

***Dow Corning*[®] Pharma-65 Reinforced Tubing**

FEATURES & BENEFITS

- Reinforced for improved burst strength
- Resistant to collapse under vacuum
- Kink-resistant
- Excellent flexibility
- Low extractables
- Contains no peroxide by-products, chlorophenyls or PCBs
- Contains no organic plasticizers, phthalates or latex additives
- Easily sterilized
- Stable over a wide temperature range
- No imparted taste or odor
- Non-wetting (hydrophobic) surface
- Made from *Silastic*[®] BioMedical Grade elastomer that exceeds United States Pharmacopeia (USP[®]) Class VI Plastics Test requirements
- Meets European Pharmacopoeia monograph 3.1.9. "Silicone elastomer for closures and tubing"
- Manufactured to the principles of applicable cGMPs
- Reduces risk of contaminating ultra-pure liquids
- Complete traceability
- Consistent performance
- Rigorous change control
- Integrated supply chain

COMPOSITION

- Platinum-cured silicone tubing containing Dacron[®] (polyester) fiber reinforcement

Fiber-reinforced pharmaceutical grade silicone tubing for high-pressure gas, steam or liquid transfer, in pharmaceutical and biotechnological manufacturing processes

APPLICATIONS

- *Dow Corning*[®] Pharma-65 Reinforced Tubing is designed for applications that require the transfer of high purity fluids where contamination is a concern. It is designed for applications where kinking may be encountered, such as processes using tubing of short bend radius.

TYPICAL PROPERTIES

Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

CTM ¹	ASTM ²	Property	Unit	Result
0099	D2240	Durometer hardness, Shore A ³		65
0137A	D412	Tensile strength at break, die C ³	MPa	7.94
			psi	1151
0137A	D412	Elongation at break, die C ³	%	890
0159A	D624	Tear strength, die B ³	kN/m	45.5
			ppi	260
		Fiber Dacron [®] Polyester Yarn ⁴		192 filament T68, low shrinkage
		Breaking force ⁴	N	97
			lbf	22
		Elongation at break ⁴	%	17

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

²ASTM: American Society for Testing and Materials.

³Typical Properties for the elastomer.

⁴Information obtained from fiber manufacturer.

DESCRIPTION

Dow Corning Pharma-65 Reinforced Tubing is the solution for transferring high purity gases or liquids under pressure (see Table I for typical Burst properties). It is a translucent silicone tubing containing a fiber braid that does not contact material on the tubing surface or within the lumen. The silicone component is a tear-resistant *Silastic*[®] BioMedical Grade platinum-

cured elastomer reinforced for added strength with 2-ply Dacron[®] fiber braid.

It is designed for use in pharmaceutical and biotechnological manufacturing processes. *Dow Corning* Pharma-65 Reinforced Tubing has a low extractables profile, which guards against contamination.

REGULATORY STATUS

Dow Corning Pharma-65

Reinforced Tubing is manufactured using *Silastic* BioMedical Grade silicone elastomer that meet or exceed the test requirements of USP Class VI Plastics (87) and (88).

Dow Corning Pharma-65

Reinforced Tubing meets the requirements of 21 CFR 177.2600 and USP (661) (Physico-chemical Tests - Plastics), and its elastomer stock complies with selected 3-A Sanitary Standards. The tubing meets the requirements of European Pharmacopoeia (Ph. Eur. or "EP") 3.1.9. "Silicone elastomer for closures and tubing."

To support use in validated processes, contact Dow Corning to obtain a Qualifications Guide for *Dow Corning Pharma Tubing*. This manual summarizes key tubing performance and regulatory data.

MANUFACTURING ENVIRONMENT

Dow Corning Pharma-65 Reinforced Tubing is manufactured under quality control guidelines. The tubing manufacturing facilities are registered with the U.S. Food and Drug Administration (FDA) and operate under a quality system based on principles of applicable current Good Manufacturing Practices.

QUALITY ASSURANCE

Dow Corning Pharma-65 Reinforced Tubing is manufactured in ISO 9001- and FDA-registered facilities, requiring appropriate documentation and traceability. Critical properties are controlled throughout the manufacturing process, to provide quality of the raw materials, elastomer and finished tubing.

STERILIZATION CONSIDERATIONS

It is the user's responsibility to validate a sterilization process for fiber-reinforced 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 (121°C/250°F minutes at 1 bar/2 psi and 132°C/270°F) and in a high-speed flash steam sterilization cycle (15 minutes at 2 bar/30 psi and 132°C/270°F).

Gamma Radiation Sterilization

Gamma irradiation studies on *Dow Corning Pharma Tubing* products have shown that doses of gamma irradiation up to 5 Mrad (50 kGy) minimally affect the physical properties (durometer, elongation, modulus, tensile, tear strength) and extractables profile of the tubing.

Ethylene Oxide Sterilization

Ethylene oxide (ETO) has been used to sterilize silicone 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.

HANDLING

PRECAUTIONS

PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT AND MATERIAL 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 DOWCORNING.COM, OR FROM

YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.

USABLE LIFE AND STORAGE

When stored in the original unopened containers, *Dow Corning Pharma-65 Reinforced Tubing* has a usable life of 36 months from the date of production.

PACKAGING INFORMATION

To serve our customers better, Dow Corning has selected the most commonly used sizes shown for *Dow Corning Pharma-65 Reinforced Tubing* (see Table 1). The standard package is a cardboard box containing a 7.62-meter (25-foot) coil, double-bagged in separately sealed polyethylene bags.

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.

ORDERING

Dow Corning Pharma-65 Reinforced Tubing is available direct from Dow Corning. For ordering information, or to discuss specific requirements, please contact Dow Corning at 1-800-248-2481 (USA) or +44-(0)1676-528000 (Europe & Middle East) or consult 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, 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 customer’s tests to ensure that our 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 our products will meet the 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.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY

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Table 1: Common Tubing Product Sizes and Burst Pressure Performance. Values stated are typical values only and are not intended for writing specifications. The user is responsible for validating the suitability of Dow Corning Pharma-65 Reinforced Tubing for their process.

Imperial (inches)				Metric (mm)			
<i>Inside Diameter</i>	<i>Outside Diameter</i>	<i>Wall</i>	<i>Burst* psi</i>	<i>Inside Diameter</i>	<i>Outside Diameter</i>	<i>Wall</i>	<i>Burst* bar</i>
0.125	0.365	0.120	893	3.175	9.271	3.048	61.6
0.187	0.447	0.130	787	4.749	11.353	3.302	54.3
0.250	0.520	0.135	837	6.350	13.208	3.429	57.7
0.312	0.592	0.140	629	7.924	15.036	3.556	43.4
0.375	0.655	0.140	597	9.525	16.637	3.556	41.2
0.500	0.800	0.150	546	12.700	20.320	3.810	37.7
0.625	0.965	0.170	470	15.875	24.511	4.318	32.4
0.750	1.100	0.175	310	19.050	27.940	4.445	21.4
0.875	1.235	0.180	308	22.225	31.369	4.572	21.4
1.000	1.360	0.180	208	25.400	34.544	4.572	14.3

*Test method described in Dow Corning Form 52-1047-01, Burst Strength Testing of Dow Corning® Pharma Tubings.