

# DuPont™ Liveo™ Pharma TPE Tubing

Sterilizable, weldable TPE tubing for biopharmaceutical processing



With the launch of new Liveo™ Pharma TPE Tubing, DuPont is now offering a thermoplastic elastomer (TPE) option for fluid transport and single-use bioprocessing applications and is facilitating adoption and compatibility with leading competitive TPE tubing offerings.

This new product range complements our silicone-based Liveo™ Pharma Tubing and Overmolded Assemblies product lines and is produced under the same high quality principles as the products our customers already know and trust.

## Key features and benefits

- Improved heat-welding, both to itself and to competitive offerings
- High tensile strength and burst resistance before and after welding
- Low extractables
- Good chemical resistance
- Minimal spallation after 24 hours of pumping
- Good clarity; stable clarity after sterilization
- Manufactured in ISO Class 7 cleanroom
- Comprehensive data package to accelerate qualification and validation under the form of a qualification guide

## Applications

- Fluid, media and solvent transport in biopharmaceutical processes and biotechnology
- Single-use assemblies
- Peristaltic pump applications
- Aseptic connection and disconnection without connectors (e.g., sampling)
- Applications where compatibility with industry benchmark TPE tubing is needed

## Typical physical properties of Liveo™ Pharma TPE Tubing

Properties are based on Liveo™ Pharma TPE Tubing with an inner diameter (I.D.) of 3/8" (9.5 mm) and an outer diameter (O.D.) of 5/8" (15.9 mm).

Specification writers: These values are not intended for use in preparing specifications. Please contact DuPont prior to writing specifications on this product.

	Property	Test standard	Mean value
	Durometer hardness	ASTM D2240	65 Shore A
	Specific gravity	ASTM D792	0.900
	Property	Test standard	Mean value
<b>Steam (121°C/30 minutes)</b>	Maximum elongation	ASTM D412 Die C	1,134%
	Modulus at 200% elongation		2.7 MPa (392 psi)
	Maximum tensile strength		9.4 MPa (1,363 psi)
	Property	Test standard	Mean value
<b>Gamma radiation (50 kGy)</b>	Maximum elongation	ASTM D412 Die C	1,031%
	Modulus at 200% elongation		2.6 MPa (377 psi)
	Maximum tensile strength		7.4 MPa (1,073 psi)

## Purity data for Liveo™ Pharma TPE Tubing

- USP <85> (Endotoxins)
- USP <665> (Extractables and Leachables) with autoclave or gamma radiation sterilization methods
- USP <788> (Particulates)
- ISO 11737-1 (Bioburdens)

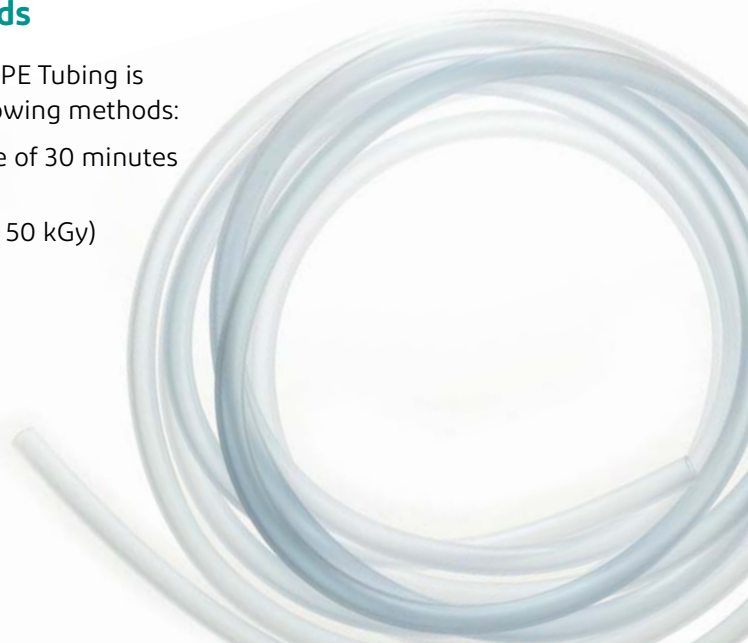
## Regulatory data for Liveo™ Pharma TPE Tubing

- ISO 10993 Biocompatibility tests (5: Cytotoxicity, 6: Muscle Implantation, 11: Acute Systemic Toxicity, 23: Intracutaneous Irritation)
- USP Class VI (Intracutaneous Reactivity, Acute Systemic Injection, Intramuscular Implant)
- Pyrogenicity (USP <151>)
- Elemental Impurities

## Sterilization methods

DuPont™ Liveo™ Pharma TPE Tubing is sterilizable using the following methods:

- Steam (1 autoclave cycle of 30 minutes at 121°C)
- Gamma radiation (up to 50 kGy)

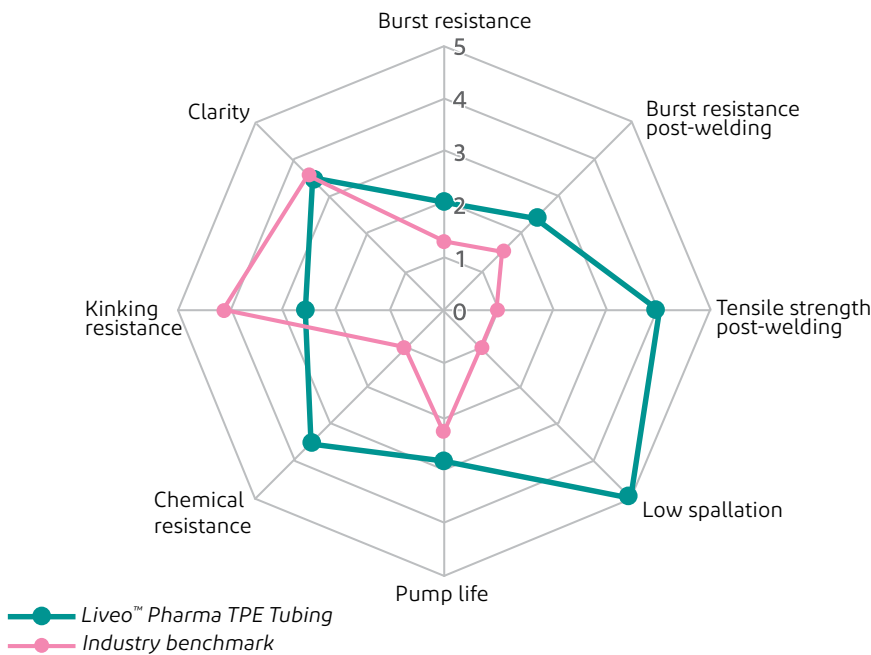


## Performance data for DuPont™ Liveo™ Pharma TPE Tubing

Comprehensive studies were conducted on material in common sizes and using different sterilization methods, including steam and gamma radiation. The following is a review of analyses comparing Liveo™ Pharma TPE Tubing to industry benchmark tubing. Further testing data is available; please contact DuPont for more details depending on your application needs.

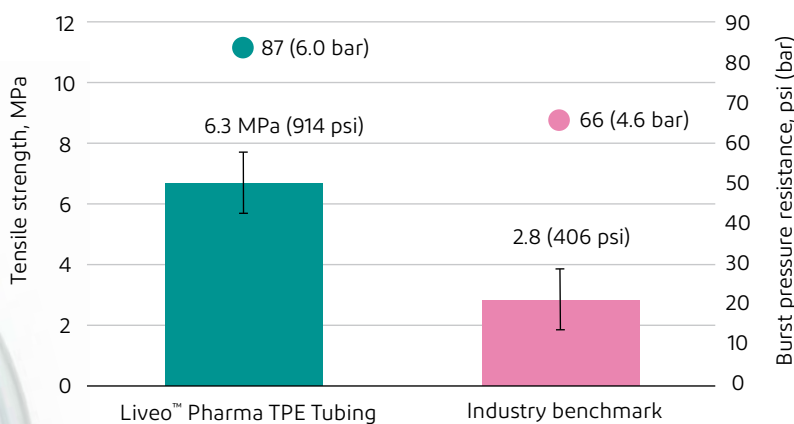
### Benchmark analysis: Summary of typical performance

Test samples steam-sterilized (autoclaved 1 cycle of 30 minutes at 121°C); 0 = lowest performance; 5 = highest performance.



### Benchmark analysis: Tensile strength after welding

Test samples autoclaved.



### Results

Liveo™ Pharma TPE Tubing showed **better tensile strength after welding** than the benchmark tubing.

Testing also revealed **better welding strength and burst pressure resistance** by Liveo™ Pharma TPE Tubing versus the benchmark tubing. Excellent welding strength and burst pressure resistance enable Liveo™ Pharma TPE Tubing to **improve the safety margin during fluid transfer applications**.

### Testing protocol

- Weldability was assessed by sterilization of the samples prior to running specific testing to measure the ability of the welded section to withstand mechanical stress before failure was observed.
- The specimens were welded using the specific Biowelder® TC preprogrammed setting.
- Tensile strength of the welded section was determined from the average maximum tensile strength as measured on dumbbells cut out from the tubing using ASTM D412 Die C.
- Liveo™ Pharma TPE Tubing welded extremely well to itself and to the benchmark tubing using aseptic tubing welders/standard recipes.
- Burst pressure resistance properties were determined according to ASTM D380 in a burst chamber apparatus by flowing water through the tubing and increasing the water pressure until ballooning and burst eventually were observed.



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