

SILASTIC® Laboratory Tubing

FEATURES

- Excellent flexibility
- Stability over a wide temperature range
- High resiliency
- No imparted taste or odor
- No added organic plasticizers, phthalates or latex additives
- Easily sterilized
- Unwetttable (hydrophobic)
- Exceeds USP Class VI Biological Reactivity Tests
- Manufactured to the principles of FDA 21 CFR 210/211 GMPs for active pharmaceutical ingredients
- Produced in an FDA-registered (CFN 1816403) and inspected healthcare facility
- No peroxide by-products

BENEFITS

- Complete traceability
- Ease of use
- Consistent performance
- Rigid change control

COMPOSITION

- Platinum-cured silicone tubing

Multipurpose translucent silicone tubing

APPLICATIONS

- SILASTIC® Laboratory Tubing is recommended for any application that requires the transfer of high purity fluids or applications requiring a highly flexible, temperature-resistant tubing.

TYPICAL PROPERTIES

Specification writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales representative prior to writing specifications on this product.

CTM ¹	ASTM	Test	Unit	Result	
				7-5224 Cat #508	7-5225 Cat #515
0099	D2240	Durometer hardness, Shore A ²		55	48
0137A	D412	Tensile strength at break, die D ³	psi	1230	1085
			MPa	8.5	7.5
0137A	D412	Elongation at break, die D ³	%	590	511
0159A	D624	Tear strength, die B ²	ppi	144	103
			kN/m	25.2	18

1. CTM: Corporate Test Method, copies of CTMs are available on request.

ASTM: American Society for Testing and Materials.

2. Typical properties for the elastomers.

3. Typical properties of the extruded tubing.

DESCRIPTION

SILASTIC Laboratory Tubing is a translucent silicone tubing made from a highly tear-resistant platinum-cured elastomer. It is recommended for multi-purpose use when fluid contamination is a concern. Use for process transfer of pharmaceutical fluids, intermediates, air, steam, water, food or beverages.

SILASTIC Laboratory Tubing is an excellent choice for many high purity fluid processing or general analytical applications.

REGULATORY STATUS

SILASTIC Laboratory Tubing is manufactured from SILASTIC® Brand Silicone Elastomers and has been tested using protocols that meet or exceed USP Biological Reactivity Tests <87> and <88>. The tubing meets the requirements of FDA 21 CFR 177.2600 and selected Dairy 3A Sanitary Standards.

HANDLING PRECAUTIONS

Product safety information required for safe use is not included. Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information. The material safety data sheet is available on the Dow Corning website at www.dowcorning.com. You can also obtain a copy from your local Dow Corning sales representative or Distributor or by calling your local Dow Corning Global Connection.

USABLE LIFE AND STORAGE

When stored at or below ambient temperature in the original unopened containers, this product has a usable life of 36 months from the date of production.

STANDARD SIZES AND PACKAGING

To better serve our customers, SILASTIC Laboratory Tubing is available in many commonly used sizes (see: Table 1).

Standard packaging for SILASTIC Laboratory Tubing is a 15-meter (50-foot) coil, packed in a sealed plastic bag and individually boxed.

LIMITATIONS

This product has not been tested or approved for any hospital or patient care use such as for temporary insertion or any *in vivo* procedures.

This product is not to be used in human implantation, or human contraceptive, reproductive, obstetrical or gynecological applications. The user shall hold Dow Corning harmless from any and all damages resulting from use of this product. It is the sole responsibility of the user to determine the safety and efficacy of this product for any specific use.

MANUFACTURING ENVIRONMENT

SILASTIC Laboratory Tubing is manufactured under strict quality control guidelines. The Healthcare Industries Materials Site (HIMS) in Hemlock, Michigan, is dedicated to the production of silicone materials for healthcare applications. It is registered with the U.S. Food and Drug Administration (FDA) as a Drug Establishment (CFN 1816403). The site quality system is based on principles of current Good Manufacturing Practices for both Active Pharmaceutical Ingredients and Medical Devices. The site has been ISO 9001-registered with BSI since 1990.

QUALITY ASSURANCE

Dow Corning manufactures SILASTIC Laboratory Tubing in a totally integrated process from raw materials to the final extruded tubing. The tubing is manufactured in an ISO 9001-registered facility, ensuring full documentation and traceability. Critical properties are controlled throughout the complete manufacturing process, ensuring quality of the raw materials, the elastomer, and the finished tubing.

STERILIZATION

CONSIDERATIONS

It is the user's responsibility to validate a sterilization process for silicone tubing. The user should conduct testing if sterilization conditions vary and/or if minor property changes could affect application performance. Common sterilization procedures include:

Autoclave (Steam Sterilization)

Silicone tubing can be effectively sterilized by steam in an autoclave. Silicone materials are more difficult to heat than materials such as thermoplastics because they have thermal insulating properties. Steam sterilization has been accomplished in a standard gravity steam sterilization cycle (30 minutes at 15psi and 121°C/250°F) and in a high-speed flash steam sterilization cycle (15 minutes at 30psi and 132°C/270°F).

Gamma Radiation Sterilization

Gamma radiation studies of the effects on the physical properties of the silicone elastomer used to produce SILASTIC Laboratory Tubing have shown that doses of radiation up to 2.5 Mrad (25kGy) do not adversely affect durometer, elongation, modulus, tensile or tear strength. Repeated gamma sterilization or processing at higher doses of radiation and for longer dosing periods may change some of the physical properties of the elastomer. Testing should be conducted by the user if sterilization conditions vary and if minor property changes could affect application performance.

Ethylene Oxide Sterilization

Ethylene oxide (ETO) has been used to sterilize SILASTIC Laboratory Tubing with no degradation of physical properties. Sterilization by this method is only recommended if procedures allow sufficient time for complete out-gassing of residual ETO and ETO by-products.

ORDERING

SILASTIC Laboratory Tubing is available through many pharmaceutical or laboratory supply distributors. For distributor information, please contact Dow Corning at
+1 800 248 2481 or +1 989 496 6000 (North America),
+44 1676 528 000 (Europe & Middle East),
+81 3 3287 8300 (Asia),
+55 19 3887 9797 (South America)
or consult www.dowcorning.com.

HEALTH AND ENVIRONMENTAL INFORMATION

To support Customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our website, www.dowcorning.com or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION - PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customers' tests to ensure that Dow Corning's products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that the product will meet the Dow Corning sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

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Table 1: Standard sizes and tolerances. Values stated are typical values only and are not intended for writing specifications.

<i>Standard sizes and tolerances</i>						
<i>SILASTIC Laboratory Tubing (Cat #508)</i>						
Metric (mm)				Imperial (inches)		
Catalog number	Inside diameter	Outside diameter	Wall	Inside diameter	Outside diameter	Wall
508-001	0.30 ± 0.08	0.64 ± 0.08	0.15	0.012 ± 0.003	0.025 ± 0.003	0.006
508-002	0.51 ± 0.13	0.94 ± 0.13	0.20	0.020 ± 0.005	0.037 ± 0.005	0.008
508-003	0.64 ± 0.13	1.19 ± 0.13	0.28	0.025 ± 0.005	0.047 ± 0.005	0.011
508-004	0.76 ± 0.15	1.65 ± 0.15	0.46	0.030 ± 0.006	0.065 ± 0.006	0.018
508-005	1.02 ± 0.18	2.16 ± 0.18	0.56	0.040 ± 0.007	0.085 ± 0.007	0.022
508-006	1.47 ± 0.20	1.96 ± 0.20	0.25	0.058 ± 0.008	0.077 ± 0.008	0.01
508-007	1.57 ± 0.23	2.41 ± 0.23	0.41	0.062 ± 0.009	0.095 ± 0.009	0.016
508-008	1.57 ± 0.23	3.18 ± 0.23	0.81	0.062 ± 0.009	0.125 ± 0.009	0.032
508-009	1.98 ± 0.25	3.18 ± 0.25	0.61	0.078 ± 0.010	0.125 ± 0.010	0.024
508-010	2.64 ± 0.28	4.88 ± 0.28	1.12	0.104 ± 0.011	0.192 ± 0.011	0.044
508-011	3.35 ± 0.30	4.65 ± 0.30	0.66	0.132 ± 0.012	0.183 ± 0.012	0.026

<i>Standard sizes and tolerances</i>						
<i>SILASTIC Laboratory Tubing (Cat #515)</i>						
Metric (mm)				Imperial (inches)		
Catalog number	Inside diameter	Outside diameter	Wall	Inside diameter	Outside diameter	Wall
515-012	3.18 ± 0.30	6.35	1.59 ± 0.15	0.125 ± 0.012	0.25	0.0625 ± 0.006
515-013	4.78 ± 0.38	7.92	1.59 ± 0.15	0.188 ± 0.015	0.312	0.0625 ± 0.006
515-014	4.78 ± 0.38	9.53	2.38 ± 0.23	0.188 ± 0.015	0.375	0.0937 ± 0.009
515-015	6.35 ± 0.43	9.53	1.59 ± 0.15	0.25 ± 0.017	0.375	0.0625 ± 0.006
515-016	6.35 ± 0.43	11.13	2.38 ± 0.23	0.25 ± 0.017	0.438	0.0937 ± 0.009
515-017	6.35 ± 0.43	12.70	3.18 ± 0.30	0.25 ± 0.017	0.5	0.125 ± 0.012
515-018	7.92 ± 0.48	12.70	2.38 ± 0.23	0.312 ± 0.019	0.5	0.0937 ± 0.009
515-019	9.53 ± 0.53	12.70	1.59 ± 0.15	0.375 ± 0.021	0.5	0.0625 ± 0.006
515-020	9.53 ± 0.53	14.30	2.38 ± 0.23	0.375 ± 0.021	0.563	0.0937 ± 0.009
515-021	9.53 ± 0.53	15.88	3.18 ± 0.30	0.375 ± 0.021	0.625	0.125 ± 0.012
515-022	12.70 ± 0.64	17.48	2.38 ± 0.23	0.5 ± 0.025	0.688	0.0937 ± 0.009
515-023	12.70 ± 0.64	19.05	3.18 ± 0.30	0.5 ± 0.025	0.75	0.125 ± 0.012
515-024	15.88 ± 0.74	22.23	3.18 ± 0.30	0.625 ± 0.029	0.875	0.125 ± 0.012