Tygon® MPF-300 TUBING

FOR MEDICAL DEVICE MANUFACTURERS

TYGON® MPF-300 TUBING

TYGON® MPF-300 is a clear, medical grade polymer not formulated with PVC or DEHP. This flexible tubing is designed to replace PVC in medical devices in which DEHP plasticizers and leachables are not desired. TYGON MPF-300 has excellent bonding strength and is ideally suited for fluid and oxygen administration applications.

BIOCOMPATABILITY

TYGON MPF-300 is a biocompatible polymer developed specifically for medical applications and tested to various elements of ISO 10993 including hemocompatibility, implantation, irritation and skin sensitization, systemic toxicity, and cytotoxicity.

PVC ALTERNATIVE TUBING - THE RIGHT CHOICE

Increasing concerns in Europe and North America regarding health hazards and environmentally friendly disposal of DEHP plasticizers led to the development of the MPF product line. TYGON MPF-300 products are not formaulated with PVC or DEHP, and can be disposed of without harmful effects on the environment.

FEATURES & BENEFITS

- PVC alternative
- Tubing is not made with plasticizers
- EtO and gamma sterilizable
- Environmentally safe disposal
- Excellent bonding to plastic connectors
- Meets criteria of various ISO 10993 tests

TYPICAL APPLICATIONS

- Fluid administration
- Oxygen administration



INNOVATION in **ACTION**

TYGON® MPF-300 TUBING

TYPICAL PHYSICAL PROPERTIES OF TYGON® MPF-300*

Property	ASTM Method	Value or Rating
Durometer Hardness (Shore A), 15 sec.	D2240-02	83
Tensile Strength, psi (MPa) (at break)	D412-98	3,595 (41.4)
Ultimate Elongation, %	D412-98	553
Tear Resistance, lb-f/inch (kN/m)	D624-91, Die C	509 (83.1)
Compression Set, Constant Deflection % @ 158°F (70°C) for 22 hours	D395-02, Method B	29
Brittle Temperature, °F (°C)	D746-98	< -112 (-80)
Specific Gravity	D792-02	1.11
Water Absorption, % 24 hours at 73°F (23°C)	D570-98	1.13
Maximum Recommended Operating Temperature °F	n/a	180 (82)
Tensile Modulus, @ 100 % Elongation, psi (MPa)	D412-98	1,546
Color	n/a	Transparent Natural

^{*}Unless otherwise noted, all tests were conducted at room temperature (73°F). Values shown were determined on 0.075" thick extruded strip or 0.075" thick molded ASTM plaques or molded ASTM durometer buttons.

TYGON MPF-300 PRODUCT CHARACTERISTICS

Tygon® MPF-300 tubing has met the following test requirements:

- · Hemolysis, as described in ISO 10993-4 (fluid path only)
- · Cytotoxicity, as described in ISO 10993-5
- · Implantation, as described in ISO 10993-6
- \cdot Skin Sensitization, as described in ISO 10993-10 (fluid path only)
- · Acute Systemic Toxicity, as described in ISO 10993-11
- · Irritation, as described in ISO 10993-23

TYGON MPF-300 STERILIZATION METHODS

EtO Yes

Gamma Yes (25 kGy)

IMPORTANT: Saint-Gobain Performance Plastics Corporation's Life Science ("Saint-Gobain") products that are used as components in the manufacture of any Medical Devices (as defined by the FDA) are sold by Saint-Gobain only and exclusively to Medical Device manufacturers for use in the manufacture, assembly or distribution of their medical devices. In addition, Saint-Gobain may at the request of a Medical Device manufacturers, to the extent viable, act as an OEM to manufacture a subcontracted finished product for such Medical Device manufacturers that could be classified by such Medical Device manufacturers as a medical device.

Medical Device manufacturers, to whom Saint-Gobain sells components or for whom Saint-Gobain acts as a subcontractor for finished products, are solely responsible for determining whether their finished products are a medical device and to the extent they determine that the finished products are medical device, the Medical Device manufacturers are obligated to be compliant with all applicable regulations and to ensure that it has received proper country-specific clearance, certification or registration authorizing the sale of such medical devices.

NOTE: This document is intended to provide information about the product to enable you to consider whether generally the Product meets your application need and is not intended to provide product specification. This document should not be considered a Product warranty or guaranty. To the extent this document mentions any tests done by Saint-Gobain, such tests are done under controlled laboratory circumstances and hence other factors in your use and application may impact such values. Saint-Gobain strongly recommends that you conduct practical tests simulating the conditions of your application to ensure that the product meets your requirements for your specific application.

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