OUPONT Liveo™ Pharma 65 Reinforced Tubing

Silicone Tubing and Assemblies

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

It is a translucent silicone tubing containing a fibre braid that does not contact material on the tubing surface or within the lumen. The silicone component is a tear-resistant BioMedical Grade platinumcured elastomer reinforced for added strength with 2-ply polyester fibre braid. It is designed for use in pharmaceutical and biotechnological manufacturing processes. Liveo[™] Pharma-65 Reinforced Tubing has a low extractables profile, which guards against contamination.

APPLICATIONS

Liveo[™] Pharma-65 Reinforced Tubing is designed for applications that require the transfer of high purity fluids where kink, high pressure and vacuum resistance is important.

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 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"
- FDA 21 CFR 177.2600 and USP 661 Physico-chemical tests Plastics
- Manufactured to the principles of applicable cGMPs
- Reduces risk of contaminating ultra-pure liquids
- Complete traceability
- Consistent performance
- Rigorous change control
- Integrated supply chain

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

3.2 9.3 3.0 62	Inside Diameter [mm]	Outside Diameter [mm]	Wall [mm]	Burst Pressure [bar]
	3.2	9.3	3.0	62

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4.8	11.4	3.3	54
6.4	13.2	3.4	58
7.9	15.0	3,6	43
9.5	16.6	3.6	41
12.7	20.3	3.8	38
15.9	24.5	4.3	32
19.1	27.9	4.4	21
22.2	31.4	4,6	21
25.4	35.5	4.6	14

PACKAGING

The standard package is a cardboard box containing a 7.6 meter coil, doublebagged in separately sealed polyethylene bags.

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.

Storage and stability 36 months Shelf life 36 months Characteristics Food contact Food contact FDA 21 CFR Additional Information 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

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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

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

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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Page: 3 of 3

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