PharmaPure® combines unsurpassed pump life with ultra-low particle spallation making it the peristaltic pump tubing of choice.

**PharmaPure® Flexibility**
PharmaPure® is a premium, low spallation, biologically compatible peristaltic pump tubing developed especially for pharmaceutical, biotechnology, and laboratory applications. This tubing meets the demanding challenges of providing unsurpassed pump life, with ultra-low particulate spallation and very low permeability.

**Characteristics**
PharmaPure’s superior flex life characteristics simplifies the manufacturing process by reducing production downtime due to pump tubing failures. PharmaPure’s 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 superior absorption characteristics, it is ideal for protecting sensitive cell cultures, fermentation, separation, purification, process monitoring, and sterile fill applications.

**Biocompatibility**
PharmaPure tubing complies fully with the requirements of USP Class VI, European Pharmacopeia 3.2.9 and FDA 21 CFR Part 177.2600 criteria and is entirely noncytotoxic, non-pyrogenic, and non-hemolytic.

To confirm the superior characteristics of PharmaPure the following tests were also performed: Genotoxicity Tests, Bacteriostasis – Fungistasis Tests, Physiochemical Testing for Elastomeric Closures (USP <381>), Physiochemical Testing for Plastics (USP <661>), Total Extractables (per 21 CFR 177.2600), and full Preservative Absorption Test Protocol evaluating Benzyl Alcohol, Phenol, Meta-Cresol, Methyl Paraben, and Propyl Paraben. PharmaPure® tubing has a masterfile with the U.S Food and Drug Administration.

**Typical Pump Applications**
- Cell Harvest and Media Process Systems
- Vaccine Manufacturing
- Bioreactor Process Lines
- Sterile Filling
- Diagnostic Test Products
- Production Filtration and Fermentation

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**Features/Benefits**
- Ultra-low Particulate Spallation
- Outlasts Silicone Tubing in Peristaltic Pumps by Up to 30 Times
- Provides an Excellent Barrier with Very Low Permeability
- Withstands Repeated Autoclaving and Sterilization
- Meets all USP Class VI and FDA Criteria
- Custom Mold and Design Capabilities
Low Spallation Pump Tubing Specifications

**PharmaPure® Series**

molded ASTM durometer buttons. Unless otherwise noted, all tests were conducted at room temperature (73°F). Values shown

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

<table>
<thead>
<tr>
<th>Property</th>
<th>ASTM Method</th>
<th>Value or Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Durometer Hardness</td>
<td>D2240-00</td>
<td>65</td>
</tr>
<tr>
<td>Shore A, 15 Sec.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tensile Strength, psi (MPa)</td>
<td>D412-98</td>
<td>700 (4.8)</td>
</tr>
<tr>
<td>Ultimate Elongation, %</td>
<td>D412-98</td>
<td>400</td>
</tr>
<tr>
<td>Tensile Stress @ 100% psi (MPa)</td>
<td>D412-98</td>
<td>375 (2.6)</td>
</tr>
<tr>
<td>Tensile Set % @ 75% of Ultimate Elongation</td>
<td>D412-98</td>
<td>38</td>
</tr>
<tr>
<td>Color</td>
<td></td>
<td>Off White</td>
</tr>
<tr>
<td>Tear Resistance, lb-ft/inch (kN/m)</td>
<td>D1004-94</td>
<td>110 (19.3)</td>
</tr>
<tr>
<td>Compression Set</td>
<td>D395-98</td>
<td>36</td>
</tr>
<tr>
<td>Constant Deflection, % @ 158°F (70°C) for 22 hours Method B</td>
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<td></td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>D792-00</td>
<td>0.92</td>
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<tr>
<td>Water Absorption, % 24 hours @ 73°F (23°C)</td>
<td>D570-98</td>
<td>0.04</td>
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<tr>
<td>Brittle Temperature, 9°F (°C)</td>
<td>D746-98</td>
<td>-89 (-67)</td>
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<tr>
<td>Low Temperature Flexibility @-40°F (-40°C)</td>
<td>D380-94</td>
<td>Passed (Still Flexible)</td>
</tr>
<tr>
<td>Flame Resistance Classification</td>
<td>UL 94-HB</td>
<td>Passed</td>
</tr>
<tr>
<td>Maximum Recommended Operating Temperature, 9°F (°C)</td>
<td></td>
<td>275 (135)</td>
</tr>
<tr>
<td>Dielectric Strength, v/mil (kV/mm)</td>
<td>D149-97a</td>
<td>567 (22.3)</td>
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</tbody>
</table>

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

**Comparative Spallation 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 at room temperature (73°F). Tubing failure is measured in hours of use prior to rupture.

**PharmaPure® Tubing**

**Silicone Tubing**

**Thermoplastic Elastomer Tubing**

**Product Characteristics**

- **Opacity**: Opaque
- **FDA Approved for Food Contact**: Yes
- **USP Class VI**: Yes
- **Sterilization**: Autoclavable/Gas/Radiation*
  *Okay at 2.5 MRad (25 kilogray)

**Relative Chemical Resistance Properties**

- **Acids**: E = Excellent F = Fair U = Unsatisfactory
- **Bases**: U = Unavailable
- **Ketones**: U = Unsatisfactory

*All tests conducted at room temperatures.

**PharmaPure® Tubing is NOT INTENDED for USE as an Implant Material**

**IMPORTANT**: It is the user’s responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics tubing for all intended uses. Laboratory and clinical tests must be conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of tubing in any particular application.

For a period of 6 months from the date of first sale, Saint-Gobain Performance Plastics Corporation warrants this product to be free from defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. THIS WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized.

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