



International Filter Products

Revolutionary systems for your industry

PharmaPure® Low Spallation Peristaltic Pump Tubing

PharmaPure® is a premium, low spallation, biologically compatible peristaltic pump tube developed especially for pharmaceutical, biotechnology and laboratory applications. This tubing meets the challenges of providing unsurpassed pump life with ultra-low particulate spallation and very low permeability. The superior flex life characteristics of PharmaPure® simplify biopharmaceutical manufacturing processes by reducing production downtime due to pump tubing failures. Its excellent wear properties allow the product to provide extremely low rates of spallation as compared to silicone and other alternate materials. Because PharmaPure® has low permeability and lower absorption characteristics, it is ideal for protecting sensitive fluids from gas ingress and concentration changes due to fluid absorption. In addition, PharmaPure has low permeability and is ideal for protecting sensitive cell cultures, fermentation, separation, purification, process monitoring and sterile filling.



Saint-Gobain
Life Sciences -
Bioprocess Solutions



PharmaPure®
Low Spallation Peristaltic
Pump Tubing



Application





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- Media Process Systems
- Vaccine Manufacturing
- Bioreactor Process Lines
- Aseptic Filling
- Diagnostic Test Products
- Filtration & Fermentation

Technical Data Sheet

Features and Benefits:

- ❖ Ultra-low particulate spallation.
- ❖ Outlasts silicone tubing in peristaltic pumps.
- ❖ Provides an excellent barrier with very low permeability.
- ❖ Withstands repeated autoclaving.
- ❖ Temperature range -67°C to 135°C (-89°F to 275°F).
- ❖ Sterilizable by gamma irradiation, ETO, and autoclave.
- ❖ All formulas are Animal-Derived Component Free.
- ❖ All-inclusive Validation Guide and the Regulatory Information Overview (RIO) are available for customers upon request.

Chemical Resistance:

Chemical Type	PharmaPure® Compatibility
Acids, Dilute/Weak	Excellent
Bases, Dilute/Weak	Excellent
Salts	Excellent
High-purity Water	Excellent
Oil / Water Emulsion	Excellent
Alcohol	Fair

Note: A comprehensive chemical compatibility chart is available upon request.

When some chemical types are not suitable, safe, or chemically compatible with PharmaPure®, Saint-Gobain offers alternative tubing series. Below, you will find chemicals that are incompatible with PharmaPure® and the suggested alternative Saint-Gobain tubing series:



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Chemical Type	Alternative Saint-Gobain Tubing Series
Acids, Concentrated / Strong	C-Flex
Bases, Concentrated / Strong	C-Flex
Alcohol	Sani-Tech
Ketones & Organic Solvent	PharmaFluor FEP

Regulatory Compliance (Biocompatibility, Physicochemical & Extractable Testing):

PharmaPure® Validation: PharmaPure® Biocompatibility, Physicochemical & Extractable Testing		
Test	Standard	Value or Rating
Ames Genotoxicity	ISO 10993-3	Passed
Hemolysis: Indirect Contact	ISO 10993-4	Passed
Tests for In Vitro Cytotoxicity	ISO 10993-5	Passed
Tests for Systemic Toxicity – Rabbit Pyrogen Test (Material Mediated)	ISO 10993-11	Passed
Sterility Tests: Bacteriostasis & Fungistasis	USP <71>	Passed
Biological Reactivity Tests, In Vitro, MEM Elution Test	USP <87>	Passed
Biological Reactivity Tests, In Vitro, Agar Diffusion Test	USP <87>	Passed
Biological Reactivity Tests, In Vivo	USP <88>	Passed
Elastomeric Closures for Injection	USP <381>	Passed
Physicochemical Tests for Plastics	USP <661>	Passed
Testing of Rubber Closures for Containers	EP 3.2.9	Passed
Extractables Data	Saint-Gobain Protocol	N/A



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Physical Properties:

Property	Standard	Formulations Value
Material of Construction	---	Multi-Layer Thermoplastic Elastomer
Appearance / Color	---	Opaque / Off White
Durometer Hardness Shore A, 15 Sec.	D2240-00	65
Tensile Strength, psi (MPa)	D412-98	700 (4.8)
Ultimate Elongation, %	D412-98	400
Tensile Stress @ 100% psi (MPa)	D412-98	375 (2.6)
Tensile Set % @ 75% of Ultimate Elongation	D412-98	38
Tear Resistance, lb.-f/inch (kN/m)	D1004-94	110 (19.3)
Compression Set Constant Deflection, % @ 158°F (70°C) for 22 hours	D395-98 Method B	36
Specific Gravity	D792-00	0.92
Water Absorption, %, 24 hours @ 73°F (23°C)	D570-98	0.04
Brittle Temperature, °F (°C)	D746-98	-89 °F (-67 °C)
Low Temperature Flexibility @-40°F (-40°C)	D380-94	Passed (Still Flexible)
Flame Resistance Classification	UL 94-HB	Passed
Maximum Recommended Operating Temp., °F (°C)	---	275 (135)
Dielectric Strength, v/mil (kV/mm)	D149-97a	567 (22.3)

Unless otherwise noted, all tests were conducted at room temperature (73°F). Values shown were determined on 0.075" thick extruded strop or 0.075" thick molder ASTM plaques or molder ASTM durometer buttons.



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Sterilization Methods:

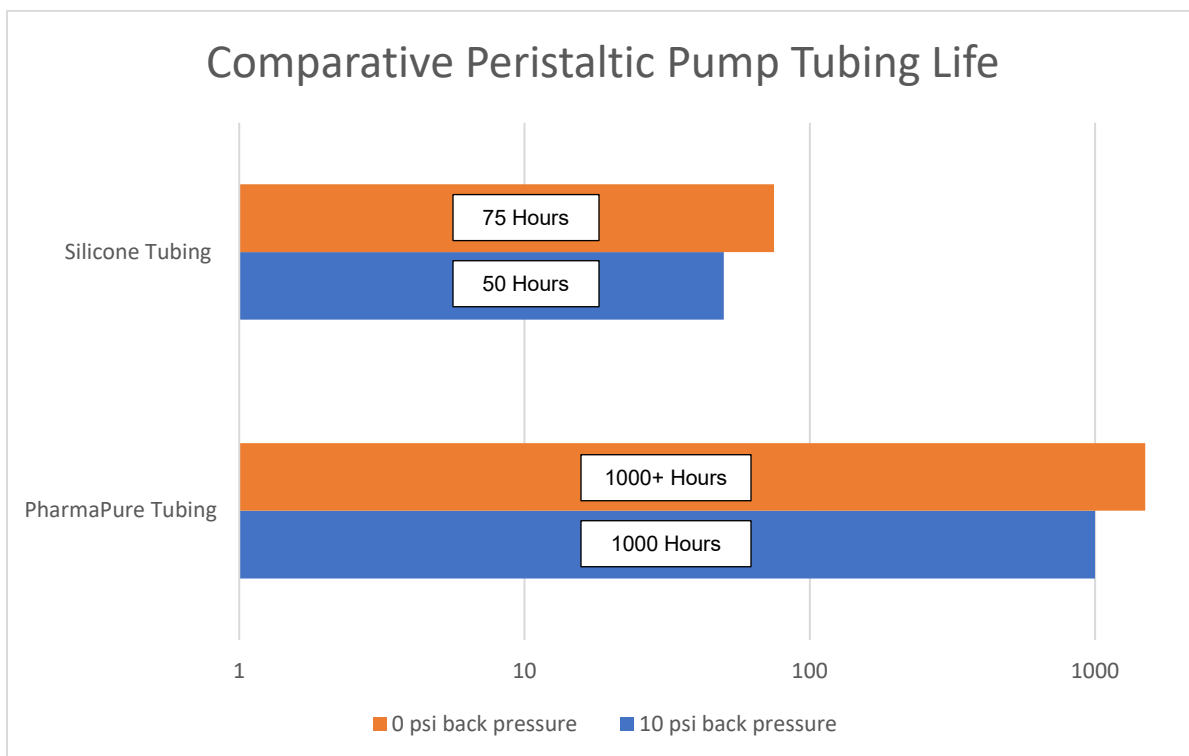
Autoclavable

Gamma Irradiation up to 25 kGy

Gas – Ethylene Oxide

Comparative Peristaltic Pump Tubing Life:

The table below depicts hours until failure of 1/4" ID x 3/8" OD tubing. In each case, a 3-roller pump head was utilized operating at 600 RPM under room temperature (73°F). Tubing failure is measured in hours of use prior to rupture.



Note: The performance of tubing in peristaltic pumping applications is affected by the conditions of use and equipment utilized, along with size and wall thickness of the tubing tested. The data above is presented for information only and should not be utilized for specification purposes.

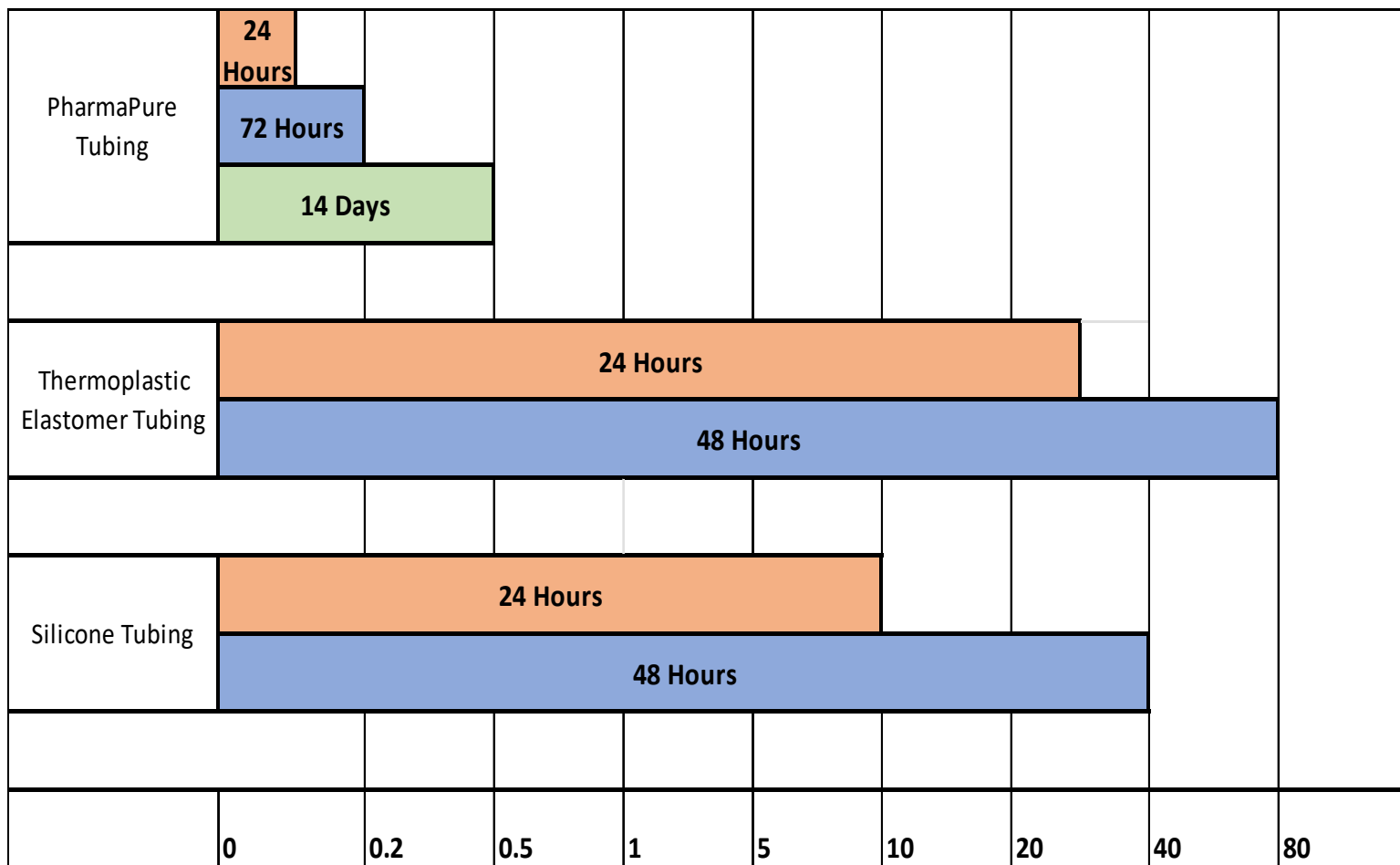


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Spallation Rate Tubing Comparison:

The following test data summarizes the spallation results of select tubing used in a peristaltic pump. In each case 1/4" ID tubing was used in a 3-roller pump head operating at 600 RPM under room temperature (73°F). Results from a minimum of 5 samples were averaged to obtain values. operating



Average Spallation Weight (mgs.)

PharmaPure® Tubing Standard Sizes:

Part Number	I.D. Inches (mm)	O.D. Inches (mm)	Wall Thickness Inches (mm)	Length Feet (m)	Minimum Bend Radius	Max. Suggested Working Pressure at	Vacuum Rating In. Hg (mm Hg)
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					Inches (mm)	73°F *psi (bar)	180°F *psi (bar)	73°F (23°C)	180°F (82°C)
AL242606	1/32 (0.8)	5/32 (4)	1/16 (1.6)	25 (7.6)	1/2 (13)	38 (2.6)	23 (1.6)	29.9 (760)	29.9 (760)
AL242002	1/16 (1.6)	1/8 (3.2)	1/32 (0.8)	25 (7.6)	1/2 (13)	20 (1.4)	13 (0.9)	29.9 (760)	29.9 (760)
AL242003	1/16 (1.6)	3/16 (4.7)	1/16 (1.6)	25 (7.6)	1/2 (13)	27 (1.9)	18 (1.2)	29.9 (760)	29.9 (760)
AL242005	3/32 (2.4)	7/32 (5.5)	1/16 (1.6)	25 (7.6)	1/2 (13)	27 (1.9)	13 (0.9)	29.9 (760)	29.9 (760)
AL242006	1/8 (3.2)	3/16 (4.8)	1/32 (0.8)	25 (7.6)	3/4 (19)	10 (0.7)	8 (0.6)	29.9 (760)	10 (254)
AL242007	1/8 (3.2)	1/4 (6.4)	1/16 (1.6)	25 (7.6)	3/4 (19)	24 (1.7)	12 (0.8)	29.9 (760)	29.9 (760)
AL242012	3/16 (4.8)	5/16 (7.9)	1/16 (1.6)	25 (7.6)	3/4 (19)	20 (1.4)	10 (0.7)	29.9 (760)	25 (635)
AL242017	1/4 (6.4)	3/8 (9.5)	1/16 (1.6)	25 (7.6)	1-1/4 (32)	15 (1.0)	7 (0.5)	29.9 (760)	15 (381)
AL242019	1/4 (6.4)	1/2 (12.7)	1/8 (3.2)	25 (7.6)	1-1/4 (32)	26 (1.8)	13 (0.9)	29.9 (760)	29.9 (760)
AL242022	5/16 (7.9)	7/16 (11.1)	1/16 (1.6)	25 (7.6)	1-1/2 (38)	13 (0.9)	7 (0.5)	29.9 (760)	10 (254)
AL242027	3/8 (9.5)	1/2 (12.7)	1/16 (1.6)	25 (7.6)	1-3/4 (44)	10 (0.7)	6 (0.4)	15 (381)	5 (127)
AL242029	3/8 (9.5)	5/8 (15.9)	1/8 (3.2)	25 (7.6)	1-1/2 (38)	19 (1.3)	10 (0.7)	29.9 (760)	29.9 (760)
AL242038	1/2 (12.7)	3/4 (19.0)	1/8 (3.2)	25 (7.6)	2-1/2 (64)	15 (1.0)	7 (0.5)	29.9 (760)	20 (508)
AL242046	5/8 (15.9)	7/8 (22.2)	1/8 (3.2)	25 (7.6)	2-3/4 (70)	12 (0.8)	6 (0.4)	25 (635)	10 (254)
AL242053	3/4 (19.0)	1 (25.4)	1/8 (3.2)	25 (7.6)	3-3/4 (95)	10 (0.7)	4 (0.3)	15 (381)	5 (127)

* Working pressures are calculated at a 1:5 ratio relative to burst pressure using ASTM D1599.