

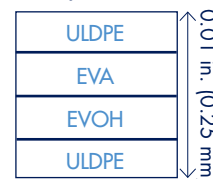
# PureFlex™ process container film

Millipore process containers are single-use flexible containers designed specifically for bioprocessing, storage and transport of biopharmaceutical fluids in sterile conditions. They are free of animal derived components.

## Product Description

PureFlex is a high purity, medical grade, coextruded film designed to provide strength, flexibility (with maximum resistance to flex-crack), excellent gas barrier performance and inert contact. The fluid contact material is made of ultra low density polyethylene (ULDPE). The gas barrier is made of polyethylene vinyl alcohol copolymers (EVOH). The outer layers are made of ethylene vinyl acetate (EVA) and ULDPE. PureFlex film contact layers comply with the Food and Drug Administration (FDA) regulation 21 CFR 177.1520.

### Film:



## PHYSICAL DATA

(Post gamma irradiation at  $\geq 45$  kGy)

Properties	Tests	Average Values
<b>Tensile Strength</b>	ASTM® D882	2700 psi (18.6 MPa)
<b>Elongation</b>	ASTM D882	570%
<b>Yield Strength</b>	ASTM D882	1360 psi (9.4 MPa)
<b>Secant Modulus</b>	ASTM D882	37 ksi (255 MPa)
<b>Toughness</b>	ASTM D882	9100 in.-lb/in. <sup>3</sup> (63 MJ/m <sup>3</sup> )
<b>Seam Strength</b>	ASTM D882	18 lbf/in. (32 N/cm)
<b>O<sub>2</sub> Transmission Rate</b>	ASTM F1307 at 23 °C	0.063 cc/100 in. <sup>2</sup> /24 hrs (0.98 cc/m <sup>2</sup> /24 hrs)
<b>CO<sub>2</sub> Transmission Rate</b>	ASTM F2476 at 23 °C	0.13 cc/100 in. <sup>2</sup> /24 hrs (2.02 g/m <sup>2</sup> /24 hrs)
<b>MVTR</b>	ASTM F1249 at 23 °C	0.034 g/100 in. <sup>2</sup> /24 hrs (0.53 g/m <sup>2</sup> /24 hrs)
<b>Haze</b>	ASTM D1003	23%
<b>Glass Transition Temperature</b>	ASTM D5026	-14.8 °F (-26 °C)
<b>Film Thickness</b>	ASTM D374	0.01 in. (0.25 mm)
<b>Operating Temperature Range*</b>		-112 to 140 °F (-80 to 60 °C)

## BIOCOMPATIBILITY DATA

(Post gamma irradiation at  $\geq 45$  kGy)

Properties	Tests	
<b>USP Class VI</b>	USP <88>	passed
<b>Cytotoxicity</b>	USP <87>	passed
<b>Bacterial Endotoxin</b>	USP <85>	passed
<b>Heavy Metals</b>	USP <661>	passed
<b>Buffering Capacity</b>	USP <661>	passed
<b>Non-volatile Residuals</b>	USP <661>	passed
<b>Residue on Ignition</b>	USP <661>	passed
<b>Hemolysis</b>	ISO 10993-4	passed
<b>Appearance</b>	EP 3.2.2.1	passed
<b>Acidity and Alkalinity</b>	EP 3.2.2.1	passed
<b>Absorbance</b>	EP 3.2.2.1	passed
<b>Reducing Substances</b>	EP 3.2.2.1	passed
<b>Transparency</b>	EP 3.2.2.1	passed
<b>Particulate Matter</b>	USP <788>	passed

\* Freezing requires the film to be supported. Note: These are average data for PureFlex film.

## Go Mobius

PureFlex film is a Mobius flexible bioprocessing technology and part of a suite of products that together provide an integrated disposable solution to improve process efficiency in biopharmaceutical development and manufacturing. From disposable process containers to capsule filters and connectors, to validated, gamma-compatible turn-key assemblies, Mobius solutions provide faster turnaround time and reliable performance, right out of the box.



## To Place an Order or Receive Technical Assistance

In the U.S. and Canada, call toll-free **1-800-MILLIPORE (1-800-645-5476)**

In the U.S., Canada and Puerto Rico, fax orders to **1-800-MILLIFX (1-800-645-5439)**

Outside of North America contact your local office.

To find the office nearest you visit [www.millipore.com/offices](http://www.millipore.com/offices)

Internet: [www.millipore.com](http://www.millipore.com)

Technical Service: [www.millipore.com/techservice](http://www.millipore.com/techservice)

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