

Silicone Tubing and Assemblies

Pharmaceutical grade silicone tubing for transferring of ultra-pure liquids, air or steam in pharmaceutical and biotechnological manufacturing processes.

APPLICATIONS

Designed for applications that require the transfer of high purity fluids where contamination is a concern like filling lines.

FEATURES & BENEFITS

- Excellent flexibility
- Greater pressure and kink resistance
- Low extractables
- Contains no peroxide by-products, chlorophenyls or PCBs
- No organic plasticizers, phthalates or latex additives
- Easily sterilized
- Stable over a wide temperature range
- High resiliency
- No impaired taste or odor
- Non-wetting (hydrophobic) surface
- Made from 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 an FDA-registered (CFN 1816403) and inspected healthcare facility
- High purity quality (USP 788 Particulate matter for Injection, USP 85 Bacterial Endotoxins, ISO 11737-1 Bioburden)
- FDA 21 CFR 177.2600 and USP 661 Physico-chemical tests Plastics
- Reduces risk of contaminating ultra-pure liquids
- Complete traceability
- Consistent performance
- Rigorous change control
- Dimensions available from small bore (0.28mm x 0.60mm) to large bore (31.8mm x 41.3mm)

Inside Diameter [mm]	Outside Diameter [mm]	Wall [mm]	Burst Pressure [bar]
3.2	6.4	1.6	8.5
4.8	8.0	1.6	7.8*

Common tubing product sizes (capability exists for these and many other sizes) and Burst properties:



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4.8	9.5	2.4	10.8
6.4	9.5	1.6	6.3*
6.4	11.1	2.4	8.4*
6.4	12.7	3.2	10.1
8.0	12.7	2.4	7.3*
9.5	12.7	1.6	4*
9.5	14.3	2.4	6.3*
9.5	15.9	3.2	7.7
12.7	17.5	2.4	4.7*
12.7	19.1	3.2	6.2
15.9	22.2	3.2	4.6
19.1	25.4	3.2	4.3

Note: Burst pressure values are typical values not intended for writing specifications. Test method is based on ASTM D380-14.

* Predicted burst pressure : a regression formula was used to calculate burst pressure of these tubing sizes not actually tested for burst strength.

SPECIAL NEEDS

DuPont has the capabilities to customise products to your specifications. Customisation includes sizes, tolerances, cut lengths, bulk packaging and spooling. For easy identification, Liveo[™] Pharma Tubing is also available marked with product name and size. Please contact your DuPont representative to discuss your specific requirements.

Quality information

The FDA registered and ISO 9001:2015 certified Healthcare Industries Materials Site (HIMS site) is responsible for ensuring consistent product quality.

Regulatory and Biocompatibility information

Product Regulatory Information document as well as Summary of health data are available from our DuPont website or upon request.

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Typical mechanical properties

Modulus at 200% strain	2.8 ^[1]	MPa	ASTM D 412
Tensile Strength	7.0	MPa	ASTM D 412
Elongation at break	>300	%	ASTM D 412
Shore A hardness	65		ASTM D 2240
Tear strength, die B	46.0	kN/m	ASTM D 624
[1]: tested on tubes with die D			
[2]: tested on tubes			

Storage and stability

Shelf life [3]: from the date of manufacture when stored in the original unopened containers

Characteristics

Food contact

FDA 21 CFR

Additional information

How to use

Information from "Chemical Resistance Guide For Elastomers IV", published by Compass Publications, La Jolla, California, can be used as a reference. It is however recommended that the DuPont product be evaluated in the real conditions of use.

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 DuPont 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. This product is not tested for specific pharmaceutical or medical device use(s). Should you wish to use this product in a specific pharmaceutical or medical device application, please contact DuPont to discuss such potential use. It remains the User's responsibility to ensure the safety, efficacy and legal and regulatory compliance in each relevant jurisdiction (including targeted geographic regions of manufacture and supply) of these materials for its intended uses. DuPont makes no representation concerning the suitability of these products for any particular medical or pharmaceutical application. Under no circumstances should these materials be considered for implantation into the human body for periods that exceed 30 days in duration.

Safety warning



60^[3] months





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Before handling, please consult the corresponding material safety data sheets. These are available upon request or can be downloaded from our DuPont website : <u>www.DuPont.com</u>

Chemical Media Resistance

Sterilisation methods

- ✓ Ethylene Oxyde
- ✓ Autoclave Steam, 30min at 120°C
- ✓ Gamma Radiation, 50 kGy

Symbols used:

✓ possibly resistant

Defined as: Supplier has sufficient indication that contact with chemical can be potentially accepted under the intended use conditions and expected service life. Criteria for assessment have to be indicated (e.g. surface aspect, volume change, property change).

🗙 not recommended - see explanation

Defined as: Not recommended for general use. However, short-term exposure under certain restricted conditions could be acceptable (e.g. fast cleaning with thorough rinsing, spills, wiping, vapor exposure).

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