film made of the PETG copolyester 6763 are comparable to testing done on polymers of similar chemical classes. This level of hydrogen peroxide absorption/adsorption is considered to be moderately low.

CONCLUSION

Testing has demonstrated the material compatibility of Eastman's Eastar PETG copolyester 6763 with the LTHPGP sterilization technology from Advanced Sterilization Products through physical and chemical testing of materials exposed to the sterilization process. PETG copolyester 6763 is commonly used as a device-packaging material by medical device manufacturers, and it can be recommended for use for packaged medical devices in the LTHPGP sterilization process.

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