

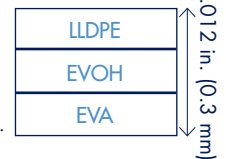
## SureFlex™ process container film

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

SureFlex process container film is manufactured utilizing a high purity, medical grade composite film designed to provide strength, flexibility (with maximum resistance to flex-crack), excellent gas barrier performance and inert contact. The fluid contact material is ethylene vinyl acetate (EVA). The gas barrier is made of polyethylene vinyl alcohol copolymers (EVOH). The outer layer is made of LLDPE.

## Film:



## PHYSICAL DATA

(Post gamma irradiation at  $\geq 25$  kGy)

Properties	Tests	Typical Values
<b>Tensile Strength*</b>	ASTM® D638	3100 psi (21.37 MPa)
<b>Elongation*</b>	ASTM D638	650%
<b>Tear Strength*</b>	ASTM D-1004	555g/ $\mu$ in.
<b>Modulus at 100% Elongation*</b>	ASTM D638	1050 psi (7.24 MPa)
<b>Puncture Resistance*</b>	FTMS 101B	22.4 lb $\bar{x}$
<b>Leak Testing</b>	Air Pressure	20 in. H <sub>2</sub> O/60 secs.
<b>Oxygen Transmission (O<sub>2</sub>)</b>	Testing performed at 25 °C ASTM D-3985	0.28 cc/100 in. <sup>2</sup> /24 hrs. (435 cc/m <sup>2</sup> /24 hrs.)
<b>Carbon Dioxide (CO<sub>2</sub>)</b>	ASTM D-1434	0.58 cc/100 in. <sup>2</sup> /24 hrs. (9.02 cc/m <sup>2</sup> /24 hrs.)
<b>Moisture Permeability</b>	E-96-80	0.11 g/100 in. <sup>2</sup> /24 hrs. (1.71 g/m <sup>2</sup> /24 hrs.)
<b>Simulated Transit Testing</b> (Filled bag chamber)	ASTM D-4169 (Level II)	Passed
<b>Operating Temperature Range*</b>		-94 to 158 °C (-70 to 70 °C)
<b>Sterilization by Gamma Irradiation</b>		$\leq 40$ kGy

## BIOCOMPATIBILITY DATA

(Post gamma irradiation at  $\geq 25$  kGy)

Properties	Tests	Typical Values
<b>Intracutaneous Toxicity</b>	USP Class VI	Passed
<b>Acute Systemic Toxicity</b>	USP Class VI	Passed
<b>Muscle Implantation</b>	USP Class VI	Passed
<b>Cytotoxicity Study</b>		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>Physicochemical</b>	USP <661>	Passed
<b>Hemolysis</b>	ISO 10993-4	Passed

\* Data pre-gamma irradiation.

\*\* Freezing requires the film to be supported.

Note: These are typical data for SureFlex film. Typical values are with a 95% confidence interval.

## Go Mobius

SureFlex 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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Lit. No. SP1001EN00 Rev. B 1/07 Printed in U.S.A. 07-040

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