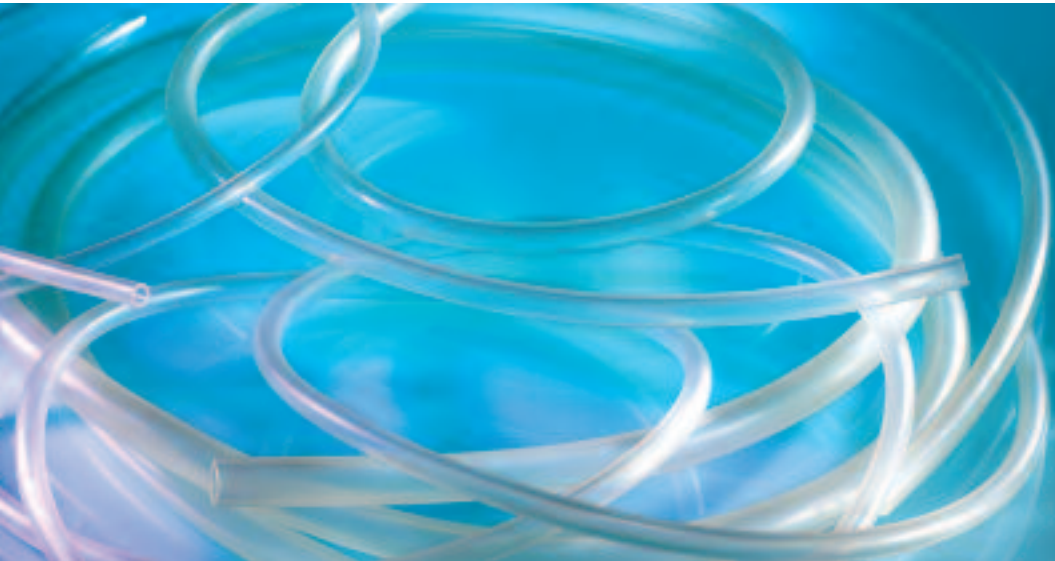


SaniPure™ 60 Biopharmaceutical Tubing



The unique characteristics of SaniPure™ 60 combine unsurpassed biocompatibility with a clear flexible tubing that is heat sealable, bondable, sterile-weldable, and moldable for custom assembly fabrications.

SaniPure™ 60

Saint-Gobain Performance Plastics has developed SaniPure™ 60, our latest innovation in polymer technology, which provides a clear, flexible, low-extractable, and biocompatible choice for sensitive fluid transfer applications. SaniPure™ 60 combines the features of traditional silicone tubing with superior peristaltic pump life, low permeability and absorption and the added enhancement of being heat sealable and bondable. This tubing answers the industry's need for a material that optimizes performance and reduces the likelihood of application failure.

Characteristics

SaniPure™ 60 has an ultra-smooth inner bore which drastically reduces potential particle entrapment and microscopic build-up during critical fluid transfer processes. This smooth fluid path also helps facilitate complete sanitation of the fluid transfer system and improves flow characteristics by reducing surface area.

The innovative design of SaniPure™ 60 creates an advanced tubing formulation that has an absorption rate lower than virtually all elastomeric tubing currently in use, making it the obvious selection when fluid integrity must be maintained throughout the process. This will also ensure that common preservatives which are added during processing are fully optimized.

Biocompatibility

SaniPure™ 60 tubing complies fully with the requirements of USP Class VI, European Pharmacopeia 3.2.9 and FDA 21 CFR Part 177.1210 criteria and is entirely non-cytotoxic, non-pyrogenic, and non-hemolytic.

To ensure the superior characteristics of SaniPure™ 60 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 a full Preservative Absorption Test Protocol evaluating Benzyl Alcohol, Phenol, Meta-Cresol, Methyl Paraben, and Propyl Paraben. SaniPure™ 60 tubing has a masterfile with the U.S Food and Drug Administration.

BIOPHARMACEUTICAL PRODUCTS

Features/Benefits

- Ultra-smooth inner bore reduces potential for particle entrapment
- Documented biocompatibility for sensitive applications
- Meets USP Class VI, EP 3.2.9 & FDA criteria
- Non-cytotoxic, non-pyrogenic, and non-hemolytic
- Extremely low absorption and adsorption compared to silicone tubing
- Heat sealable, bondable, sterile-weldable, and custom moldable for assemblies
- Superior peristaltic pump life
- Fully autoclavable and sterilizable

Typical Applications

- Sterile filling and processing
- Cell harvest and media process systems
- Vaccine production
- Production filtration and fermentation
- Cell and tissue culture transport
- Drug delivery systems
- Diagnostic equipment and laboratory research
- Bioreactor process lines
- High-purity water transfer



SaniPure™ 6o Tubing Inventoried Sizes

Part Number	I.D. (inches)	O.D. (inches)	Wall Thickness (inches)	Length (feet)	Minimum Bend Radius (inches)	Maximum Working Pressure at 73°F (psi)*	Working Pressure at 180°F (psi)*
AN100001	1/32	3/32	1/32	50	1/4	20	11
AN100002	1/16	1/8	1/32	50	1/4	19	8
AN100003	1/16	3/16	1/16	50	1/2	35	14
AN100007	1/8	1/4	1/16	50	1/2	20	9
AN100012	3/16	5/16	1/16	50	3/4	13	6
AN100013	3/16	3/8	3/32	50	3/4	23	10
AN100017	1/4	3/8	1/16	50	1	15	7
AN100018	1/4	7/16	3/32	50	1	20	8
AN100019	1/4	1/2	1/8	50	1	26	9
AN100027	3/8	1/2	1/16	50	2	11	5
AN100029	3/8	5/8	1/8	50	1-1/4	16	6
AN100038	1/2	3/4	1/8	50	2-1/2	15	6

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

The values listed for working and burst pressures are derived from tests conducted under controlled laboratory conditions. Many factors will reduce the tubing's ability to withstand pressures, including temperature, chemical attack, stress, pulsation and the attachment to fittings. It is imperative that the user conduct tests simulating the conditions of the application prior to specifying the tubing for use.

Relative Chemical Resistance Properties*

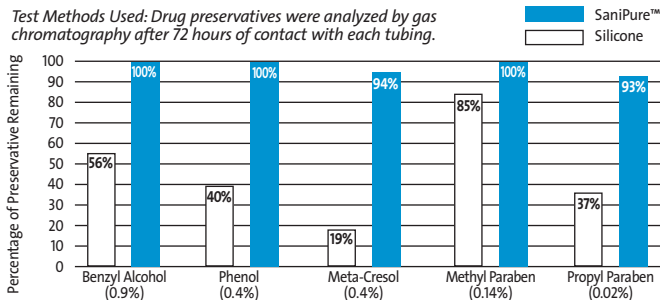
Acids			Bases			Salts	Alcohols	Ketones
conc.	med.	weak	conc.	med.	weak			
G	G	E	G	G	E	E	F-G	F-G

E = Excellent G = Good F = Fair U = Unsatisfactory

*All tests conducted at room temperature.

Comparative Absorption/Adsorption of SaniPure™ 6o Tubing vs. Silicone Tubing

Test Methods Used: Drug preservatives were analyzed by gas chromatography after 72 hours of contact with each tubing.



Sterilization Methods

Autoclavable	Yes
Gas (Ethylene Oxide)	Yes
Radiation (Up to 5.0 MRad)	Yes

BIOPHARMACEUTICAL PRODUCTS

Come through clean.™

Saint-Gobain Performance Plastics

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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.

Saint-Gobain Performance Plastics Corporation assumes no obligations or liability for any advice furnished by it, or for results obtained with respect to those products. All such advice is given and accepted at the buyer's risk.

SaniPure™ 6o Typical Physical Properties

Property	ASTM Method	Value or Rating
Durometer Hardness Shore A, 15 Sec	D2240-02	60
Tensile Strength psi (MPa)	D412-98	1,630 (11.2)
Ultimate Elongation, %	D412-98	770
Tear Resistance lb-f/inch (kN/m)	D1004-94 Die C	190 (33.3)
Compression Set Constant Deflection, % @ 158°F (70°C) for 22 hrs.	D395-01 Method B	55
Brittle Temperature @ °F (°C)	D746-98	-87 (-66)
Specific Gravity	D792-00	0.90
Water Absorption, % 24 hrs. @ 73°F (23°C)	D570-98	0.07
Maximum Recommended Temp., °F (°C)	—	275 (135)
Color	—	Clear
Dielectric Strength v/mil (kV/mm)	D149-97	550 (21.6)
Tensile Modulus @ 300% psi (MPa)	D412-98	555 (3.83)
Tensile Set, % (@75% of ultimate elongation)	D412-98	100
Low Temp. Flexibility, -40°F (-40°C)	D380-94	Passed (still flexible)

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.

Product Approvals

USP Class VI	Yes
European Pharmacopoeia 3.2.9	Yes
FDA Approved for Food Contact	Yes

Distributed By:

SANI-PURE™ 6o TUBING IS NOT INTENDED FOR USE AS AN IMPLANT MATERIAL

SaniPure™ is a trademark.

