



SOLVAY
asking more from chemistry®

Effects of Gamma Irradiation on Mechanical Properties of Specialty Polymers

Single-use technology has been one of the most significant changes in biopharmaceutical manufacturing over the past 20 years. Key driving factors include greater flexibility, reduced resources for cleaning and cleaning validation, and faster turnaround between products and batches, resulting in reduced capital costs and increased speed to market.

Gamma irradiation is the technology of choice to sterilize components used in single-use systems (SUS). Most microbes typically fail to retain mechanical integrity after exposure to 50 kGy, and the same is true for many commodity and mid-range polymers.

In response to the industry's growing need for higher performing polymers, Solvay evaluated the effect of 50 kGy gamma irradiation on the mechanical properties of its medical-grade polymers. Test results for the following products are reported in this bulletin:

- Udel® PSU (polysulfone)
- Veradel® HC PESU (polyethersulfone)
- Radel® PPSU (polyphenylsulfone)
- AvaSpire® PAEK (polyaryletherketone)
- KetaSpire® PEEK (polyetheretherketone)
- Ixef® PARA (polyarylamide)

These materials were also subjected to USP Class VI biological testing and proven to meet requirements, both before and after gamma irradiation.

Mechanical Properties Testing

Test samples were prepared by injection molding from currently available production lots. Standard published injection molding parameters for each resin were used to prepare ASTM D638 Type I tensile bars and ASTM D570 flexural bars. Samples had a nominal 3.12-mm thickness for both as-molded and gamma-sterilized testing specimens and were stored in a climate-controlled lab environment kept at 23 °C and 50% relative humidity at Solvay's laboratories in Alpharetta, GA, which have ISO 9001 certification and A2LA ISO 17025 accreditation.

Test results comparing the mechanical properties before and after 50 kGy gamma irradiation are summarized in Figures 1 through 4. As can be seen, this procedure has a nominal effect on mechanical properties.

Figure 1: Tensile modulus (ASTM D638)

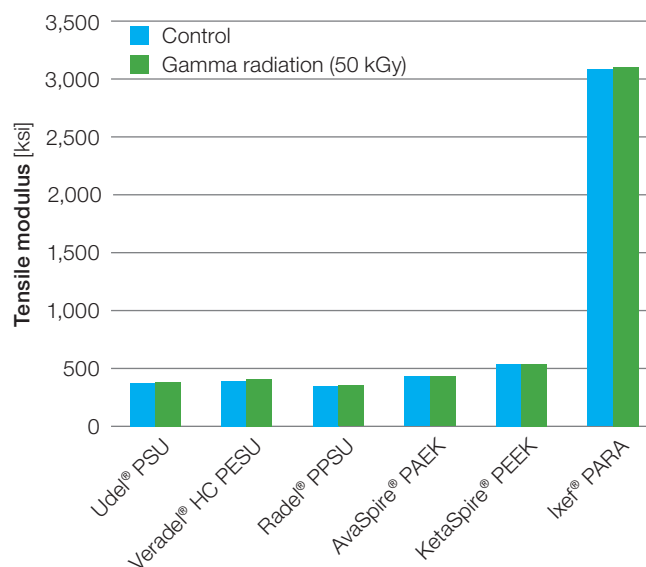


Figure 2: Tensile strength (ASTM D638)

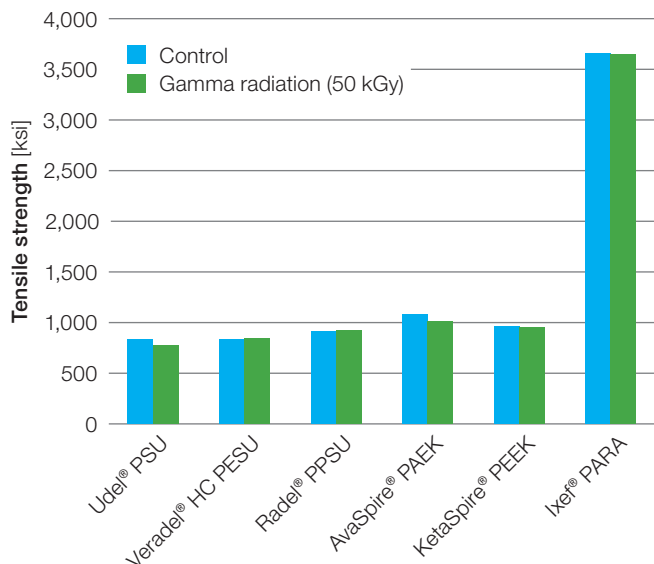


Figure 4: Flexural strength (ASTM D790)

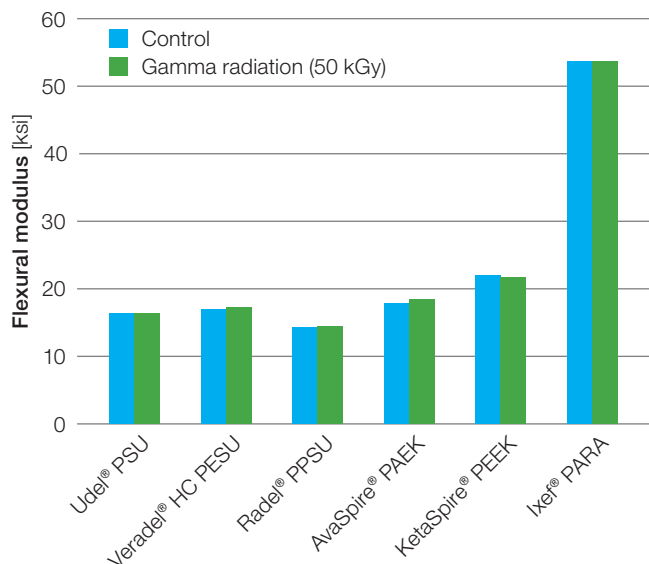
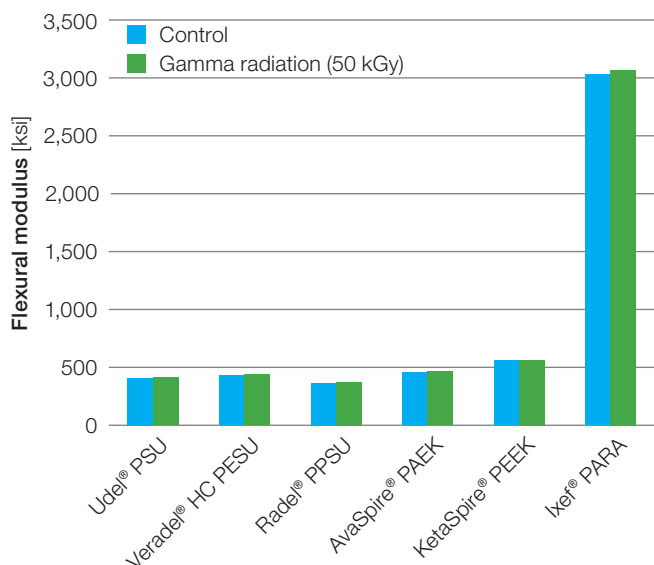


Figure 3: Flexural modulus (ASTM D790)



www.solvay.com

SpecialtyPolymers.EMEA@solvay.com | Europe, Middle East and Africa

SpecialtyPolymers.Americas@solvay.com | Americas

SpecialtyPolymers.Asia@solvay.com | Asia Pacific



SOLVAY

asking more from chemistry®

Safety Data Sheets (SDS) are available by emailing us or contacting your sales representative. Always consult the appropriate SDS before using any of our products. Neither Solvay Specialty Polymers nor any of its affiliates makes any warranty, express or implied, including merchantability or fitness for use, or accepts any liability in connection with this product, related information or its use. Some applications of which Solvay's products may be proposed to be used are regulated or restricted by applicable laws and regulations or by national or international standards and in some cases by Solvay's recommendation, including applications of food/feed, water treatment, medical, pharmaceuticals, and personal care. Only products designated as part of the Solviva® family of biomaterials may be considered as candidates for use in implantable medical devices. The user alone must finally determine suitability of any information or products for any contemplated use in compliance with applicable law, the manner of use and whether any patents are infringed. The information and the products are for use by technically skilled persons at their own discretion and risk and does not relate to the use of this product in combination with any other substance or any other process. This is not a license under any patent or other proprietary right. All trademarks and registered trademarks are property of the companies that comprise Solvay Group or their respective owners.

© 2017 Solvay Specialty Polymers. All rights reserved. D 09/2017 | R 11/2017 | Version 1.1 Design by ahlersheinel.com