

***Dow Corning*[®] Pharma Advanced Pump Tubing**

FEATURES & BENEFITS

- Up to four times the pump life of standard platinum cured silicone tubing
- Excellent flexibility
- High resiliency
- Low extractables
- Contains no organic plasticizers, phthalates or latex additives
- No peroxide by-products, chlorophenyls or PCBs
- Easily sterilized
- 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 FDA 21 CFR 210/211 cGMPs for Pharmaceutical products
- Produced in a FDA registered (CFN 1816403) and inspected healthcare facility
- Added pump life can reduce material usage and process shut downs
- Reduces risk of contaminating ultra-pure liquids
- Complete traceability
- Consistent performance
- Rigorous change control

COMPOSITION

- Platinum-cured silicone tubing

Pharmaceutical grade silicone tubing designed for pumping of ultra-pure liquids in pharmaceutical and biotechnological manufacturing processes

APPLICATIONS

- For use in peristaltic pumps where durability is required. *Dow Corning*[®] Advanced Pump Tubing offers up to four times the pump life of standard platinum cure silicone tubing.

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*	ASTM**	Property	Unit	Result
0099	D2240	Durometer hardness, shore A ¹		50
0137A	D412	Tensile strength at break, die D ²	MPa	8.9
			psi	1290
0137A	D412	Elongation at break, die D ²	%	590
0137A	D412	Modulus at 200%, die D ²	MPa	3.0
			psi	435
0159A	D624	Tear strength, Die B ¹	kN/m	40.3
			ppi	230

¹Typical properties for the elastomer.

²Typical properties of the extruded tubing.

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

**ASTM: American Society for Testing and Materials.

DESCRIPTION

Dow Corning[®] Pharma Advanced Pump Tubing is a translucent silicone tubing made from a proprietary platinum-cured elastomer. This elastomer contains "low hysteresis" technology that translates into tubing with extended peristaltic pump performance. This product has been designed for use in pharmaceutical and biotechnological manufacturing processes.

Dow Corning Pharma Advanced Pump Tubing has up to four times the

pump life of standard platinum cured silicone tubing products. This makes it ideal for pumping applications that require long-term delivery of fluids reducing both change out time and costs.

REGULATORY STATUS

Dow Corning Pharma Advanced Pump Tubing is manufactured using *Silastic* BioMedical Grade silicone elastomer that meets or exceeds the test requirements of USP Class VI Plastics (87) and (88).

Dow Corning Pharma Advanced Pump Tubing meets the requirements of FDA 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 Advanced Pump Tubing is manufactured under quality control guidelines. The Healthcare Industries Materials Site in Hemlock, MI, is dedicated to the production of silicone materials for healthcare applications. It is registered with the FDA (CFN 1816403) as a Drug Establishment. The site quality system is based on principles of current Good Manufacturing Practices for both Bulk Pharmaceutical Products and Medical Devices. The site is ISO 9001-registered.

QUALITY ASSURANCE

Dow Corning manufactures *Dow Corning* Pharma Advanced Pump Tubing in a totally integrated process from raw materials to the final extruded tubing. Our quality system, described above, provides full documentation and complete traceability.

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. Because of the thermal insulating properties of silicone it is more difficult to heat than other materials such as thermoplastics. Sterilization can be accomplished using a standard gravity steam cycle (30 minutes at 1bar/15psi and 121°C/250°F) and in high speed flash steam sterilization cycle (15 minutes at 2bar/30psi and 132°C/270°F).

Gamma Radiation Sterilization

Gamma irradiation studies of the 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 Advanced Pump Tubing has a usable life of 36 months from the date of production.

PACKAGING INFORMATION

To serve our customers better, we can provide *Dow Corning* Pharma Advanced Pump Tubing in a variety of dimensions, including the most commonly used sizes shown in Table 1. Standard package is a 15-meter (50 foot) coil, double bagged in separately sealed polyethylene bags contained in a cardboard box.

SPECIAL NEEDS

Dow Corning has the capabilities to customize products to your specifications. Customization includes tubing dimension, tolerance, cut lengths, bulk packaging and spooling. *Dow Corning* Pharma Advanced Pump Tubing is also available marked with product name and size. Please contact your local *Dow Corning* representative to discuss your specific requirements.

LIMITATIONS

This product is neither tested nor 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 Advanced Pump 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 INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Table 1: Common tubing product sizes. Capability exists for these and many other sizes.

Imperial (inches)			Metric (mm)		
Inside Diameter	Outside Diameter	Wall	Inside Diameter	Outside Diameter	Wall
0.125	0.250	0.063	3.175	6.350	1.588
0.188	0.313	0.063	4.775	7.950	1.588
0.188	0.375	0.094	4.775	9.525	2.375
0.250	0.375	0.063	6.350	9.525	1.588
0.250	0.438	0.094	6.350	11.113	2.381
0.250	0.500	0.125	6.350	12.700	3.175
0.313	0.500	0.094	7.950	12.700	2.375
0.375	0.500	0.063	9.525	12.700	1.588
0.375	0.563	0.094	9.525	14.300	2.388
0.375	0.625	0.125	9.525	15.875	3.175
0.500	0.688	0.094	12.700	17.463	2.381
0.500	0.750	0.125	12.700	19.050	3.175
0.625	0.875	0.125	15.875	22.225	3.175
0.750	1.000	0.125	19.050	25.400	3.175

Table 2: Burst Properties.

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 Advanced Pump Tubing for their process.

Inside diameter imperial inches	Outside Diameter	Burst pressure' (psi)	Inside diameter metric (mm)	Outside diameter	Burst Pressure' (bar)
0.125	0.250	79	3.175	6.350	5.4
0.188	0.375	69	4.775	9.525	4.8
0.250	0.500	75	6.350	12.700	5.2
0.375	0.625	50	9.525	15.875	3.4
0.500	0.750	37	12.700	19.050	2.6
0.625	0.875	33	15.875	22.225	2.3
0.750	1.000	24	19.050	25.400	1.7

¹Test method described in Dow Corning Form 52-1047-01, Burst Strength Testing of *Dow Corning*® Pharma Tubings.