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Ixef® PARA in Single-Use Instruments

Ixef® polyarylamide (PARA) compounds uniquely combine high strength and rigidity with high flow and an ultra-smooth finish that's on par with painted metal. They can be injection molded into complex shapes with thin cross-sections and long flow lengths. Ixef® 1022 is a 50% glass fiber reinforced compound that can replace metal to make single-use medical instruments that are light weight and highly resistant to mechanical stress.

High-energy gamma radiation is a cost-effective method for the bulk sterilization of single-use medical instruments. This document presents data that shows sterilization with gamma radiation does not degrade the mechanical properties of Ixef® 1022 and Ixef® GS-1022, which is a line of gamma-stabilized colored compounds.

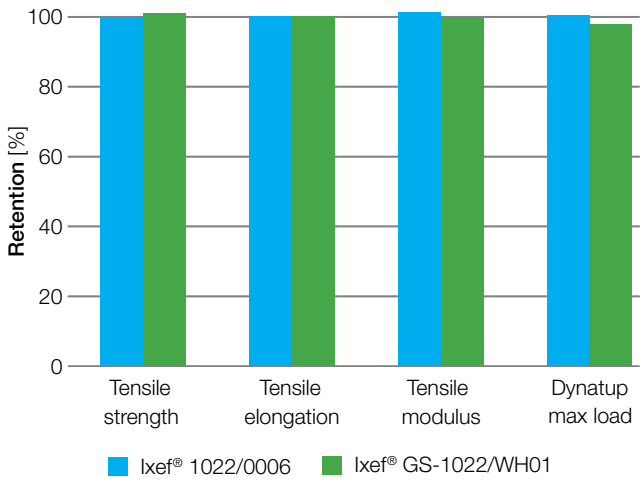
Mechanical Properties

To measure the effect of gamma sterilization on the mechanical properties of Ixef® PARA, standard test specimens were radiated at dose levels of 20 kGy and 40 kGy. The radiated specimens were then tested using the appropriate ASTM test method and the results compared to those of control samples that had not been radiated. Test results are presented in Table 1 and summarized in Figure 1.

Table 1: Effect of gamma radiation on mechanical properties

		Units	Ixef® 1022/0006	Ixef® GS-1022/WH01	ASTM Method
Tensile strength	No exposure	MPa (psi)	294 (42,600)	240 (34,800)	D638
	After 40 kGy	MPa (psi)	294 (42,600)	242 (35,100)	
	% Retention		100	101	
Tensile elongation	No exposure	%	2.5	1.6	D638
	After 40 kGy	%	2.5	1.6	
	% Retention		100	100	
Tensile modulus	No exposure	GPa (kpsi)	18.4 (2,670)	21.9 (3,170)	D638
	After 40 kGy	GPa (kpsi)	18.6 (2,700)	21.8 (3,160)	
	% Retention		101	100	
Dynatup max load	No exposure	kg (lb)	181 (400)	128 (283)	D3763
	After 40 kGy	kg (lb)	182 (402)	125 (277)	
	% Retention		100	98	

Figure 1: Property retention after 40 kGy gamma radiation



Color Stability

To evaluate the effect of gamma sterilization on Ixef® GS-1022 colored compounds, test samples were measured with a spectrophotometer before and after radiation. The data in Table 2 is expressed using the CIE system where "L" denotes light vs. dark, "a" denotes red/green, and "b" denotes blue/yellow.

Table 2: Color change due to 40 kGy gamma radiation(1)

	Ixef® 1022/0006		Ixef® GS-1022/WH01	
CIE	0 kGy	40 kGy	0 kGy	40 kGy
L	80.97	65.93	90.42	91.34
a	– 4.42	0.34	– 1.88	– 1.35
b	6.65	38.68	3.36	6.83
ΔE		35.70		4.65

(1) There will be a shift in color when comparing pre-gamma sterilization and post-gamma sterilization colors. It is also expected that the colors will revert to some degree, back toward the as-molded color. Lighter colors may display the greatest variation.

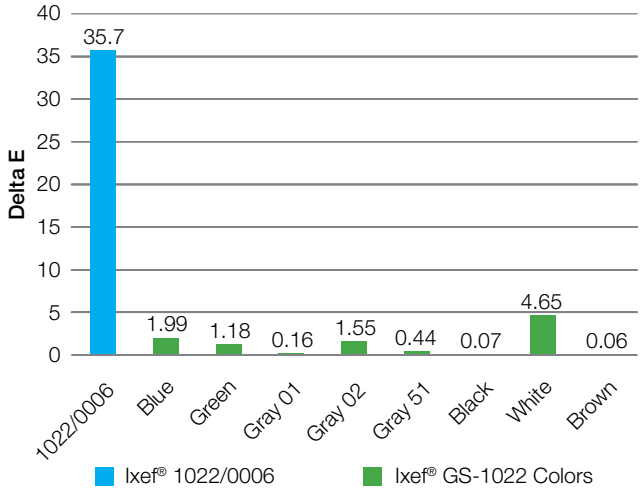
One method for expressing the difference between two colors is the value ΔE, which is calculated using this equation.

$$\Delta E = (\Delta L2 + \Delta a2 + \Delta b2)\ 0.5$$

High values of ΔE indicate a substantial color difference. It is generally accepted that a ΔE of 1 or less is difficult for the human eye to perceive. The data in Table 2 shows that there is a significant color change with natural-colored Ixef® 1022/0006; however, the color change for Ixef® GS-1022/WH01 is significantly less.

Several other gamma-stabilized Ixef® GS-1022 colors were tested. Colors were measured before and after radiation and the ΔE calculated. Test results are compared to Ixef® 1022/006 in Figure 2. The low ΔE values imply that most observers would not perceive a significant change in color.

Figure 2: Comparison of Ixef® GS-1022 colors after 40 kGy gamma radiation



Conclusion

Ixef® 1022 tolerates gamma-radiation sterilization very well, with virtually no loss of mechanical properties. Natural-colored resin shows a tendency to discolor when radiated, with a shift toward green. Gamma-stablized colors show nominal color change when exposed to the same level of gamma radiaton.

www.solvay.com

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

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