Ensuring patient safety: the role of PETG over APET in sterile medical packaging

EASTMAN

Table of Contents

Executive Summary

This paper examines the advantages of PETG (polyethylene terephthalate glycol-modified) over APET (amorphous polyethylene terephthalate) in sterile-barrier rigid medical packaging applications. Ensuring the integrity and sterility of medical packaging is crucial to safeguarding patient health. For many years, Eastman's Eastar™ 6763 has been the preferred PETG for such applications, and it will serve as the benchmark for all PETG data referenced in this paper.

Key Findings

Crystallinity and Brittleness:

PETG is an amorphous copolyester with strong resistance to crystallization, specifically designed through its chemical composition to maintain an amorphous structure. This structure enhances its impact resistance, reduces brittleness, and improves flexibility. In contrast, APET is designed to be a semi-crystalline material that can easily crystallize under specific conditions. When APET crystallizes, the material becomes brittle, increasing the risk of package failure and compromising device sterility. APET films are produced by extruding PET and quickly cooling it to retain an amorphous structure, but during sterilization and aging, the material tends to crystallize, affecting package performance.

Sterilization Compatibility:

PETG is compatible with common forms of sterilization, which primarily include ethylene oxide and gamma sterilization. The data in this report demonstrates the significant loss of toughness that is associated with APET following sterilization, attributed to crystallization. Using APET in sterile barrier applications poses a risk to package and device sterility due to its semi-crystalline nature and increased brittleness.

Shelf Life and Aging:

APET loses impact strength compared to PETG after one year of shelf life. This data indicates that APET would have a higher probability of failure after aging than PETG.

Other Considerations:

PETG maintains low haze and high clarity after extrusion, thermoforming, and sterilization. In contrast, APET's semi-crystalline structure can lead to increased haze and loss of clarity after processing and sterilization due to crystallization. PETG's ease of processing and cutting simplifies manufacturing, reducing complexity and costs. There is an approximate 5% yield advantage when processing PETG compared to APET. The chemical composition of PETG resists crystallization ensuring maximum package integrity.

Conclusion

PETG is the preferred polymer for protecting devices in rigid sterile packaging, offering significant advantages over APET. Its superior mechanical properties, sterilization compatibility, ease of processing, and resistance to crystallization make it ideal for the rigorous demands of sterile-rigid medical packaging.

This paper provides a comprehensive analysis of both materials, reinforcing PETG as the optimal choice for sterile-barrier rigid medical packaging applications.

Introduction

APET is a common name for clear, amorphous PET (polyethylene terephthalate). APET is not inherently amorphous, but it is processed in such a way to "lock in" the amorphous structure before it has a chance to crystallize. It is a low-cost commodity polymer that is often used in applications such as bottling, packaging, etc. APET is a homopolymer polyester that is traditionally manufactured with terephthalic acid or dimethyl terephthalate and ethylene glycol. However, it is common for manufacturers to slightly modify PET with other glycols or acids to alter the properties. While these modifications result in a copolymer structure, these materials are often referred to as "APET" or "modified APET. In this paper, APET is defined as any polyester that meets recycling identification class 1 (RIC#1) as defined by the California Assembly Bill (#906) and by ASTM D7611:

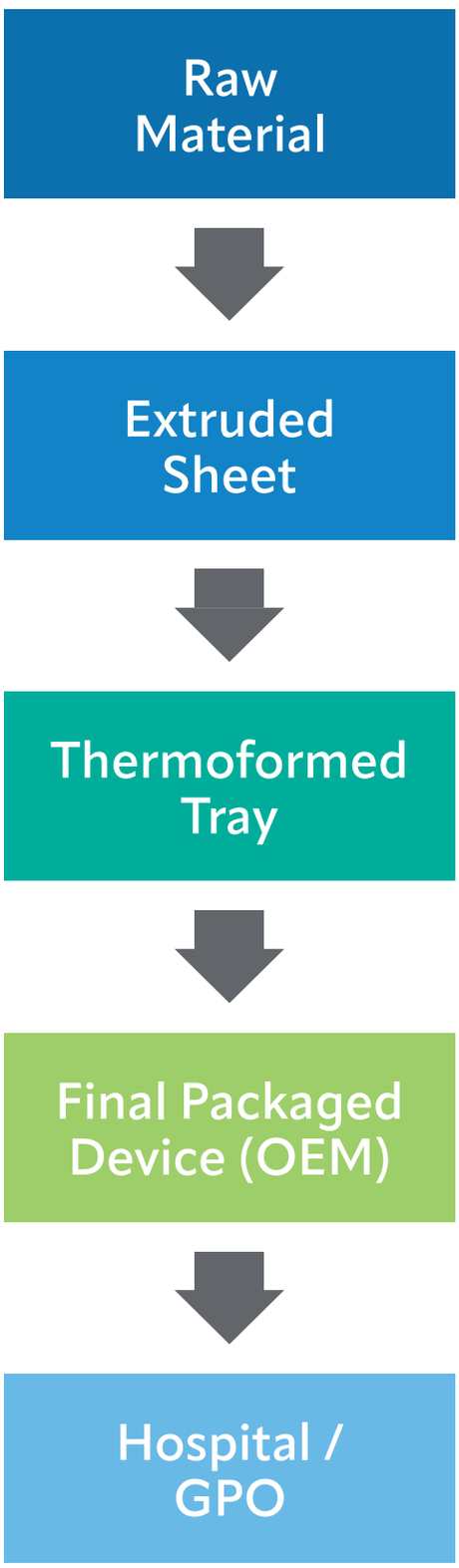
a) The terephthalic acid or dimethyl terephthalate and monoethylene glycol reacted constitutes at least 90 percent of the mass of the monomer reacted to form the polymer.

b) The plastic exhibits a melting peak temperature that is between 225 degrees Celsius and 255 degrees Celsius, as determined during the second thermal scan using procedure 10.1 as set forth in ASTM International (ASTM) D3418 with a heating rate of a sample at 10 degrees Celsius per minute (California Public Resources Code § 18013 (2018)).

PETG is a glycol modified version of PET, typically modified with cyclohexanedimethanol (CHDM) as the co-monomer. The chemical composition of PETG is uniquely tuned to provide ease of processing, toughness, and clarity. It is often used in applications that demand high levels of performance, such as rigid medical packaging where toughness and clarity are key requirements. Eastman's Eastar™ 6763 is a PETG, and is inherently amorphous, which means it is unlikely to crystallize, even under adverse conditions.

Value Chain Partners

The sterile medical packaging value chain is a complex network of interconnected businesses that spans from the initial selection of raw material resin to the final delivery of medical devices to hospitals. At every stage of this chain, the choice of raw materials is critical, as it significantly influences the processes and operational behaviors required by each partner involved. Ensuring the right material selection not only impacts the quality and safety of the packaging but also optimizes efficiency and compliance throughout the entire production and delivery process. The differences between PETG and APET at each value chain are described to the right.



Raw Material

PETG pellets are clear amorphous granules, whereas APET pellets are typically supplied in crystalline form. Both materials are hygroscopic and should be dried prior to extrusion. APET requires a much higher drying temperature due to the crystalline nature of the pellets. Additionally, the acceptable moisture level for APET needs to be significantly lower than PETG to minimize the level of degradation during processing.

Table 1: Typical drying conditions for PETG and APET

Material	Typical Drying Temperature	Typical Drying Time	Acceptable Moisture Level
PETG	65°C (150°F)	4-6 hrs	0.02 %
APET	150°C (300°F)	4-6 hrs	0.005 %

Extruded Sheet

PETG and APET exhibit distinct differences in processing temperatures and crystallinity due to their structural properties. PETG, being an amorphous copolyester, necessitates lower processing temperatures compared to APET. This characteristic makes PETG a more adaptable material during extrusion, as it inherently resists crystallization. In contrast, APET requires precise temperature control; inadequate quenching on chill rolls can result in delayed cooling, thereby increasing crystallinity in the final product. Additionally, PETG's ease of processing contributes to approximately 5% higher material yield than APET during extrusion, highlighting its efficiency in manufacturing applications.

Table 2: Typical extrusion processing temperatures for PETG and APET.

Material	Typical Processing Temperature
PETG	249-271°C (480-520°F)
APET	275-295°C (530-565°F)

Thermoformed Tray

When comparing thermoforming PETG to APET, PETG stands out due to its superior design flexibility, reduced brittleness, and enhanced cutting capabilities. PETG is modified to improve its formability, allowing for more intricate and complex shapes without the risk of cracking or breaking, which can be a limitation with APET. This increased design freedom makes PETG highly desirable for applications requiring detailed and precise molds that are commonly observed in medical device packaging. Additionally, PETG's reduced brittleness ensures durability and resilience, making it less prone to damage during processing and handling. Its improved cutting characteristics further enhance its appeal, allowing for cleaner, more accurate cuts, which is crucial in achieving high-quality finished products. These attributes make PETG a preferred choice for manufacturers looking to optimize performance and aesthetics in their thermoformed products.

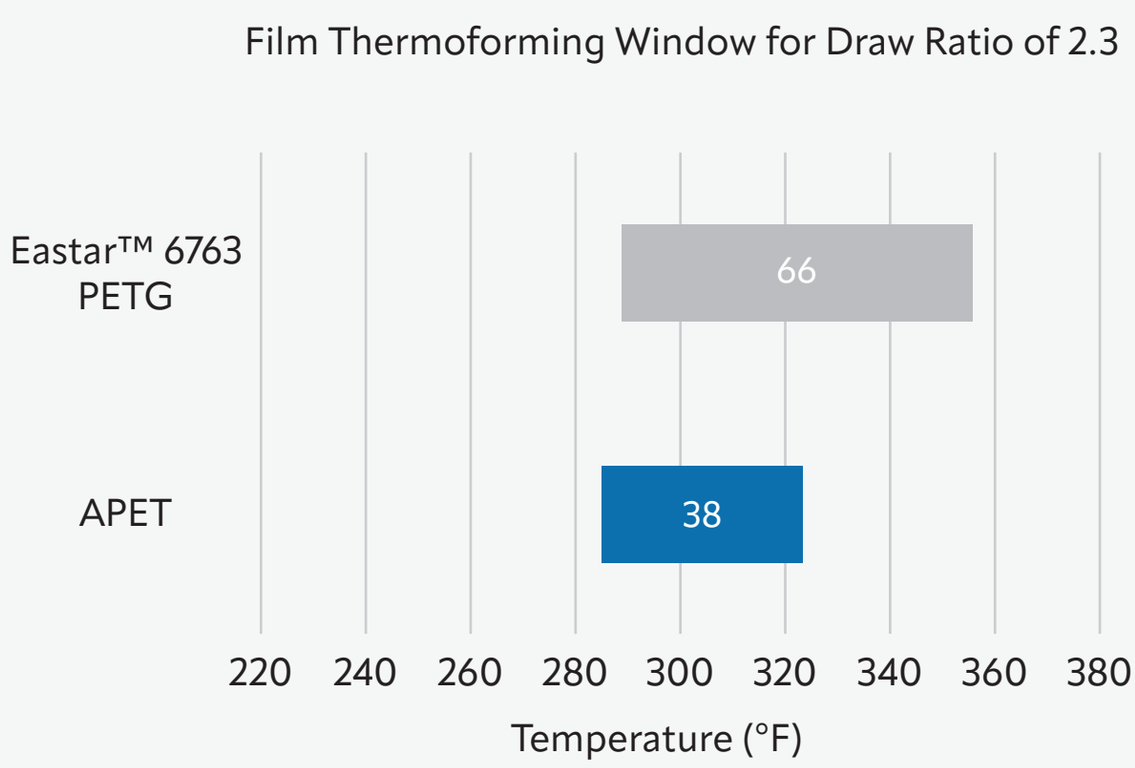


Figure 1: Thermoforming window for PETG and APET at a draw ratio of 2.3.

Final Packaged Device (OEM)

Sterilization plays a vital role in the value chain to guarantee that packaged medical devices are safe for patient use. Ethylene oxide and gamma irradiation are two prevalent sterilization methods. The chemical structure of PETG is specifically designed to improve its compatibility with these sterilization techniques. In contrast, APET is more susceptible to embrittlement during sterilization, which can result in package failure, thereby compromising sterility and patient safety. APET demonstrates a higher color shift when compared to PETG after gamma radiation, as indicated in Figure 2. This color shift leads to increased yellowness (higher b*), which affects the overall aesthetics and clarity of the final packaged device.

Photographs of molded resins before and after exposure to 50kGy gamma radiation

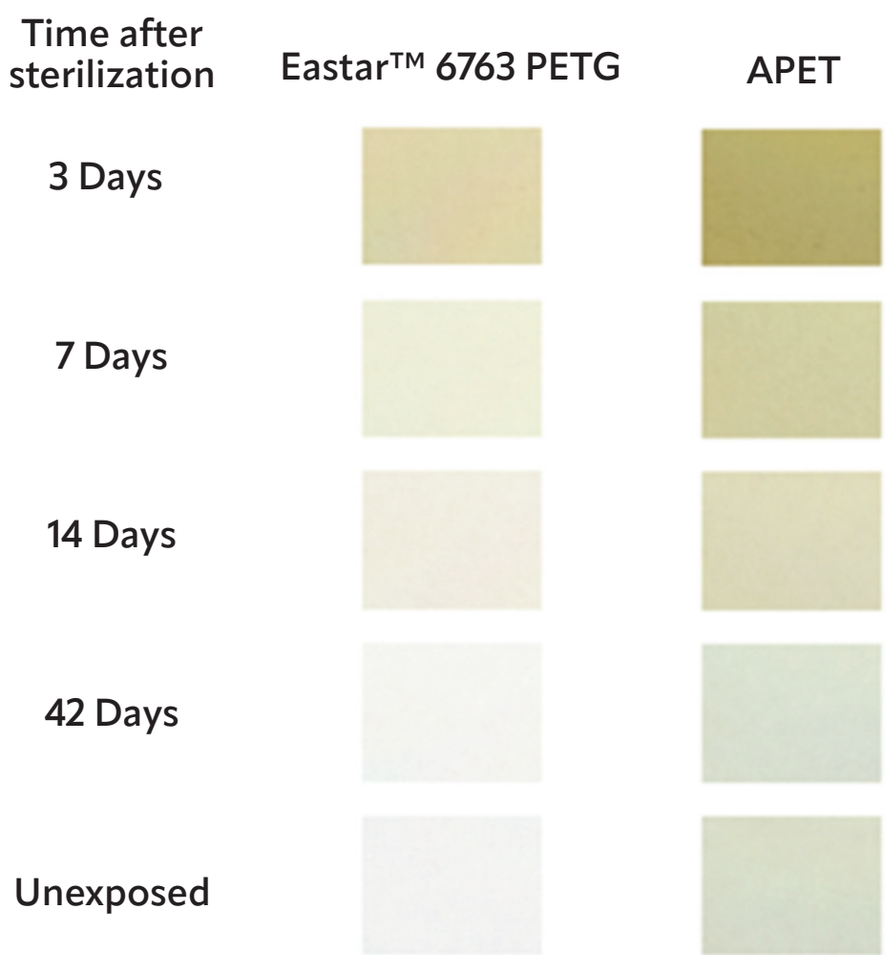


Figure 2: Photographs of molded PETG and APET resins before and after 50kGy of gamma radiation.

Rigid medical packaging offers significant advantages for original equipment manufacturers (OEMs) when it comes to the final packaging of medical devices. It provides strong protection, ensuring that sensitive devices remain sterile and intact from production through to end-use, which is vital for patient safety and adherence to regulatory standards. The durability of PETG rigid packaging reduces the likelihood of physical damage and contamination, thereby reassuring healthcare providers and patients. It's important to note that testing shows comparable performance between PETG and APET regarding Tyvek peel strength (Rhein, 1994). However, APET may be negatively impacted by the sealing process if excessive heat is applied, potentially leading to crystallization.

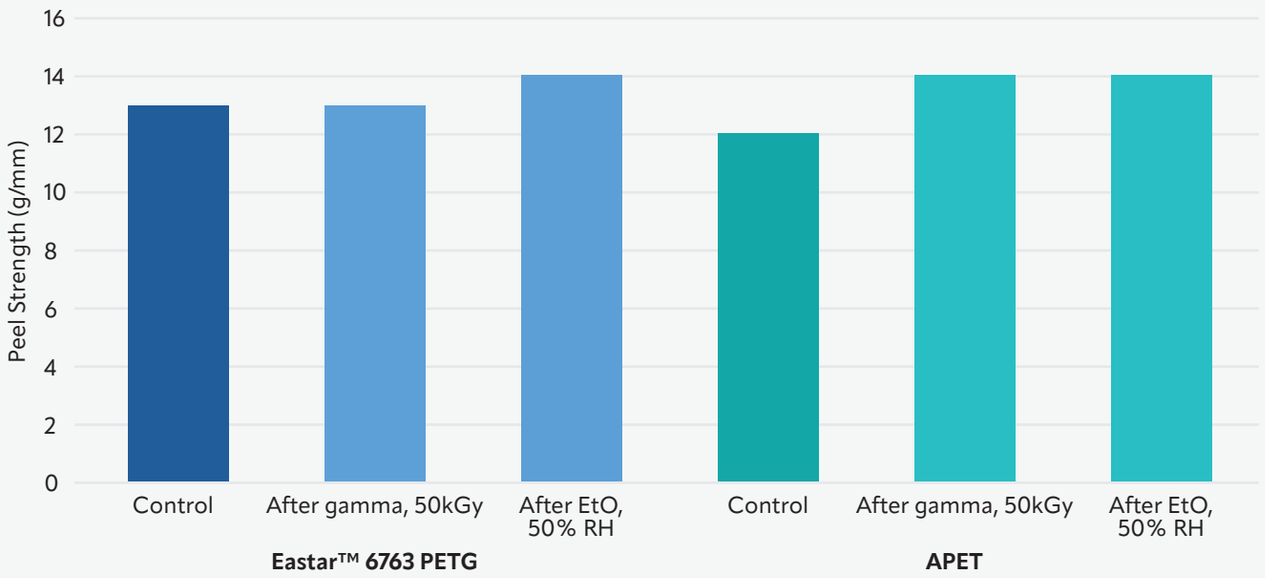


Figure 3: Peel strength testing on Tyvek® lidding sealed to Eastar™ 6763 PETG and APET showing comparable performance both as a standard control and after gamma radiation at 50kGy and EtO sterilization at 60°C, 50%RH.

Hospital / Group Purchasing Organization (GPO)

Utilizing rigid medical packaging provides significant benefits for hospitals or Group Purchasing Organizations (GPOs). A primary advantage is the enhanced protection these packages offer, as they are specifically designed to shield delicate medical instruments and supplies from damage during transport and storage. This minimizes the risk of contamination and ensures equipment remains sterile, which is crucial for patient safety and upholding high care standards. APET is classified under resin identification code 1 (RIC#1) and is often preferred for its potential to enhance packaging sustainability. In contrast, PETG falls under RIC#7 (other) and is not widely accepted for commercial recycling. Although most hospital waste ends up in landfills or is incinerated, discussions around recyclability persist, despite existing logistical challenges.

Key Property Comparisons

Thermal Properties

Differential scanning calorimetry (DSC) was used to evaluate the thermal properties of Eastar™ 6763 (PETG) and two common APET materials. The primary focus was to determine the glass transition temperature, crystallization kinetics, and melting point. Eastar™ 6763 did not exhibit crystallinity or a melting point during either scan. Both APET samples demonstrated levels of crystallinity and melting points. The absence of a cold crystallization peak and melting point in Eastar™ 6763 demonstrates its inherent resistance to crystallization. This resistance to crystallization is one of the primary factors that PETG outperforms APET and is easier to process. Crystalline domains in APET lead to brittleness, which becomes a primary failure mode when the material is subjected to impact force.

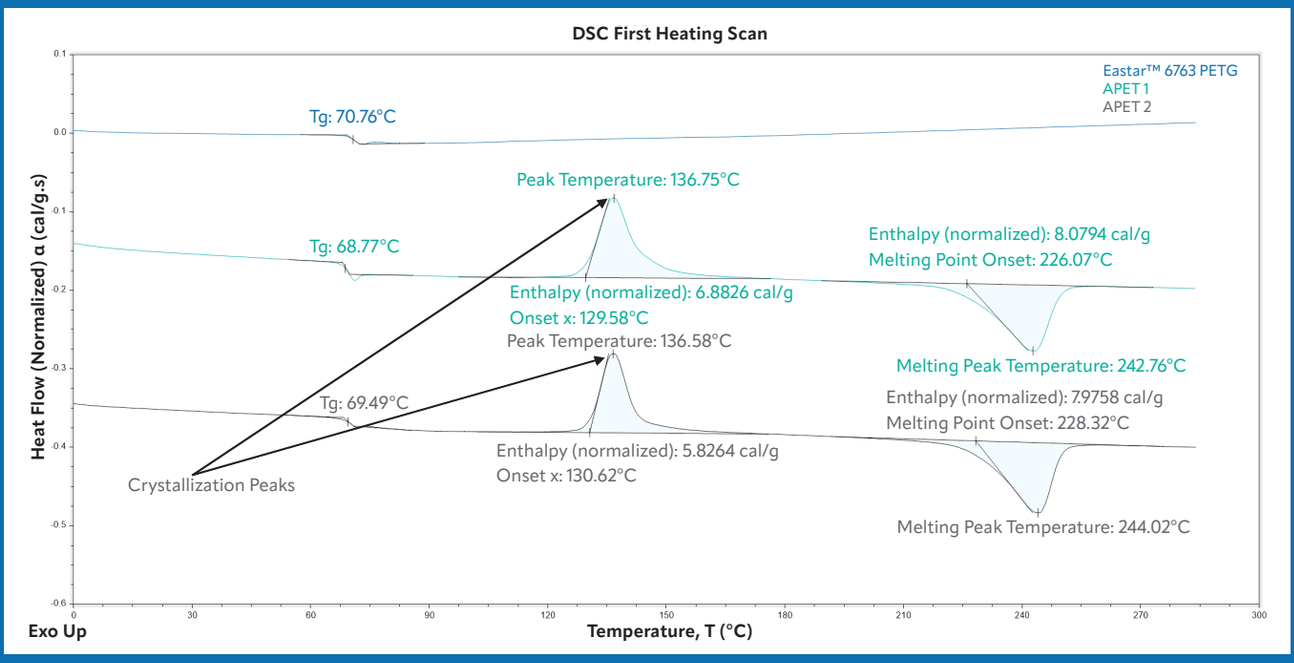


Figure 4: Differential scanning calorimetry (first heating profile) of extruded and thermoformed trays manufactured with Eastar™ 6763 PETG and two common APET materials at a heating profile of 10°C/min. The curves were shifted along the y-axis to clearly show the transitions for each curve (hence heat flow values are arbitrary).

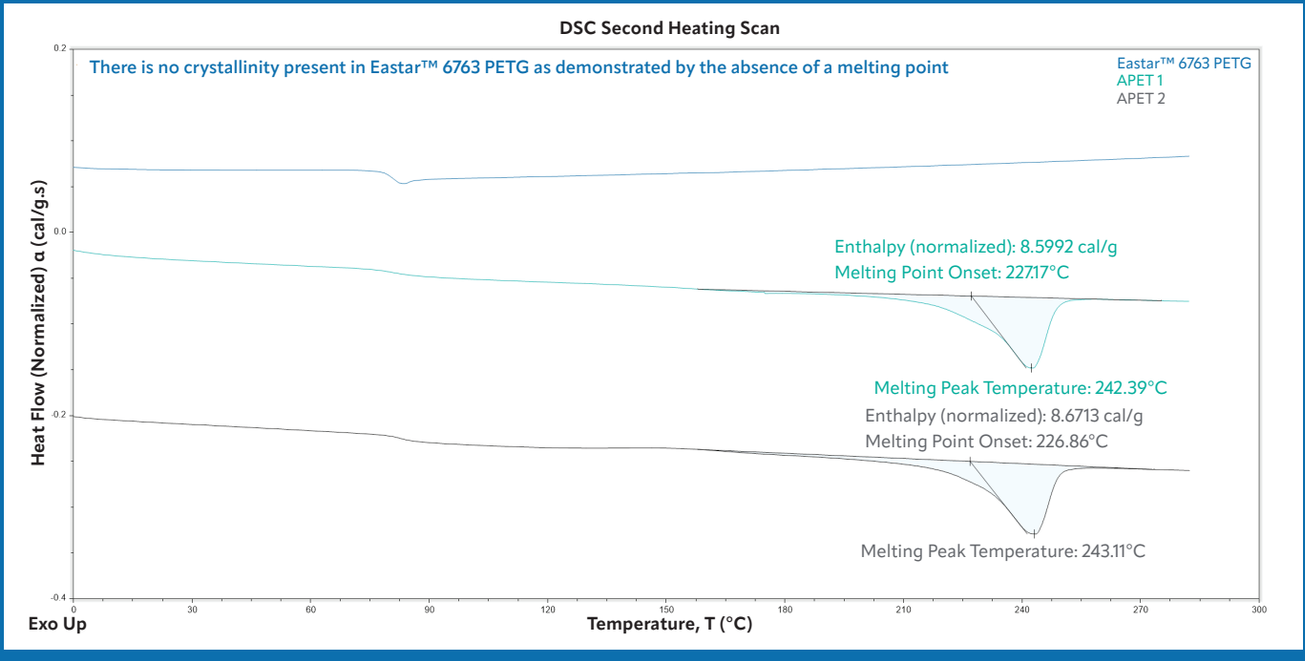


Figure 5: Differential scanning calorimetry (second heating profile) of extruded and thermoformed trays manufactured with Eastar™ 6763 PETG and two common APET materials at a heating profile of 10°C/min. The curves were shifted along the y-axis to clearly show the transitions for each curve (hence heat flow values are arbitrary).

Post-Sterilization Mechanical Properties

Toughness, as measured via Notched IZOD impact strength, was evaluated on 1/8″ molded parts of both Eastar™ 6763 and low-modified APET via ASTM D256. The results demonstrate the superior impact strength of Eastar™ 6763 when compared to APET in both sterile and non-sterile settings. APET already has a significant disadvantage when it comes to impact strength, but this is further amplified post-sterilization. In this study, three different sterilization conditions were evaluated: non-sterile, double cycle gamma sterilization, and double cycle ethylene oxide (EtO) sterilization. Ethylene oxide sterilization had the highest effect on impact strength, with APET losing nearly 20% compared to the non-sterilized samples (see Figure 6) (Hawkins, 2009).

Tensile testing was also evaluated on 1/8″ molded parts of both Eastar™ 6763 and low-modified APET via ASTM D638. The results demonstrate the extra stress induced by both gamma and ethylene oxide sterilization in APET when compared to Eastar™ 6763. Increased stress leads to increased stiffness and brittleness which can increase the risk of package failure thus compromising sterility. It is also important to note that thermoforming will typically lead to further increased stress in the formed article. This, combined with the sterilization-induced stress, is an important factor to consider when determining the best material for the application.

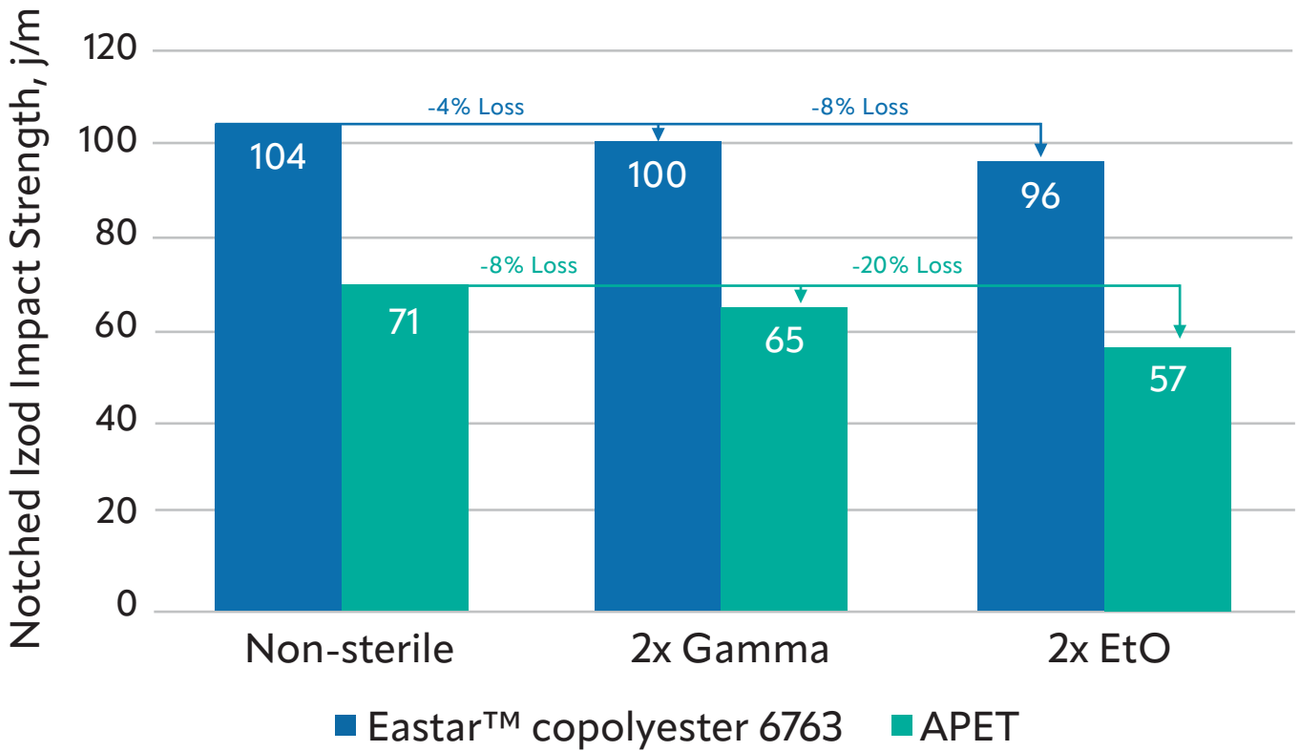


Figure 6: Notched IZOD impact strength via ASTM D256 on sterilized 1/8" molded samples.

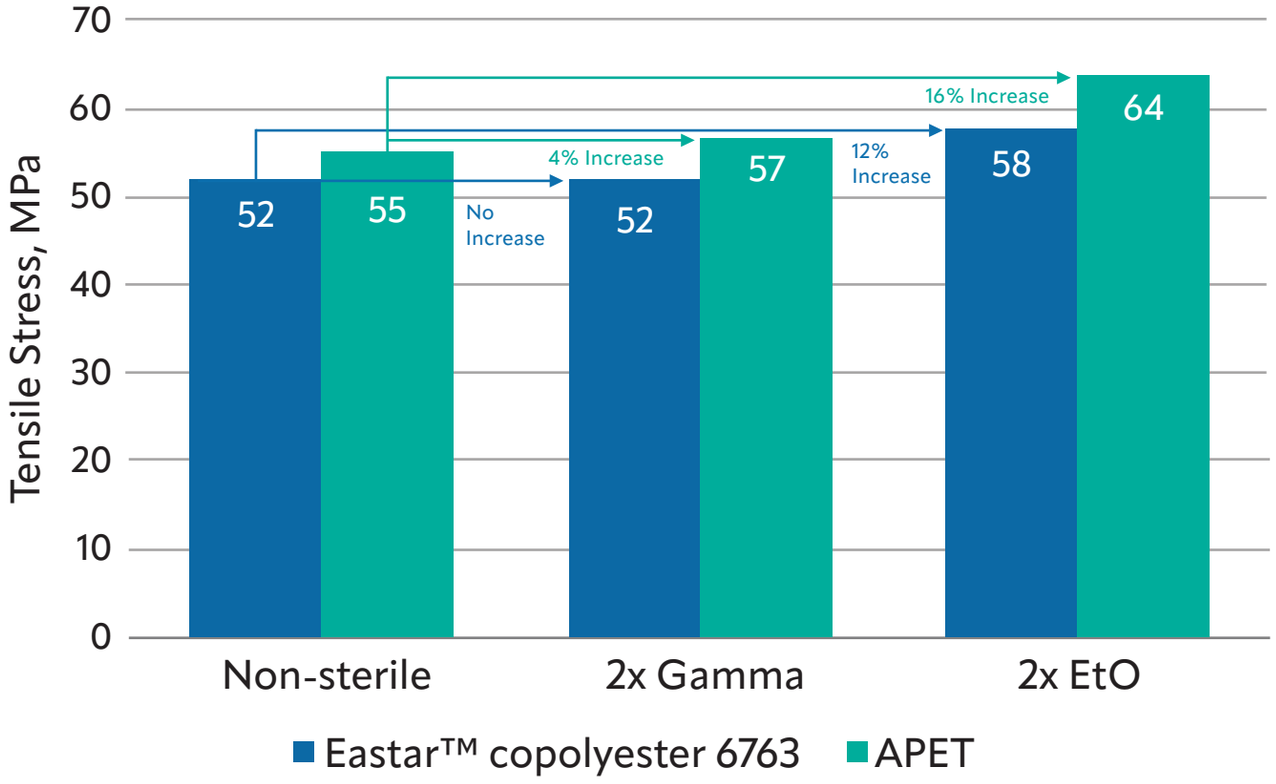


Figure 7: Tensile testing via ASTM D638 on sterilized 1/8" molded samples.

Physical Aging

Physical aging occurs in all amorphous polymers kept below their glass transition temperature (Tg). When rapidly cooled below Tg, such as after injection molding or extrusion, these polymers enter a non-equilibrium state with excess free volume. Over time, the polymer chains rearrange to reach thermodynamic equilibrium, reducing free volume and slowing molecular motion (Pecorini, 2003). This densification can lead to embrittlement. Therefore, ensuring the appropriate shelf-life for sterile, rigid medical packaging under typical storage conditions is crucial. As shown in Figure 8, Eastar™ 6763 remains non-brittle after 52 weeks at 23°C (Hawkins, 2009).

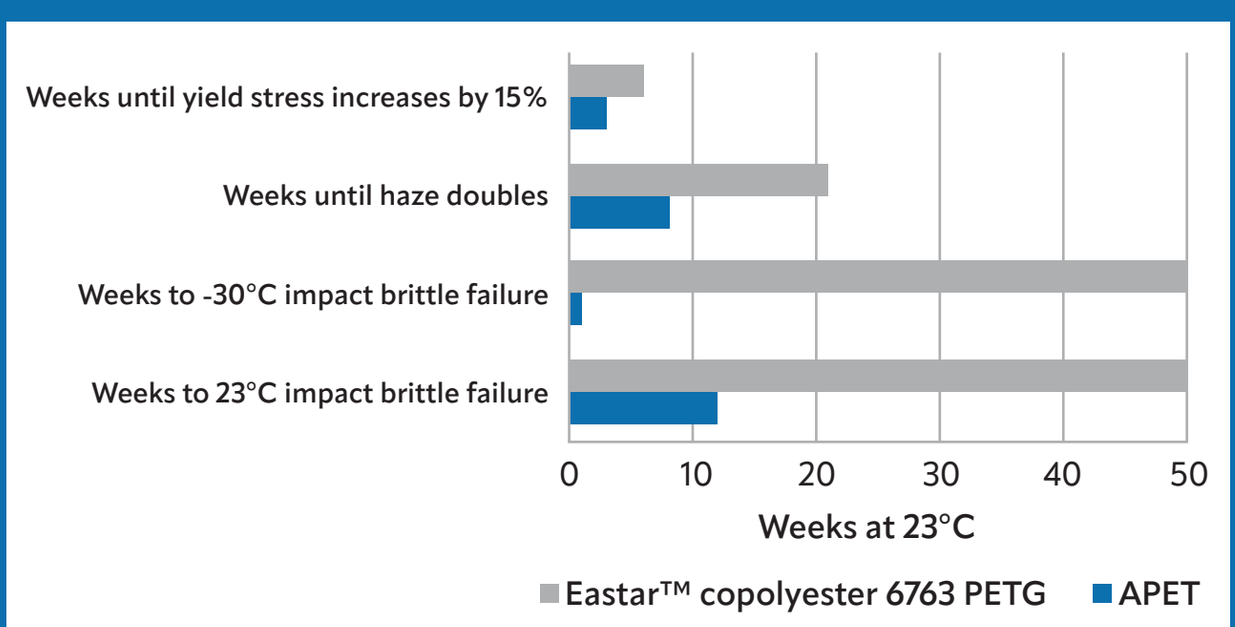


Figure 8. Physical aging comparison between Eastar™ 6763 and low-modified APET on 10mil extruded sheet.

Conclusion

This paper demonstrates why PETG, particularly Eastar™ 6763, has been the preferred material for sterile-barrier rigid medical packaging for decades. PETG is engineered to endure sterilization, transit, and storage, ensuring vital protection for medical devices. Eastar™ 6763 also provides significant design flexibility for packaging engineers, enabling innovative device designs without sacrificing performance. Its cost-effectiveness goes beyond resin pricing, offering overall cost reductions through efficient sterilization and compact shipping. While APET may suffice for some non-sterile packaging, its risks outweigh the minor cost savings in sterile applications.

EASTAR™ 6763

Protect what matters most.

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