Pharma-Line™ I Series

Thermoplastic peristaltic Pump Tubing



Manufactured from biocompatible thermoplastic and extruded to precise dimensional tolerances, our Pharma-Line™ I tubing was developed to be compatible with all major peristaltic pumps. Pharma-Line™ I provides an excellent alternative to silicone tubing when resistance to chemicals (such as acetone or methylene chloride) is a concern.

- ISO Class 7 cleanroom manufacturing
- Standard and custom sizes available
- Manufactured for pharmaceutical and biopharmaceutical applications

Key Features

- Thermoplastic vulcanite (TPV)
- Opaque
- Excellent Pump Performance
- Good Chemical Resistance
- Tasteless, odorless
- Contains no phthalate plasticizers or peroxides that can leach out into process fluid
- Sterilization Methods: autoclave, gamma irradiation, and chemical sterilants
- Hardness: durometer 70 Shore A
- Packaging: Double bagged
- Working Low Temperature Range:* -80°F (-62°C)
  Working High Temperature Range: 275°F (135°C)

  *Embrittlement Temperature

Applications

- Peristaltic Pumps
- Pinch Valves
- Filling
- Bioreactor process lines
- Fluid transfer
- Diagnostics and laboratory testing
- Single use assemblies

Compliance

- US Pharmacopeia 43, National Formulary 38 (USP), General Chapter <88> Class VI Biological Reactivity Tests, In Vivo (2020)
- ISO 10993 (various parts)
- USP 661.2
- Request our comprehensive extractables and biocompatibility study for this product: sanisure.com/resources

Physical	Typical Values
Specific Gravity	0.952
Hardness (Shore A, at 10 Sec.)	70
Tensile Stress	-
Across Flow: 100% Strain	365 psi
Flow: 100% Strain, 70°F	540 psi
Tensile Strength	-
Across Flow: 100% Strain,	588 psi
Flow: 100% Strain, 73°F	697 psi
Tensile Elongation	290%
Across Flow: Break 73°F	290%
Flow: Break 73°F	240%
Compression Set %	-
72°F, 22.0 Hours	17%
158°F, 22.0 Hours	58%
212°F, 22.0 Hours	69%

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Regulatory Testing

Biocompatibility USP <87> and USP <88>*	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <87> • USP <88>
Biocompatibility Cont. (ISO 10993 and USP Class VI)*	A Representative sample of the compound used to manufacture this product has been tested according to ISO 10993 and USP Class VI testing requirements. The sample met the requirements of the following tests: • Systemic Injection Test (USP Class VI and ISO 10993) • Intracutaneous Toxicity Test (USP Class VI and ISO 10993) • Intramuscular Implantation Test (USP Class VI and ISO 10993) • Agar Diffusion (ISO 10993-5) • L929 MEM Elution (ISO 10993-5) • Hemolysis-Rabbit Blood (ISO 10993-4)
Extractables - USP*	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP<665> • USP <661.2>
Endotoxin Testing*	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <85>
Particulate Testing*	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • USP <788>

*The assessment is available upon request at https://sanisure.com/resources/

Presence of Substance

Based on the information provided to SaniSure by its raw material suppliers, we have found that the material listed above does not intentionally contain the following substances:

- Bisphenol A (BPA)
- Latex / Natural Rubber Latex / Natural Rubber
- Melamine
- N-Nitrosamines
- Phthalates
- According to the raw material supplier, there may be a trace residual amount of phthalate(s) from the olefin component(s) utilized in this compound, which would be an impurity left from the catalytic system.
- Polyvinyl chloride (PVC)
- Slip Agents

Regulatory Compliances

Based on the information made available to us by our raw material supplier, the above material is compliant to the below list of regulatory requirements.

- RoHS Compliant
- REACH Compliant
- Conflict Minerals
- California Proposition 65
- ICH Q3D Elemental Impurities

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Animal Derivatives, Plant Derivatives, BSE/TSE Statement*

The product listed above does contain a tallow derived substance. The tallow derived raw material used in the manufacture of our product is in compliance with the Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3) because the processing exceeds the following condition from section 6.4 of the note: transesterification or hydrolysis at not less than 200 °C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production), therefore presents minimal or no risk of transmitting BSE/TSE. Please note we do not routinely test for these materials. Our information is based on data provided by our suppliers.

Genetically Modified Organisms (GMO's)

GMO's may be present in the product listed above as a result of specific characteristics of the raw materials utilized by SaniSure's supplier and/or of their manufacturing process(es).

Allergens

Based on the information provided to SaniSure by its raw material suppliers, we have found that the material listed above does not intentionally contain any known sources of the following Allergens:

- Milk
- Eggs
- Fish
- Crustacean shellfish
- tree nuts (e.g., almonds, pecans, or walnuts)
- wheat
- peanuts and soybeans
- celery
- cottonseed
- gluten including grain (i.e. cereals)
- legumes
- lupin
- mollusks
- monosodium glutamate (MSG)
- mustard
- poppy seeds
- sesame seeds
- sodium metabisulfite
- sulfites
- sulfur dioxide
- sunflower seeds.

Note: SaniSure has been notified by our raw material supplier that at least one component may contain a soybean source. SaniSure does not intentionally add or use these substances in the manufacturing process of this product(s).

*Please note that the information provided is based on best available knowledge; we do not test for the presence of trace amounts of substances that may be introduced our products as contaminants. We do not routinely analyze our products for the presence of the above reportable substances; however, based on information provided by our supplier and to the best of our knowledge, the above material is free from animal derivatives.

Manufacturing Standard

The above material is manufactured in an ISO 9001:2015 accredited facility. This product is manufactured in an unclassified, controlled environment.

Dimensional Tolerance

Inside and outside diameter tolerances are maintained to RMA E1 tolerances.

Sterilization

Gamma Irradiation:

The recommended maximum dosage for gamma irradiation of the above product is 50 kGy. When required of SaniSure, the standard range for gamma irradiation of products is between 27.5 and 45 kGy.

Autoclave:

The above product is generally compatible with autoclave sterilization. Please note that users must validate their sterilization conditions and procedure to ensure this product is suitable for a particular application.

Shelf Life and Storage Conditions

If stored according to the following recommendations, SaniSure recommends that customers dispose of this product after seven (7) years from the date of manufacturing. Store this product in an ambient temperature and humidity environment. The product should be free from exposure to direct outside weather influences and stored in a dark space out of direct contact with light. The area should be free from volatile solvents, corrosive gases, or other potentially harmful vapors. Stack the product flat in an opaque container during storage. The container should be kept off the floor (e.g., on shelving or skids) and remain closed and sealed while in storage. The product should be free of kinking and not be subjected to crushing forces from the weight of the product above it.

SaniSure makes no representations or warranties as to the accuracy of the information contained or referenced herein. Most results mentioned above are based on single lots of material. Although a lot-to-lot variance would not be expected to show different results, this data should not be construed as a warranty of fitness for use. Prior to use for any application, the user has the sole responsibility for determining the suitability of these products in any application. Based on the information made available to us by our material suppliers, Perfluoroalkoxy (PFA) in the form of finished articles is not expected to emit or release chemicals under normal circumstances and is therefore exempt from REACH registration.

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Sizing Chart Standard Offerings

Part Number	Pump Size	ID		OD		Wall Thickness		Working Pressure (psi)	Burst Pressure (psi)	Vacuum Rating (hg)	Bend Radius(in)
		(inch)	(mm)	(inch)	(mm)	(inch)	(mm)				
PHI-031X093-50		0.031	0.8	0.093	2.4	0.031	0.8	51.7	155.2		
PHI-031X156-50	13	0.031	0.8	0.156	4.0	0.062	1.6	69.2	207.5	29.5	0.25
PHI-062X125-50		0.062	1.6	0.125	3.2	0.031	0.8	34.9	104.6		0.5
PHI-062X187-50	14	0.062	1.6	0.187	4.7	0.062	1.6	51.3	153.9	29.5	0.25
PHI-062X250-50	120	0.062	1.6	0.250	6.4	0.094	2.4	61.8	185.4	29.5	0.5
PHI-093X218-50		0.093	2.4	0.218	5.5	0.062	1.6	41.6	124.7	29.5	0.75
PHI-125X187-50		0.125	3.2	0.187	4.7	0.031	0.8	20.6	61.7		0.5
PHI-125X250-50	16	0.125	3.2	0.250	6.4	0.062	1.6	34.5	103.5	29.5	1
PHI-125X312-50	120	0.125	3.2	0.312	7.9	0.094	2.4	44.4	133.2	29.5	1
PHI-125X500-50		0.125	3.2	0.500	12.7	0.188	4.8	62.1	186.2		2.25
PHI-187X312-50		0.187	4.7	0.312	7.9	0.062	1.6	25.9	77.7	29.5	1.75
PHI-187X375-50	15	0.187	4.7	0.375	9.5	0.094	2.4	34.6	103.8	29.5	1.25
PHI-187X437-50		0.187	4.7	0.437	11.1	0.094	2.4	41.4	124.3	29.5	2.75
PHI-250X375-50		0.250	6.4	0.375	9.5	0.062	1.6	20.7	62.1	25	2.5
PHI-250X437-50	24	0.250	6.4	0.437	11.1	0.094	2.4	28.2	84.5	29.5	
PHI-250X500-50	26	0.250	6.4	0.500	12.7	0.125	3.2	34.5	103.5	29.5	3.25
PHI-312X437-50	18	0.312	7.9	0.437	11.1	0.062	1.6	17.1	51.3	5	2.25
PHI-312X500-50	35	0.312	7.9	0.500	12.7	0.094	2.4	23.8	71.4	29.5	
PHI-375X500-50		0.375	9.5	0.500	12.7	0.062	1.6				
PHI-375X562-50	36	0.375	9.5	0.562	14.3	0.094	2.4	20.6	61.9	15	2.75
PHI-375X625-50	73	0.375	9.5	0.625	15.9	0.125	3.2	25.9	77.6	29.5	4
PHI-375X750-50		0.375	9.5	0.750	19.1	0.187	4.7				4
PHI-500X750-50	82	0.500	12.7	0.750	19.1	0.125	3.2	20.7	62.1	15	5.5
PHI-500X875-50		0.500	12.7	0.875	22.2	0.187	4.7	28.2	84.6	29.5	
PHI-625X875-50	184	0.625	15.9	0.875	22.2	0.125	3.2	17.2	51.7	15	5.25
PHI-625X1000-50	88	0.625	15.9	1.000	25.4	0.185	4.7	23.9	71.6	29.5	9.75
PHI-750X1000-50		0.750	19.1	0.750	19.1	0.125	3.2	14.8	44.3		
PHI-750X1062-50		0.750	19.1	0.750	19.1	0.156	4.0	17.8	53.4		
PHI-750X1125-50	90	0.750	19.1	0.625	15.9	0.187	4.7	20.7	62.1	0	
PHI-750X1250-50		0.750	19.1	0.875	22.2	0.250	6.4	25.9	77.6		
PHI-1000X1250-50		1.000	25.4	1.250	31.8	0.125	3.2				
PHI-1000X1375-50	92	1.000	25.4	1.370	34.8	0.187	4.7	16.3	49	0	
PHI-3MMx7MM-50			3		7		2				
PHI-6MMx12MM-50			6		12		3				
PHI-8MMx16MM-50			8		16		4				
PH|10MMx17MM-50			10		17		3.5				

NOTE: Standard coil length is 50 feet. Other length and spools available, consult factory.

Custom sizes available

Vacuum Rating
Note: Testing conducted on tubing maintained in a straight configuration (no bends) at a standard laboratory temperature of 23°C, in accordance with ISO 7233 Method A.

Bend Radius:
Note: Testing conducted at standard laboratory temperature of 23°C, in accordance with ISO 10619-1 Method A1.

Burst
Note: Tested at 23°C Temp

Tubing has printing
Also available with no print upon request

Please contact our quality department for the most up-to-date regulatory information. Specifications in this document are subject to change without notice.

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