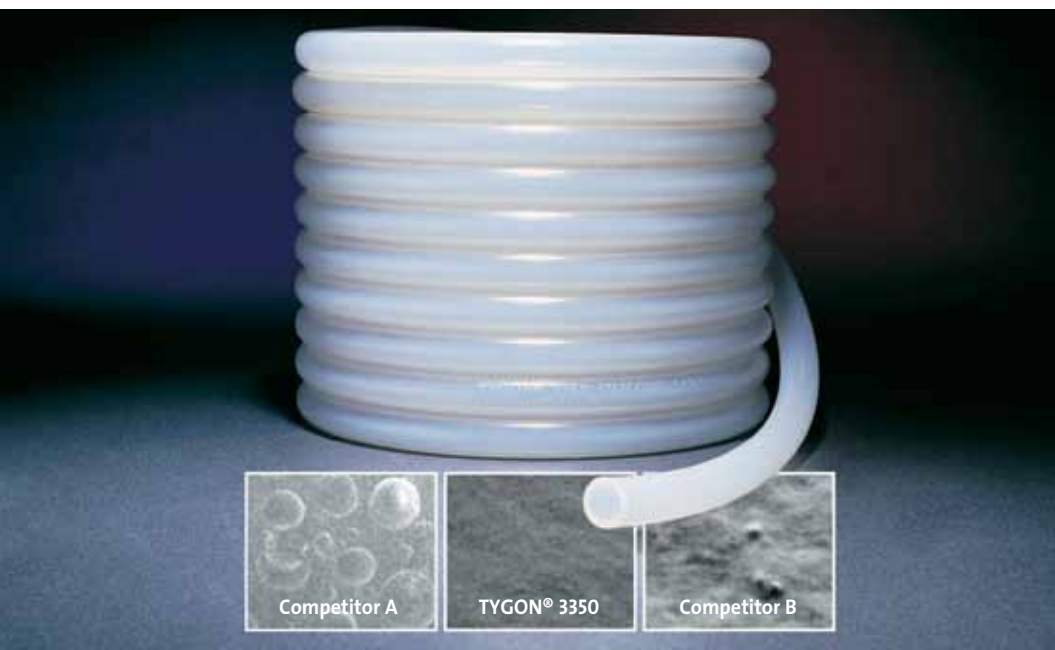


# TYGON® 3350 Sanitary Silicone Tubing



In a comparison of images of the inner surfaces of TYGON® 3350 silicone tubing and two competitors (captured at 500 x magnification with an electron scanning microscope), TYGON clearly exhibits superior smoothness. As a result, potential for particle entrapment is greatly reduced.

## “Engineered” Ultra-Smooth Inner Surface

The inner surface of TYGON® 3350 silicone tubing has been designed to reduce the risk of particle entrapment and microscopic build-up during fluid transfer. In-house analysis of the inner surface of TYGON® 3350 silicone tubing compared to other silicone tubing shows that it is up to threetimes smoother. In addition, when compared to stainless steel tubing, TYGON® 3350 tubing exhibits a smoother surface by a factor of up to 40.

A smoother fluid path also helps to facilitate complete sanitation of a fluid transfer system. Even in repeat use applications, TYGON® 3350 silicone tubing may prevent residue build-up, aiding in complete cleaning and sterilization.

Additionally, the smooth inner surface of the TYGON® 3350 silicone tubing improves fluid flow characteristics by reducing surface area.

## Lower Extractables and Superior Biocompatibility

TYGON® 3350 silicone tubing is compounded to meet the most demanding requirements of biocompatibility. In-house extractability tests have shown that TYGON® 3350 silicone tubing has a low extractable content. Lower extractables help to maintain the purity of transported fluids in sensitive applications.

Platinum-cured TYGON® 3350 silicone tubing complies fully with the requirements of the USP Class VI Criteria and is entirely non-toxic, non-hemolytic and non-pyrogenic. Additionally, TYGON® 3350 silicone tubing meets 3-A Sanitary Standards, FDA 21 CFR Part 177.2600 Criteria. TYGON® 3350 silicone tubing also complies with the ISO 10993 guidelines for contact with blood (or other body fluids and tissue) for up to 30 days as listed in the FDA GP-95. TYGON® 3350 has a Master File with the U.S. Food and Drug Administration.

## BIOPHARMACEUTICAL PRODUCTS

*The platinum-cured silicone tubing with an ultra-smooth inner surface for sanitary transfer of sensitive fluids*

### Features/Benefits

- Ultra-smooth inner bore reduces potential for particle entrapment
- Minimal extractables help maintain fluid integrity
- Documented biocompatibility for sensitive applications
- Excellent fluid flow characteristics
- Fully tested to ISO 10993 standards to facilitate validation process
- Complete inventory of standard sizes available, including metric sizes

### Typical Applications

- Pharmaceutical and cosmetic processing
- Medical devices
- Cell harvest and media process systems
- Sterile fill lines
- Water for injection (WFI) transfer
- Chemistry and blood analyzers
- Liquid chromatography

## TYGON® 3350 Tubing Inventory Sizes

Part Number	I.D. (inches)	O.D. (inches)	Wall Thickness (inches)	Length (feet)	Minimum Bend Radius (inches)	Max. Suggested Working Pressure at		Vacuum Rating In. of Mercury at	
						73°F (psi)*	320°F (psi)	73°F	320°F
ABW00001	1/32	3/32	1/32	50	1/8	22	21	29.9	29.9
ABW00002	1/16	1/8	1/32	50	1/4	14	13	29.9	29.9
ABW00003	1/16	3/16	1/16	50	1/4	22	21	29.9	29.9
ABW00004	3/32	5/32	1/32	50	1/4	11	10	29.9	29.9
ABW00005	3/32	7/32	1/16	50	1/4	18	16	29.9	29.9
ABW00006	1/8	3/16	1/32	50	3/8	9	8	20.0	15.0
ABW00007	1/8	1/4	1/16	50	1/2	14	13	29.9	29.9
ABW00009	5/32	7/32	1/32	50	3/4	7	6	10.0	10.0
ABW00011	3/16	1/4	1/32	50	1	7	6	5.0	5.0
ABW00012	3/16	5/16	1/16	50	1/2	11	10	25.0	25.0
ABW00013	3/16	3/8	3/32	50	3/8	14	13	29.9	29.9
ABW00014	3/16	7/16	1/8	50	3/8	18	16	29.9	29.9
ABW00016	1/4	5/16	1/32	50	1-1/2	5	4	1.0	1.0
ABW00017	1/4	3/8	1/16	50	3/4	9	8	15.0	15.0
ABW00018	1/4	7/16	3/32	50	5/8	12	11	29.9	29.9
ABW00019	1/4	1/2	1/8	50	5/8	14	13	29.9	29.9
ABW00022	5/16	7/16	1/16	50	1-1/4	7	6	5.0	5.0
ABW00023	5/16	1/2	3/32	50	5/8	10	9	20.0	20.0
ABW00027	3/8	1/2	1/16	50	1-1/2	9	8	5.0	5.0
ABW00028	3/8	9/16	3/32	50	1	11	10	20.0	15.0
ABW00029	3/8	5/8	1/8	50	1	12	11	29.9	29.9
ABW00032	7/16	9/16	1/16	50	1-1/2	4	3	2.0	2.0
ABW00033	7/16	5/8	3/32	50	1-3/4	8	7	10.0	10.0
ABW00036	1/2	5/8	1/16	50	3	5	4	1.0	1.0
ABW00037	1/2	11/16	3/32	50	1-3/4	7	6	5.0	5.0
ABW00038	1/2	3/4	1/8	50	1-1/2	9	8	15.0	15.0
ABW00045	5/8	13/16	3/32	50	3	6	5	5.0	0.0
ABW00046	5/8	7/8	1/8	50	2-1/2	7	6	10.0	10.0
ABW00053	3/4	1	1/8	50	2-1/2	7	6	1.0	1.0
ABW00062	1	1-1/4	1/8	50	5	5	4	0.0	0.0
ABW00069	1-1/4	1-1/2	1/8	50	6	5	4	0.0	0.0
ABW00074	1-1/2	2	1/4	50	7	6	5	1.0	1.0

The values listed for working and burst pressures are derived from tests conducted under controlled laboratory conditions. Many factors will reduce the tubing's ability to withstand pressures, including temperature, chemical attack, stress, pulsation and the attachment to fittings. It is imperative that the user conduct tests simulating the conditions of the application prior to specifying the tubing for use.

**TYGON TUBING IS NOT INTENDED FOR USE AS AN IMPLANT MATERIAL**

TYGON® is a registered trademark.

## BIOPHARMACEUTICAL PRODUCTS

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**IMPORTANT:** It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics tubing for all intended uses. Laboratory and clinical tests conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of tubing in any particular application.

For a period of 6 months from the date of first sale, Saint-Gobain Performance Plastics Corporation warrants this product to be free from defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. THIS WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized.

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## TYGON® 3350 Metric Sizes

Part Number	I.D. (mm)	O.D. (mm)	Wall Thickness (mm)	Length (m)	Minimum Bend Radius (inches)	Max. Suggested Working Pressure at		Vacuum Rating In. of Mercury at	
						73°F (psi)*	320°F (psi)	73°F	320°F
ABW1S1501	1	2	.5	15	3/8	9	8	29.9	29.9
ABW1S1502	2	4	1	15	1/2	9	8	29.9	29.9
ABW1S1503	5	8	1.5	15	3/4	7	6	25.0	25.0
ABW1S1504	6	9	1.5	15	7/8	6	5	15.0	15.0
ABW1S1505	7	10	1.5	15	1	6	5	10.0	10.0
ABW1S1506	8	12	2	15	1-1/2	6	5	15.0	15.0
ABW1S1507	10	14	2	15	2	5.5	4.5	5.0	5.0
ABW1S1508	12	16	2	15	2-1/2	5	4	5.0	5.0
ABW1S1509	18	24	3	15	3	5	4	5.0	5.0

\*Safety factor of 5 to 1 ratio of burst pressure to working pressure.

## TYGON® 3350 Typical Physical Properties

Property	ASTM Method	Value or Rating
Durometer Hardness Shore A, 15 Sec	D2240	50
Color	—	Translucent
Tensile Strength psi (MPa)	D412	1,450 (10)
Ultimate Elongation, %	D412	770
Tear Resistance lb-f/inch (kN/m)	D624 Die B	200 (35)
Specific Gravity	D792	1.14
Water Absorption, % 24 hrs. @ 23°C	D570	0.11
Compression Set Constant Deflection, % @ 158°F (70°C) for 22 hrs. @ 347°F (175°C) for 22 hrs.	D395 Method B	7 35
Brittleness by Impact Temp., °F (°C)	D746	-112 (-80)
Maximum Recommended Operating Temp., °F (°C)	—	400 (204)
Dielectric Strength v/mil (kV/mm)	D149	480 (19.0)
Tensile Modulus, @ 200% Elongation, psi (MPa)	D412	280 (1.9)

Unless otherwise noted, all tests were conducted at room temperature (73°F [22.8°C]). Values shown were determined on 0.075" thick molded ASTM plaques or molded ASTM duro-meter buttons.

## Sterilization of TYGON® 3350

Autoclavable — Steam 30 minutes at 15 psi (250°F).

Gas — Ethylene Oxide.

Radiation — up to 5.0 Mrad.

## TYGON® 3350 Toxicological Profile

The biocompatibility of TYGON 3350 has been tested and found to be non-toxic in the following test protocols:

- USP Systematic Toxicity and Intracutaneous Reactivity
- USP Intramuscular Implant
- USP Physico Chemical Tests
- Cytotoxicity
- USP Pyrogen Test
- Blood Compatibility