PLTS-Q50 BioPh Silicone Tubing

SaniSure's PLTS-Q50 was developed as a more affordable platinum silicone tubing for Single Use applications. With a shore A of 50 it is softer and compliant and works well with bulk transfer and general pumping applications.

- ISO Class 7 clean room manufacturing
- Standard and customer sizes available
- Manufactured for pharmaceutical and biomedical applications

Key Features

- Platinum cured Silicone
- Translucent(Good Clarity)
- Hardness: durometer 50 Shore A
- Tasteless, odorless, noncytotoxic and nonhemolytic
- Contains no phthalate plasticizers or peroxides that can leach out into transported fluid
- Low-binding surface minimizes absorption of proteins and food products
- Sterilization Methods: autoclave, gamma radiation, EtO, and chemical sterilants
- Working Low Temperature Range: -100°F (-73.3°C)
- Working High Temperature Range: 400°F (204.4°C)

Compliance

- U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <88> Class VI, Biological Reactivity Tests, In Vivo (2020)
- U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <87> Class VI, Biological Reactivity Tests, In Vivo (2020)
- ISO 10993 (various parts)
- Request our comprehensive extractables and biocompatibility study for this product: sanisure.com/resources

Applications

- Single Use
- Transfer Lines
- Cell media processing
- Bioreactor process lines
- Production filtration and fermentation
- Diagnostics and laboratory testing

Physical	Typical Values
Shore A Hardness	50
Tensile (PSI)	1232 (Min.)
Elongation (%)	450 (Min.)
Tear Strength* PPI	171 (Min.)

PLTS-Q50 BioPh Silicone Tubing

Regulatory Testing

Biocompatibility (USP 87 and USP 88)[2]	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)[1]	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) • Sensitization (Kligman Maximization) (ISO 10993-10) • Mutagenicity (Ames Assay) (ISO 10993-3
Extractables - USP[2]	Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below: • BPOG • USP 661.2

[1]The biocompatibility information listed in this section is based on information provided by our compound source. Testing is based on single lots, although lot-to-lot variance would not be expected to show different results.

[2]The assessment is available upon request at https://sanisure.com/get-report/

Manufacturing Standard

The above material is manufactured in an ISO 9001:2015 accredited facility. Furthermore, this product is manufactured in an ISO 14644-1 Class 7 cleanroom.

Dimensional Tolerance

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

Presence of Substance

Based on the information made available to SaniSure by its material supplier, none of the following compounds are intentionally added in as a 'raw material' or as a 'process aid' to the above product:

• Bisphenol A (BPA)
• Melamine
• Latex
• N-Nitrosamines
• Phthalates
• Slip Agents

European Union REACH Directive Substances of Very High Concern (SVHC)

The above product is known to contain the below SVHC in the listed quantities. This information is based on the EU REACH list as of June 08, 2021. (219 substances)

Chemical Name	CAS-No	Concentration
Dodecamethylcyclohexasiloxane	540-97-6	≤0,223%
Decamethylcyclopentasiloxane	541-02-6	≤0,22%
Octamethylcyclotetrasiloxane	556-67-2	≤0,19%

PLTS-Q50 BioPh Silicone Tubing

Animal Derivatives, Plant Derivatives, BSE/TSE Statement*

This product line is formulated from entirely synthetic ingredients; therefore, these polymers contain no animal byproducts, no substances of animal origin, nor are the polymers derived from specified risk materials for BSE/TSE.

Genetically Modified Organisms (GMO)
This product is not manufactured with any genetically modified organisms (GMO'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.

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 25 and 40 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. Below are some examples of common autoclave conditions:

- 30 minutes at 121C (250F)
- 10 minutes at 132C (270F)

Shelf Life and Storage Conditions

If stored according to the following recommendations, SaniSure recommends that customers dispose of this product after eight (8) years from the date of manufacturing. Store this product in a dry inside environment with a target ambient temperature of 77°F and humidity of less than 65%. 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.

PLTS-Q50 BioPh Silicone Tubing

Sizing Chart

Part Number	Pump Size	ID		OD		Wall Thickness	
		(inch)	(mm)	(inch)	(mm)	(inch)	(mm)
PLTS-Q50-062x187	N/A	0.062	1.5	0.187	4.7	0.062	1.587
PLTS-Q50-093x218	N/A	0.093	2.3	0.218	5.5	0.062	1.587
PLTS-Q50-093x281	N/A	0.093	2.3	0.281	7.1	0.094	2.387
PLTS-Q50-125x250	N/A	0.125	3.1	0.25	6.3	0.062	1.587
PLTS-Q50-125x312	N/A	0.125	3.1	0.312	7.9	0.093	2.373
PLTS-Q50-187x312	N/A	0.187	4.7	0.312	7.9	0.062	1.587
PLTS-Q50-187x375	N/A	0.187	4.7	0.375	9.5	0.094	2.387
PLTS-Q50-250x375	N/A	0.25	6.3	0.375	9.5	0.062	1.587
PLTS-Q50-250x437	N/A	0.25	6.3	0.437	11.	0.093	2.373
PLTS-Q50-250x500	N/A	0.25	6.3	0.5	12.7	0.125	3.175
PLTS-Q50-312x437	N/A	0.312	7.9	0.437	11.10	0.093	2.373
PLTS-Q50-312x500	N/A	0.312	7.9	0.5	12.7	0.125	3.175
PLTS-Q50-312x562	N/A	0.312	7.9	0.562	14.27	0.125	3.175
PLTS-Q50-375x500	N/A	0.375	9.5	0.5	12.7	0.094	2.387
PLTS-Q50-375x562	N/A	0.375	9.5	0.562	14.27	0.125	3.175
PLTS-Q50-375x625	N/A	0.375	9.5	0.625	15.88	0.125	3.175
PLTS-Q50-500x687	N/A	0.5	12.7	0.687	17.46	0.156	3.962
PLTS-Q50-500x750	N/A	0.5	12.7	0.75	19.05	0.125	3.175
PLTS-Q50-625x875	N/A	0.625	15.8	0.875	22.2	0.062	1.587
PLTS-Q50-750x1000	N/A	0.75	19.0	1	25.4	0.062	1.587
PLTS-Q50-750x1125	N/A	0.75	19.0	1.125	28.5	0.062	1.587
PLTS-Q50-875x1125	N/A	0.875	22.2	1.125	28.5	0.062	1.587
PLTS-Q50-875x1250	N/A	0.875	22.2	1.25	31.7	0.187	4.762
PLTS-Q50-1000x1250	N/A	1	25.4	1.25	31.7	0.187	4.762
PLTS-Q50-1000x1375	N/A	1	25.4	1.375	34.9	0.187	4.762

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

Tubing has no printing

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

Authorized Distributor

CLEAR SOLUTIONS, INC.

970 Calle Negocio
San Clemente, CA 92673
info@clearsolutionscorp.com
(949) 429-8922
clearsolutionscorp.com

Sparta SaniSure®, Inc.

18 White Lake Road
Sparta, NJ 0787
New York, USA
+1 (805) 920.7264
SalesSupport-US@sanisure.com

Stapleford SaniSure®, Ltd.

49 Pasture Road
Stapleford, Nottingham
UK NG9 8HR, United Kingdom
+352 2633731
SalesSupport-US@sanisure.com

sanisure.com

SANISURE®
Solution Based Innovation

Specifications subject to change without notice. Copyright SaniSure GmbH. DE, Version 01