

Technical Bulletin

Bag Chambers

Materials

Multilayer film construction with LDPE fluid contact layer, EVOH gas barrier and nylon outer layer.

Physical Properties

	ASTM ¹	Units	Typical Value
Thickness			
50 ml - 1 liter Chamber	N/A	mils	7.0
2 liter - 500 liter Chamber	N/A	mils	12.0
Tensile Strength (MD)	D882A	psi	5300
Tear Resistance	D1922	grams	>800
Seam Strength	D882	lbs/in	>25
Dart Impact	D1709	grams	>1600
Operating Temperature	N/A	°C	-80 to +60
O ₂ Transmission Rate	F-1927	cc/100 in ² /24 hr	0.02
CO ₂ Transmission Rate ²	N/A	cc/100 in ² /24 hr	<0.06

(1) ASTM test results reported using 7.0 mil chamber construction

(2) CO₂ transmission rate reported using raw material performance data

Biological & Particulate Testing

	Test Protocol	Result
Cytotoxicity, <i>In Vitro</i>	ISO-10993-5	Pass
Biological Reactivity, <i>In Vivo</i> (USP Class VI)	USP <88>	Pass
Endotoxin	USP <85>	Pass
Particulate Matter	USP <788> EP <2.9>	Pass
Polyethylene with Additives for Containers	EP <3.1.5>	Pass
Physicochemical Tests for Plastics	USP <661>	Pass
Sterile Purified Water (Oxidizable Substances)	USP <1231>	Pass

Sterilization

	Test Protocol	Result
Microbiological Validation of 25kGy Radiation Sterilization	ANSI/AAMI/ISO 11137	10 ⁻⁶ SAL 3 Year Expiry

Animal-Derived Components

All chamber materials are free of animal-derived components.

Saint-Gobain Performance Plastics

15301 Highway 55
Plymouth, MN 55447
Tel: (763) 398-1560
Fax: (763) 398-1589

IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain Performance Plastics assumes no responsibility for any product failures that occur due to misuse of the materials it provides arising out of the design, fabrication or application of the products into which the materials are incorporated.

SAINT-GOBAIN PERFORMANCE PLASTICS DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

WARRANTY: For a period of 12 months from the date of first sale, Saint-Gobain Performance Plastics 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.