

PLTS-LH Platinum-Cured Silicone Tubing Regulatory Statement

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 Tolerances

Inside and outside diameter tolerances are maintained to RMA E1 tolerances. Overall length tolerance is maintained to +6in. (min.) / -0 in.

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 – USP²**

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

- **Extractables - FDA Food Contact¹**

Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:

- FDA 21 CFR 177.2600

- **Endotoxin Testing²**

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 Testing²**

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

¹The 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.

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

Presence of Substances

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

Restriction of Hazardous Substances (RoHS)

Polybrominated Diphenylethers (PBDEs), Polybrominated Biphenyls (PBBs), lead, mercury, hexavalent chromium, or cadmium are neither used as raw materials nor intentionally added to the SaniSure product listed above. Thus, we believe that this product meets Directive 2002/95/EC ("RoHS"), as amended by Commission Decision 2005/618/EC.

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%

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:

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. If you have any questions concerning this document or if we can be of further assistance, please do not hesitate to contact us. Please do not hesitate to contact our quality department at quality.nj@sanisure.com or 973.383.2834 for more information.

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