Compatibility of RADEL® Polyphenylsulfone with Steam Sterilization

The ability to withstand repeated sterilization is a critical requirement for any material used in reusable medical devices. Steam sterilization is the most commonly used method and uses pressurized steam at 121 to 134°C (250 to 273°F) for up to 18 minutes. As with all sterilization techniques, medical devices are chemically washed and disinfected prior to autoclaving. They may also be exposed to other chemicals, such as morpholine, which are often added to central steam sterilization systems to inhibit corrosion in the lines. All things considered, it is one of the most severe sterilization environments for materials.

Engineered for especially harsh environments, RADEL polyphenylsulfone (PPSU) can be steam sterilized more than a thousand cycles. For over 12 years, this remarkably strong polymer has successfully replaced metals like stainless steel and aluminum in a wide variety of applications, including sterilization cases and trays, surgical and dental instrument handles, endoscopic devices, anesthesiology equipment, and joint replacement trials.

The success of RADEL PPSU can be attributed to several key performance attributes that are inherent to the polymer:

1) high heat resistance
2) long-term thermal stability,
3) resistance to prolonged hot water exposure,
4) broad range of chemical compatability, and
5) exceptional toughness and durability.

Thermal Properties

RADEL is an amorphous polymer with a glass transition temperature (Tg) of 220°C (428°F). This is the temperature at which the polymer transitions from a glassy state to a rubbery state and generally represents the upper temperature limit for short-term use.

RADEL PPSU has a heat deflection temperature (HDT) of 207°C (405°F) at 1.8 MPa (264 psi) by ASTM D 638. This value is a relative measure of the polymer's ability to perform at an elevated temperature while supporting a load. In general, the maximum operating temperature for amorphous polymers is 5 to 10°C (9 to 18°F) below the HDT value.

RADEL polyphenylsulfone has extreme thermal stability. In the thermogravimetric analysis (TGA) test, a temperature of 496°C (925°F) causes only a 1% weight loss.

Hydrolytic Stability

RADEL PPSU has excellent retention of mechanical properties after long-term exposure to hot water. Test bars molded from RADEL PPSU were completely immersed in a 90°C (194°F) water bath for 16,000 hours (almost two years). The results in Table 1 show that RADEL PPSU retained over 85% of its mechanical properties.

Table 1

Mechanical Properties After 16,000-Hour Immersion in 90°C (194°F) Water

Property	Retention, %
Tensile strength	99.9
Tensile modulus	94.1
Elongation at yield	85.0
Notched Izod impact	117.6

Compatibility with Steam Additives

Tensile and flexural test specimens molded from RADEL PPSU were tested to determine as-molded mechanical properties. Additional specimens from the same resin lot were exposed to steam cycles at 132°C (270°F) with 50 ppm morpholine added. Each cycle consisted of a 2-minute heat up and pressurization, 30 minutes at 132°C (270°F) at 27 psig (186 Pa) steam pressure, 2-minute depressurization, and a 10-minute hold. Specimens were removed after 1,000 steam cycles and tested.

The results are reported in Table 2. Although the tensile elongation value is reduced it is still in the highly-ductile region. This combined with the high notched Izod value indicate that practical toughness is still excellent. The finished parts will not become brittle.

Table 2

Mechanical Properties Before and After 1,000 Steam Cycles at 132°C (270°F) with 50 ppm Morpholine

Property	Units	As-Molded	After 1000 Cycles
Tensile strength	psi	11,000	12,000
	MPa	76	83
Tensile modulus	kpsi	361	365
	GPa	2.49	2.52
Tensile elongation	%	80	50
Flexural strength	psi	18,800	18,300
	MPa	130	126
Flexural modulus	kpsi	354	365
	GPa	2.44	2.52
Notched Izod impact	ft-lb/in	14.1	12.8
	J/m	752	683

Compatibility With Enzymatic Solutions

Test specimens, 5” x 0.5” x 0.125” (127 mm x 13 mm x 3.2 mm), molded from RADEL PPSU were exposed to steam cycles while under constant stress. Stress was achieved by hanging weights from one end of each test bar while the other end was supported as a cantilever beam. The applied loads resulted in stresses of 2000 psi (13.6 MPa) or 4,000 psi (27.2 MPa).

Four commonly used enzymatic solutions were tested. For each of the enzyme solutions, test bars were soaked and then exposed to a 30-minute sterilization cycle with steam containing 50 ppm morpholine at 134°C (273°F). Test results after 22 steam-soak cycles are shown in Table 3. RADEL PPSU demonstrates excellent compatibility, even when the applied stress was doubled.

Table 3

Compatibility with Enzymatic Agents

Enzymatic Agent	Applied Stress		RADEL R
	psi	MPa	
Enzol®	0	0	OK
1 oz/gal (8 ml/l)	2,000	13.8	OK
	4,000	27.6	1 tiny craze
XMC-10	0	0	OK
1 oz/gal (8 ml/l)	2,000	13.8	OK
	4,000	27.6	1 tiny craze
KLENZYME®	0	0	OK
2 oz/gal (16 ml/l)	2,000	13.8	OK
	4,000	27.6	OK
BIOZYME®	0	0	OK
1.5 oz/gal (12 ml/l)	2,000	13.8	OK
	4,000	27.6	OK

Compatibility with Disinfectants

A separate study was conducted using steam without morpholine and four commonly used disinfectants. An applied strain of 0.8%, which corresponds to a stress

of about 3,000 psi (21 MPa), was applied to test bars in the same cantilever position as described above. Before each steam cycle, the test bars were disinfected with one of disinfectants. RADEL PPSU was unaffected by this treatment, even after 600 cycles. The test results are shown in Table 4, and they indicate that RADEL PPSU was not significantly affected by any of these agents.

Table 4

Compatibility with Disinfectants with 0.8% Applied Stress After 600 Cycles

Disinfectants	RADEL R
Helipur® (phenol based)	OK
Kohrsolin®	OK
Neodisher® Septo (aldehyde based)	OK
Triton™ DF-16 (alcohol and tenside based)	OK

Exceptional Toughness and Durability

Test bars steam sterilized for 1,000 cycles at 132°C (270°F) with 50 ppm morpholine were tested for retention of practical toughness using an instrumented falling-dart impact test (Dynatup). Results are shown in Table 5.

Table 5

Practical Toughness After 1,000 Steam Cycles at 132°C (270°F) with 50 ppm Morpholine

Instrumented impact

Property	Units	As-Molded	After 1000 Cycles
Total energy	ft-lb	42.3	40.8
	J	57.3	55.3
Maximum load	lb	1330	1303
	N	5900	5800

During another study, flexural bars molded from RADEL PPSU were exposed to repeated steam sterilization while under constant stress. A weight was hung from the free end of the 5-inch (127-mm) bar while the other end was clamped in a cantilever beam arrangement. The weight used created a stress of 1,000 psi (6.9 MPa). After 1,000 steam cycles, the test bars were virtually unaffected and showed no signs of mechanical failure such as cracking or crazing.

These tests together illustrate the excellent super-toughness of the resin, even after repeated autoclaving with steam additives.

Conclusion

Steam sterilization, especially with amine corrosion inhibitors, degrades many plastic materials. Radel PPSU has exceptional resistance to steam sterilization under stress, even in the presence of aggressive disinfectants and enzymatic cleansing agents. Additionally, the resin has excellent mechanical properties, with tremendous impact, that are not significantly affected by long term thermal aging or repeated chemical exposure. As a result, Radel polyphenylsulfone has been successfully used for over a decade in reusable sterilizable medical applications such as orthopedic surgical instruments and steam sterilization cases, trays and containers.

Since each application has its unique performance requirements and design criteria, it is important that specialized testing be conducted by the design engineer to evaluate the resin under conditions that best simulate the function of the component or system in its intended use.

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