Effect of Gamma Sterilization on Select TPE Materials

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The Global Leader in Specialty Compounding

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Abstract *– It is widely known and published that modern sterilization techniques used in the healthcare industry can have a detrimental effect on thermoplastic polymers. In particular, gamma sterilization, which is the most common ionization method, can cause substantial changes to occur in polymeric materials. Polymer chain scission and cross linking can both occur, altering the physical properties and appearance of materials and ultimately affecting the functionality of a device utilizing these materials.*

RTP Company's TPE (Thermoplastic Elastomer) Division has initiated a series of projects to measure the effect different sterilization methods have on RTP Company's standard TPE products used in medical devices. This paper discusses the effect gamma sterilization has on these various TPE compounds produced by RTP Company for the healthcare industry.

Introduction

Advancements in TPE technology, particularly in the development of bondable grades, along with the improvements made in multi-shot processing techniques, have expanded the role and use of TPE materials in medical devices.

Benefits such as improved ergonomics, part consolidation, and reductions in secondary operations are driving product designers to incorporate TPEs into every conceivable human touch zone.

Advanced processing techniques have made overmolded grips, co-extrusions, impact protection covers, and molded-in gaskets and seals cost-effective options when designing and producing medical devices such as surgical tools, catheters, environmental seals, blood vial caps, septums, syringe components and tubing.

Replacement of thermoset rubber continues as the performance capabilities of TPEs expands and meets or exceeds rubber performance. Material advancements coupled with the efficiency offered by TPE processing have made innovative designs, part consolidation, and reduced assembly steps a reality for designers and processors. The ultimate result is a dramatic improvement in per part cost. Innovation is driving growth for TPEs as designers and OEMs strive to improve existing products, introduce new products, and add value to their medical devices.

Expansion of TPEs into the healthcare industry, especially for disposables, has increased the demand for accurate sterilization performance data pertaining to TPEs. Many different TPE variations exist, and each chemistry is affected differently by the sterilization process.

Certain TPE compounds are blends of a rubber phase and a thermoplastic phase. These compounds may also incorporate a plasticizer to further soften the rubber phase. These are known as dual or multi-phase compounds. With multiple phases, there are more variables to consider when materials are sterilized with gamma radiation. In addition, trends in the TPE industry continue to move toward innovative alloys and blends to expand performance windows and create new, function-specific products.

Understanding TPEs

All TPE materials are composed of hard and soft domains or "phases." These different phases contribute different performance properties to a material. Typically, the hard phase contributes engineering properties such as tensile, tear, and heat resistance. The soft phase contributes elastomeric properties such as compression set, tensile set, flexibility, and low temperature performance.

Thermoplastic vulcanizates (TPV) and compounded styrenic block copolymers (SBC) are blends of hard thermoplastics and soft rubbery polymers that make up their respective hard and soft phases. Thermoplastic polyurethanes (TPU), co-polyether-ester elastomers (COPE), and polyether block amides (PEBA) are all block copolymers that have both crystalline (hard) and amorphous (soft) blocks distributed along their polymer chains and it is the crystallization of the hard blocks into discrete domains upon cooling that results in the hard / soft phase morphology of a TPE. Blends and alloys based on various combinations of homopolymers and block copolymers and that may exhibit unusual hard / soft phase morphologies with unique properties are also possible.

Thus, it may not always be easy to identify which phase of the material is affected most by gamma sterilization.

RTP Company is a compounder; therefore, the materials evaluated in this study are either dual phase SBCs, TPVs or TPE alloys with multiple phases. Straight TPU, COPE, or PEBA materials have not been tested because data for these materials is already available in the marketplace.

With multiple phases in each compound and different mechanisms of polymer alteration taking place, analysis of molecular level effects of gamma sterilization is a very complex challenge. In this paper, RTP Company has not attempted to analyze specific molecular level alterations. Rather, our observations are relevant to the properties tested with some interpretation of the observed results.

Injection Molding to Achieve Bonding

Multi-shot molding is the processing technology that is driving much of the growth of TPEs in the medical industry. However, there are different molding processes that can be utilized to bond one material to another. The specific process used is usually determined by the volume of parts required for any particular application. Smaller volume applications may be better suited to insert molding while larger part volumes allow a processor to enjoy the economic benefits of true multi-shot molding.

Insert Molding – A two-step process where the substrate part is molded separately moved to a second tool/press to have the TPE overmolded onto the substrate. The advantage with this method is lower tooling and equipment costs versus multi-shot molding. The disadvantages to this process are slower overall cycles and potentially increased cost of labor due to more part handling. Additionally, the bonding situation is less favorable, which can affect difficult-to-bond material combinations. The rigid part has a chance to cool and therefore is "less active." A cooler, less active polymer is less receptive to the TPE overmold as potential sites for polymer interaction may be tied up as the material cools and are no longer available.

Multi-Shot Molding – A two-step process in which the substrate material is molded and then shuttled to the second shot position within the same molding press by the use of a stripper plate or rotary turntable. The part is contained within common tool steel during the injection of both the first shot (substrate) and second shot (TPE) position.

Advances in tooling technology are resulting in exciting new designs and processes. While two shots are common in multi-shot applications, three and four shot processes are becoming more and more common and expanding the complexity of application designs.

Sterilization

Sterilization is a thermal, chemical, or radiation process designed to destroy and/or remove all forms of microbial life, including bacterial spores. Sterilization can be accomplished by the following methods:

- Ethylene Oxide
- Radiation – Electron Beam and Isotope (Gamma)
- Steam Autoclave
- Dry Heat
- Peroxide Gas Plasma
- Concentrated Peracetic Acid

Gamma sterilization is fast becoming the preferred method to sterilize medical devices in high volume and is the subject of this study.

Both Gamma and E-beam sterilization can affect the properties of thermoplastic materials. The mechanisms of these alterations at the molecular level are known and can result in cross-linking and chain scission. These alterations take place at the same time, but one usually predominates.

Our focus was on the effects gamma sterilization has on select physical properties rather than on what happens at the molecular level. To best mimic a worst case scenario, three radiation exposure levels were tested:

- Sample 1 = 25 kGy (2.5 MRads) = normal, one time sterilization process
- Sample 2 = 50 kGy (5.0 MRads) = 2x's the normal sterilization process
- Sample 3 = 75 kGys (7.5 MRads) = 3x's the normal sterilization process

Actual radiation exposure for this study was conducted by STERIS Isomedix Services. The radiation source was Cobalt 60 and a rotary turntable was used for even and accurate exposure. The delivered dosage was within 2.4% of the specified dosage.

The goal of our study was to determine what key physical and visual property changes took place in a select group of RTP Company TPE compounds when exposed to various levels of gamma radiation. Our focus was on tensile strength, modulus @100% elongation, tear strength, Shore hardness, and yellow index.

The strength properties provide information on the integrity of the material while the modulus and hardness properties provide information on the "feel" of the material. Yellow index is a common measurement employed in the pre-coloring process of TPE and other thermoplastic materials, it is also an indicator of degradation in many polymers. Bond strength to various substrates was also analyzed for both standard "bonding grades" as well as our more general purpose grades.

Materials

RTP Company is a custom compounder of specialty TPE materials and offers both standard products as well as custom formulations. All products chosen for this study were standard materials and none were specifically stabilized for the gamma sterilization process. Not all hardness grades were tested. The extreme hardness grades were chosen to provide a representative view of each product family. The complete list of materials with a brief description is as follows:

- *RTP 6035-50A* – A proprietary compound offering water-like clarity and select bondability to PS and PP. This compound can be used to replace silicone rubber in some applications and is commonly used in conjunction with RTP Company's special effect color technologies. The Shore hardness is 50A.
- *RTP 6003-45A* – A proprietary compound specifically formulated for excellent adhesion to various amorphous substrates such as PC, ABS, PC/ABS, and PC/PMMA. The RTP 6003 Series is RTP Company's premier bonding series. The Shore hardness is 45A.
- *RTP 6003-75A* – A proprietary compound specifically formulated for excellent adhesion to various amorphous substrates such as PC, ABS, PC/ABS, and PC/PMMA. The Shore hardness is 75A.
- *RTP 6002-45A* – A proprietary compound specifically formulated for excellent adhesion to various amorphous substrates such as PC, ABS, PC/ABS, and PC/PMMA. The Shore hardness is 45A.

- *RTP 6002-75A* – A proprietary compound specifically formulated for excellent adhesion to various amorphous substrates such as PC, ABS, PC/ABS, and PC/PMMA. The Shore hardness is 75A.
- *RTP 2700 S-70A* – RTP Company's standard SEBS compound with a hardness of Shore A 70.
- *RTP 2700 S-30A* – RTP Company's standard SEBS compound with a hardness of Shore A 30.
- *RTP 2800 B-85A* – A TPV alloy based on a cross linked EPDM rubber phase and modified for improved tear strength. It has a Shore A durometer of 85A.
- *RTP 2800 B-45A* – A TPV alloy based on a cross-linked EPDM rubber phase and modified for improved tear strength. It has a Shore A durometer of 45A.

Bonding Combinations

When bonding TPE materials to rigid, thermoplastic substrates, not all materials are equal. Good bonding requires material combinations to have similar surface energy properties, good wetability and flow behavior of the TPE overmold material, and molecular interaction between the TPE material and the rigid substrate. These material combinations were tested for peel strength:

- RTP 6003-45A vs. Polycarbonate
- RTP 6003-75A vs. Polycarbonate
- RTP 6002-45A vs. Polycarbonate
- RTP 6002-75A vs. Polycarbonate
- RTP 2800 B-85A vs. Polypropylene
- RTP 2700 S-70A vs. Polypropylene

Properties Tested

To test the effect of the gamma sterilization process on the materials, the following properties were evaluated:

- Tensile strength (psi) per ASTM D 412
- Tensile modulus @100% elongation (psi) per ASTM D 412
- Tear Strength (pli) per ASTM D 624
- Shore A hardness per ASTM D 2240
- Yellowness index – RTP procedure based on ASTM E313 and ASTM D1925 (withdrawn by ASTM in 1995)
- Peel Strength (pli) per RTP TP-55 – done on bonding grades

Properties were measured before (control) and after exposure to three different dosages of radiation, and all physical property and yellowness index testing was conducted at the RTP Company.

Table 1 provides a summary of the property tests and a brief description of each test.

Table 1 – Summary of Test Procedures

Property	Test Method	General Overview
Tensile Strength	ASTM D 412	Maximum stress that a material can withstand without yielding when subject to a stretching load.
Tensile Modulus	ASTM D 412	The ratio of stress to strain in a material that is elastically deformed.
Tear Strength	ASTM D 624	Measure of force required to tear a material – good measure of material integrity.
Shore A Hardness	ASTM D 2240	Industry standard for measure of hardness or durometer.
Yellowness Index	RTP Methodology	Measurement of color fastness and possible polymer degradation.
Peel Strength	RTP TP-55 (Similar to ASTM E 429 Method B)	TPE molded onto a rigid substrate via cold insert method. Measure of the force required to separate the two materials.

Property Relevance

Properties were chosen to analyze possible changes to both the hard phase and soft phase of the TPE compounds. These measurements represent the different properties that are commonly applicable to the wide variety of medical device applications possible. There are other properties that can be tested and may be the subject of future studies.

Tensile Strength – This property is a good measurement of the physical strength and integrity of a TPE product and is more commonly used with TPEs than flexural strength. It is relevant to applications that experience pulling force (tubes, ID bracelets, molded hanger hooks etc.). Severe polymer degradation causes a significant drop in this property. Changes to this property can also be indications of changes to the hard phase of a dual phase material or the hard segments of a copolymer.

Tensile Modulus – Changes in modulus, or stiffness, can be indicative of changes in feel and perceived hardness and are relevant to applications that must exhibit flexibility, stretchiness, and feel. Crosslinking can raise the modulus of a material while chain degradation will cause the modulus to drop.

Tear Strength – This test can be viewed as a measure of a TPE material's integrity. Polymer degradation can lead to poor material integrity and lower tear values.

Shore A hardness – The most common measurement of elastomeric materials is hardness, although not always the most meaningful. RTP Company encourages that this property be evaluated in conjunction with modulus values to truly gauge a material's hardness. A change in this value can be viewed a change in the soft phase of a TPE compound.

Yellow Index – This test is commonly used with colored materials to gauge a material's colorfastness and long term color stability, also a good indicator of polymer degradation. Color is viewed by consumers as a key property by itself. Establishing and maintaining critical color tolerances can determine the success of an application. Colored TPEs are often used in grips and overmolded applications to provide contrast and a compelling appearance.

Peel Strength – This test measures the integrity of the bond between a TPE and a rigid substrate. RTP Company's method uses a T-bar that is molded via cold insert techniques. This is a worst case scenario versus true two-shot molding methods where the substrate would still be hot and "active." Failure can be cohesive in which the TPE material itself fails before the actual bond fails or adhesive in which the bond fails and the TPE is peeled completely away from the substrate. Often both types of failure take place and an estimate of the percent of cohesive to adhesive failure is made.

Sterilization Procedure

The photon source for sterilization was Cobalt 60, and compounds were exposed on individual turntables to ensure dosage was closely controlled and that that dosage was consistent for all samples. The materials were exposed to:

Table 2 – Dosages and Exposure Times for Gamma Treatment of TPE Samples

Sterilization Level	Delivered Dose	Exposure Time
Control	None	0 minutes
1	25.0-26.1 kGy	148 minutes
2	50.8-54.4 kGy	307 minutes
3	75.1-76.8 kGy	446 minutes

Typically, 25 kGy (2.5 MRads) is the minimum dosage used to sterilize a polymer, and higher dosages of 42-50 kGy (4.2-5.0 MRads) are often used to ensure an acceptable sterilization. The highest level of 75.1-76.8 kGys (7.51-7.68 MRads) is an extreme level that can be encountered in real world applications.

The different sample sets are labeled according to their respective doses. Level 1 corresponds with 25.0-26.1 kGys, level 2 corresponds with 50.8-54.4 kGys, and level 3 corresponds with 75.1-76.8 kGys. The control set consists of non-irradiated samples of each material. The standard deviation, calculated for tensile strength, tensile modulus, and tear strength tests is shown to provide an indication of the consistency of the effects.

Data

Table 3 – Summary of Physical Properties

Material	Steril-ization Level	Tensile Strength (psi)	Std. Dev.	Tensile Modulus @100% (psi)	Std. Dev.	Tear (pli)	Std. Dev.	Shore A hardness
RTP 6035-50A	Control	1484	44.73	206	1.30	192	9.52	56
	1	1420 (-4%)	18.85	200 (-3%)	2.25	203 (+6%)	5.01	55
	2	1233 (-17%)	28.22	207 (0%)	1.59	188 (-2%)	2.52	54
	3	1189 (-20%)	29.14	196 (-5%)	3.98	192 (0%)	6.63	54
RTP 6003-45A	Control	674	22.13	189	1.13	132	1.98	45
	1	730 (+8%)	23.77	194 (+3%)	1.21	132 (0%)	4.80	44
	2	794 (+18%)	33.29	191 (+1%)	4.17	139 (+5%)	4.81	43
	3	790 (+17%)	38.67	186 (-2%)	4.70	139 (+5%)	7.32	43
RTP 6003-75A	Control	1501	89.32	531	3.71	334	13.53	75
	1	1682 (+12%)	75.18	550 (+3.5%)	7.62	330 (-1%)	6.89	73
	2	1907 (+27%)	72.95	572 (+8%)	6.13	349 (+4%)	5.57	77
	3	1957 (+30%)	73.63	569 (+7%)	3.60	341 (+2%)	7.33	74
RTP 6002-45A	Control	1424	46.43	219	4.33	160	7.77	46
	1	1421 (0%)	28.72	217 (-1%)	5.31	161 (0%)	4.62	45
	2	1399 (-2%)	27.30	218 (0%)	0.74	164 (+2.5%)	6.50	45
	3	1439 (+1%)	31.67	210 (-4%)	3.82	166 (+4%)	5.30	44
RTP 6002-75A	Control	1918	108.10	693	6.96	329	4.26	79
	1	1943 (+1%	65.01	687 (-1%)	6.12	333 (+1%)	4.38	76
	2	1972 (+3%)	74.68	691 (0%)	2.74	335 (+2%)	4.05	76
	3	1852 (+3.5%)	237.03	670 (-3%)	2.45	334 (+1.5%)	5.31	76
RTP 2700 S-70A	Control	1393	176.90	380	3.46	223	6.28	71
	1	1425 (+2%)	74.56	373 (-2%)	2.39	218 (-2%)	8.71	71
	2	1235 (-12%)	41.74	371 (-2%)	4.07	213 (-4%)	5.06	68
	3	1212 (-13%)	44.64	356 (-6%)	4.88	208 (-7%)	7.78	69

Table 3 continues on next page

Table 3 (Continued from previous page) – Summary of Physical Properties

Material	Steril-ization Level	Tensile Strength (psi)	Std. Dev.	Tensile Modulus @100% (psi)	Std. Dev.	Tear (pli)	Std. Dev.	Shore A hardness
RTP 2700 S-30A	Control	767	88.91	99	2.79	114	13.87	34
	1	916 (+19%)	51.18	96 (-3%)	2.29	103 (-10%)	11.08	31
	2	920 (+20%)	75.37	94 (-5%)	0.93	113 (-1%)	5.89	28
	3	928 (+21%)	79.20	86 (-13%)	1.61	120 (+5%)	7.99	28
RTP 6003-75A	Control	1501	89.32	531	3.71	334	13.53	75
	1	1682 (+12%)	75.18	550 (+3.5%)	7.62	330 (-1%)	6.89	73
	2	1907 (+27%)	72.95	572 (+8%)	6.13	349 (+4%)	5.57	77
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	3	928 (+21%)	79.20	86 (-13%)	1.61	120 (+5%)	7.99	28
RTP 2800 B-85A	Control	1367	101.23	863	8.58	263	3.01	88
	1	1214 (-11%)	67.36	840 (-3%)	15.06	239 (-9%)	4.15	86
	2	1116 (-18%)	28.28	826 (-4%)	4.11	233 (-11.5%)	6.20	84
	3	995 (-27%)	21.84	797 (-8%)	3.58	218 (-17%)	6.52	87
RTP 2800 B-45A	Control	592	5.89	246	4.55	97	1.90	54
	1	527 (-11%)	16.37	230 (-7%)	4.26	92 (-5%)	3.41	52
	2	469 (-21%)	7.64	222 (-10%)	6.29	84 (-13%)	1.74	52
	3	426 (28%)	5.31	194 (-21%)	2.74	79 (-19%)	1.84	51

Control = No gamma radiation exposure or sterilization

Table 4 – Summary of Yellow Index

Material	Sterilization Level	YI	DYI
RTP 6035-50A	1	3.50	0.99
	2	3.85	1.34
	3	3.96	1.45
	Control	2.51	
RTP 6003-45A	1	13.69	3.77
	2	16.62	6.70
	3	16.46	6.54
	Control	9.92	
RTP 6003-75A	1	17.24	1.91
	2	18.39	3.06
	3	19.57	4.25
	Control	15.32	
RTP 6002-45A	1	14.16	9.16
	2	20.85	15.84
	3	27.43	22.42
	Control	5.01	
RTP 6002-75A	1	25.56	10.91
	2	35.02	20.37
	3	39.97	25.32
	Control	14.65	
RTP 2700 S-70A	1	10.66	3.82
	2	12.35	5.51
	3	11.86	5.02
	Control	6.84	
RTP 2700 S-30A	1	10.40	2.96
	2	10.83	3.39
	3	11.63	4.19
	Control	7.44	
RTP 2800 B-85A	1	19.13	5.10
	2	19.54	5.51
	3	20.42	6.39
	Control	14.03	
RTP 2800 B-45A	1	21.32	5.84
	2	20.61	5.13
	3	21.78	6.30
	Control	18.48	

Table 5 – Bonding Data

Material	Sterilization Level	Peel Strength	Standard Dev.
RTP 6003-45A	Control	14.9	2.52
	1	20.6	1.18
	2	20.9	2.58
	3	20.6	4.84
RTP 6003-75A	Control	73.4	2.35
	1	72.0	DNC
	2	72.0	DNC
	3	67.6	DNC
RTP 6002-45A	Control	14.4	2.23
	1	13.0	1.11
	2	10.1	0.64
	3	11.7	1.81
RTP 6002-75A	Control	21.0	3.34
	1	28.7	7.58
	2	20.1	3.41
	3	23.1	6.38
RTP 2700 S-70A	Control	33.2	1.34
	1	35.8	1.64
	2	32.8	2.67
	3	31.6	3.27
RTP 2800 B- 85A	Control	16.4	1.30
	1	20.3	1.82
	2	23.2	1.76
	3	22.2	2.02

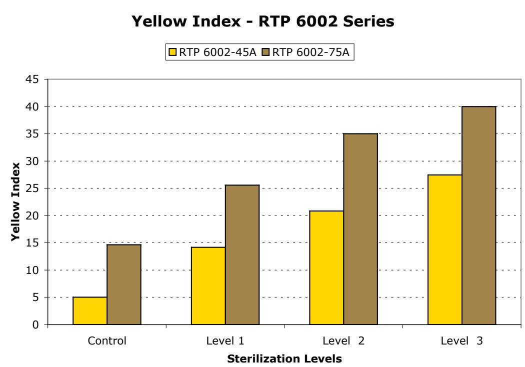
Control = No gamma radiation exposure or sterilization
DNC = Did not calculate

Data Discussion

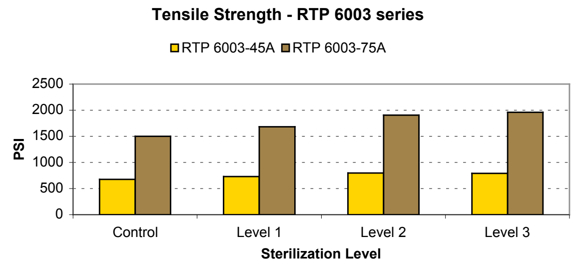
From the data tables, several observations can be made.

1) Sterilization level 1 is the common industry level and sterilization level 2 is considered excessive but is often used in practice to ensure complete sterilization. None of the RTP Company materials exhibited either catastrophic property loss or enough property loss to preclude us from recommending these products for medical applications that would be gamma sterilized at these levels.

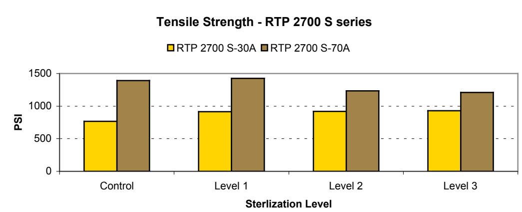
2) RTP 6002 Series materials yellowed severely while physical properties were maintained. With each increased dosage of radiation, the severity of the color shift increased significantly. RTP Company would not recommend this product for applications that would require tight color standards.

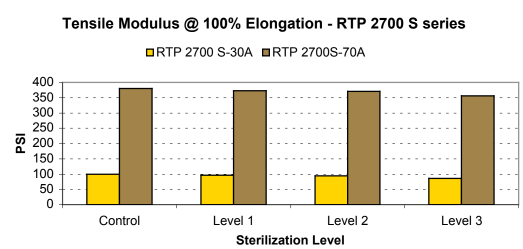


3) The RTP 6003 Series materials exhibited an increase in tensile strength properties, which may be indicative of some mild cross-linking. In particular, the harder grade, Shore A 75, exhibited a significant increase in tensile strength. Tensile modulus and tear strength properties did not follow the same trend. These property trends would suggest cross-linking is taking place in the hard phase of this compound. RTP 6003-75A has a higher ratio of hard phase to soft phase than RTP 6003-45A and, therefore, any cross-linking effect has more influence in the Shore A 75 durometer product.



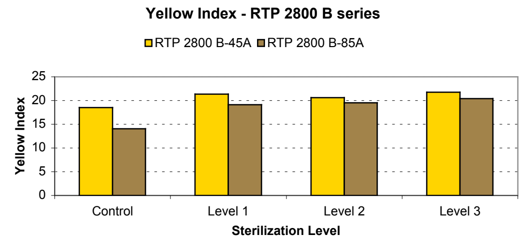
4) RTP 2700 S-30A showed an increase in tensile strength but a drop in tensile modulus @100% strain. Further investigation showed an increase in tensile elongation (not reported). These indicators could point to mild cross-linking in the rubber phase with some polymer scission in the thermoplastic phase of this compound. The harder SEBS compound (RTP 2700 S-70A) did not follow this property trend. RTP 2700 S-70A contains a larger proportion of hard phase polypropylene and less rubber phase than RTP 2700 S-30A. Therefore, the properties of RTP 2700 S-70A reflect the alterations to the hard phase PP more than in the case of RTP 2700 S-30A.





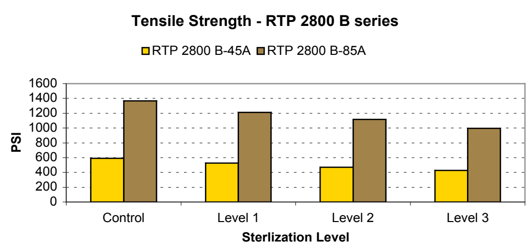
5) The RTP 2800 B materials showed the second highest degree of color shift with the most significant shift coming from the initial dose of radiation but not changing severely as the dose increased (in contrast to the RTP 6002 Series, which continued to fade at higher doses). The hard phase of these compounds

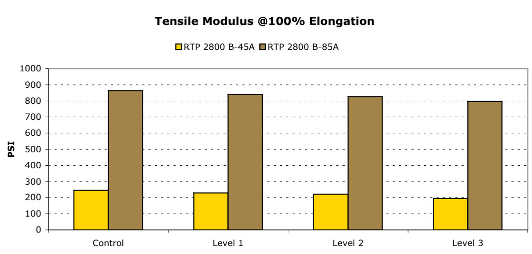
are polypropylene, which is known to undergo color shift when exposed to gamma radiation if not specifically stabilized for sterilization process.

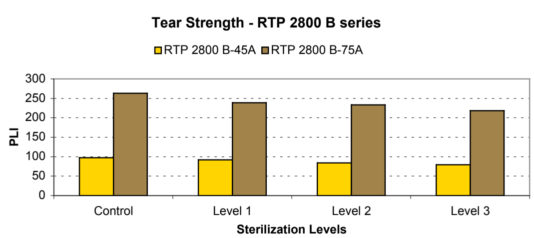


6) Measured hardness changes appeared to be minimal in all cases. The biggest fluctuation in hardness was six durometer points for the RTP 2700 S-30A material.

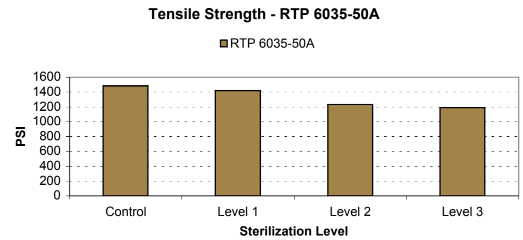
7) The RTP 2800 B materials showed a significant drop in tensile strength, tensile modulus, and tear strength as radiation dosage increased. These property changes can be attributed to polymer degradation of the hard polypropylene phase.





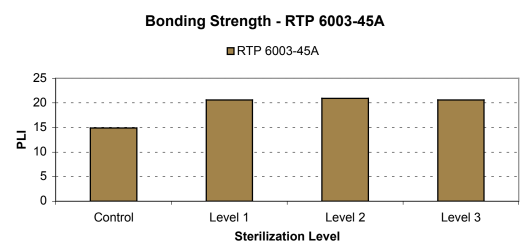


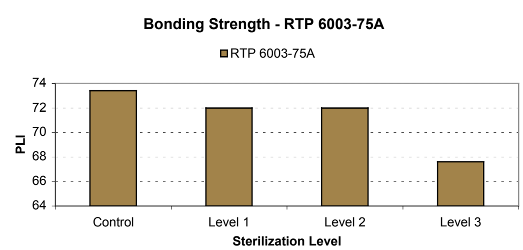
8) The RTP 6035-50A showed a drop in tensile strength which would indicate some polymer degradation, but changes in the other measured properties do not clearly confirm this trend.



Bonding Data Discussion

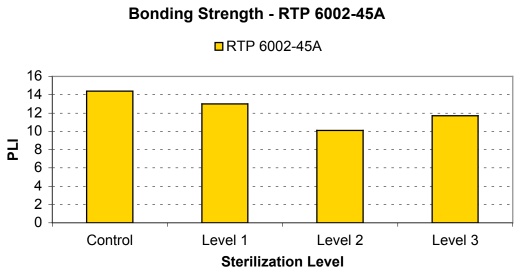
1) RTP 6003 Series materials are RTP Company's premier bonding grades and showed excellent retention of bond strength after all exposure doses. Differences in actual peel strength are a function of the products formulations. However, the maintenance of bond strength is similar for both products. The gamma sterilization process does not appear to degrade bond strength versus polycarbonate.

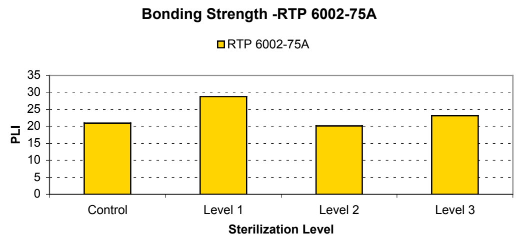




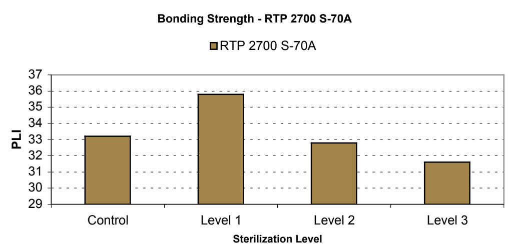
2) RTP 6002 Series materials are also bonding grades and show more effects from the gamma sterilization process. The bond properties of the harder grade were more erratic, yet overall maintained a level of functional bond strength through all three exposure levels. The 45

Shore A product showed a consistent drop in bond properties through all exposures.

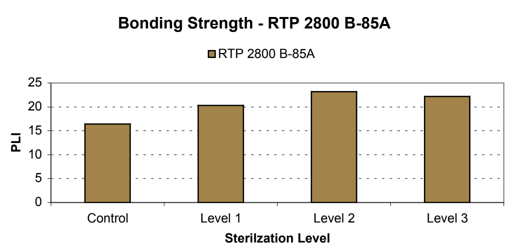




3) The bond strength for RTP 2700 S-70A versus PP first displayed an increase after one exposure, but then a drop after the second and third exposures. The overall level of bond strength is very good and at all three levels remains very functional for an actual end-use application. The overall drop is minor.



4) RTP 2800 B-85A showed a consistent increase in bond strength versus PP through all three exposure levels. This trend indicates that bond strength should remain functional during increased gamma radiation exposure.



5) Bonding data for all products needs to be evaluated in conjunction with the physical property data when selecting a TPE material for an actual medical device application.

Conclusions

TPE material selection for any application can be a complex process. For medical applications, in addition to typical physical property criteria used to judge materials, how a compound handles sterilization is a critical factor that needs to be considered.

This initial sterilization experiment suggests that RTP Company TPE compounds survived the various levels of radiation quite well. Each of the compounds tested reacted to gamma sterilization differently and exhibited changes, both positive and negative, in the physical properties tested. There was not an alarming change in properties that would cause RTP Company not to recommend any of these products for use in medical devices that would be gamma sterilized. However, functional performance and the gamma radiation effects should always be considered in conjunction when selecting TPEs for an application that will be gamma sterilized.

The color shift exhibited by the RTP 6002 Series materials is significant. For applications where cosmetic finish or color fastness is critical, these results will influence material recommendations, and investigation into improved stabilizer technology is warranted.

Finally, the results of this study will provide RTP Company with direction for new product development and product improvement specifically for medical devices.

Acknowledgements

Karl Hemmerich, General Manager and Corporate Technical Advisor at Isomedix Corporation served as a technical advisor in this paper and assisted in the development of the radiation dose matrix. Karl has authored several articles and papers on the subject of radiation sterilization and has many years of experience in this field. Actual sterilization was conducted at STERIS Isomedix Services' laboratory scale facility.

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About RTP Company

RTP Company is a global, independent, custom compounder of thermoplastic and thermoplastic elastomer materials with eight manufacturing facilities strategically positioned around the world. RTP Company's TPE Division is one of five business units and is focused entirely on specialty thermoplastic elastomer compounds. RTP Company products are used in a variety of markets including medical, industrial, consumer, electrical & electronics, electronic packaging, and automotive.

About STERIS Isomedix Services

STERIS Isomedix services is a contract sterilizer with 21 facilities and capabilities in gamma, electron beam, and ethylene oxide sterilization. Facilities range from laboratory scale to large, production level sterilization services. With this range of capabilities and extensive years of experience, STERIS Isomedix offers flexibility that is unique to their industry.

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