

Ultimus® Single-Use Process Container Film

Engineered for superior strength and leak resistance

Ultimus® film was designed to meet the needs of more challenging single-use applications such as large-volume liquid processing. Our Ultimus® film technology provides enhanced bag strength, improved durability and leak resistance through a novel strength layer reinforced by woven nylon. The ultra-low-density polyethylene (ULDPE) fluid contact layer does not contain Irgafos® 168 to support healthy cell growth. The film was rigorously tested for extractables to support your risk assessment in suitability for the process application, the product, and the patient. The gas barrier layer is made of Ethylene Vinyl Alcohol copolymer (EVOH). The Low-Density Polyethylene (LDPE) outer layer increases the film's resistance to leak formation. The strength layer, strategically placed between layers of Ethylene Vinyl Acetate (EVA), is comprised of a woven nylon structure that significantly increases the overall durability of the film.

Cutting-edge Design with Woven Nylon

Our innovative approach of incorporating woven nylon into the film composition, exponentially improved the durability and strength of Ultimus® film. This woven nylon layer ensures the film's robustness while providing the ease of handling, flexibility, and conformity to a container that single-use processing demands.

Ultimus® film is available in Mobius® 3D process containers providing a stronger, more durable solution to solve your single-use manufacturing challenges.

Benefits

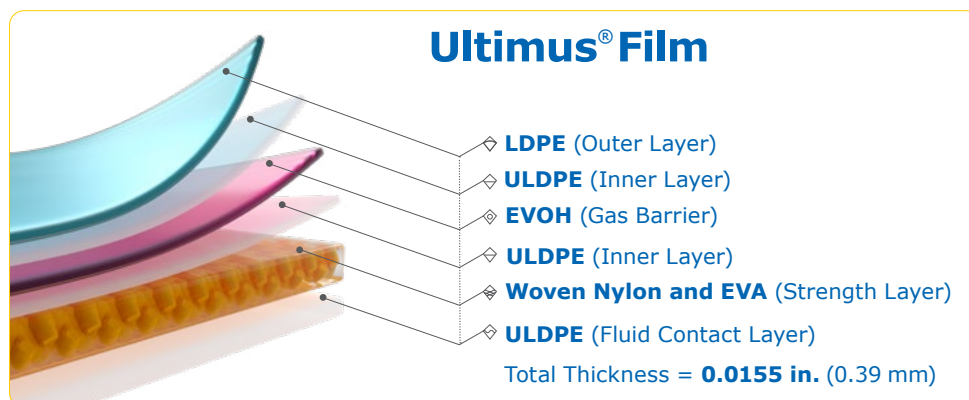
- Extreme durability for superior strength and leak resistance
- Reduced leak rate, minimizing product loss
- Supports healthy cell growth
- Improves operational efficiency and minimizes disruption

Features

- Woven nylon structure provides reinforced strength
- 10x* Extreme Abrasion Resistance
- 2.8x* Greater Tensile Strength
- 2x* Reinforced Puncture Resistance
- Superior* Flex Durability
- ISTA 3E Transport Test Verified**
- Irgafos® 168 free
- Comprehensive Extractables Data

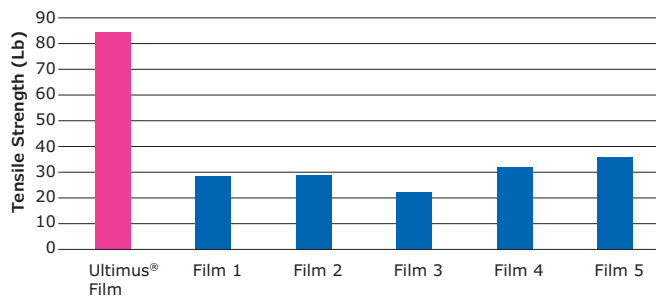
*Compared to the average results of five commercially available single-use bioprocessing films tested. Refer to TB5661EN Demonstrated Strength and Durability of Ultimus® Film Tech brief for more information.

** ISTA 3E Transport Test Verified using Mobius® 500 L Container with Ultimus® Film in 500 L Stainless Steel Bin

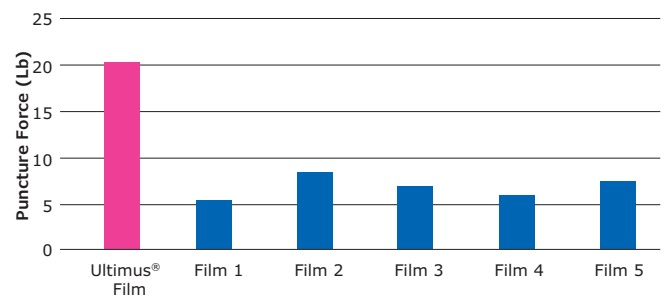


Comparing Ultimus® Film with Industry Films*

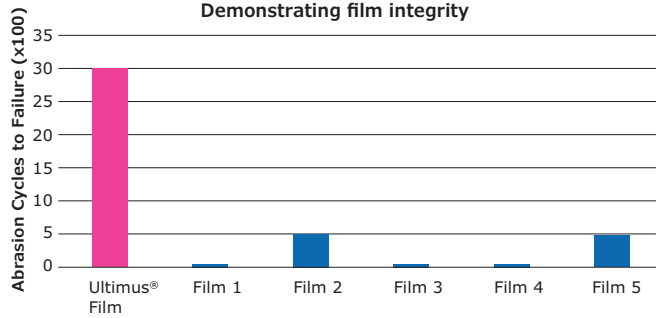
Demonstrating material strength and flexibility



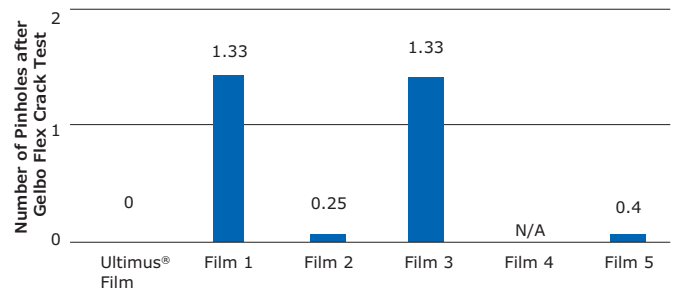
Demonstrating penetration resistance



Demonstrating film integrity



Demonstrating flex durability under extreme handling or use



*Based on tests performed on Ultimus® film and 5 other single-use industry films. For more information, please read our Technical Brief Lit. No. TB5661EN.



1000 L Mobius® Assembly with Ultimus® Film and Lynx® CDR Connector in a Mobius® Collapsible Bin

The Emprove® Program - your fast track through regulatory challenges

Complementing our Mobius® single-use portfolio, the Emprove® Program provides three types of dossiers to support different stages of development and manufacturing operations including material qualification, risk assessment and process optimization. The dossiers consolidate comprehensive product-

specific testing data (including complete set of Extractables profile according to USP <665> & BioPhorum standard conditions), quality statements and regulatory information in a readily-available format to simplify your compliance needs.

Visit SigmaAldrich.com/emprove

Specifications

Properties	Tests	Ultimus® Film Average Values
Abrasion Resistance at 500 g	ASTM F3300 -18	4007 strokes
Puncture Resistance	ASTM F-1306 -16	31.3 lbf (139.23 N)
Flex Durability	ASTM F-392	No holes at 900 cycles
Tensile Strength at Break (psi)	ASTM D882	5200 psi (35.9 MPa)
Elongation	ASTM D882	Test not applicable due to the reinforced structure.*
Yield Strength	ASTM D882	Calculation is not meaningful due to the reinforced structure.* Refer to tensile strength at break.
Modulus (Young's)	ASTM D882	31.1 kpsi (214.4 Mpa)
Toughness	ASTM D882	Test not applicable due to the reinforced structure.*
Seam Strength	ASTM D882	57.2 lbf
O ₂ Transmission Rate	ASTM F1307 at 23 °C	0.009 cc/100 in. ² /24 hrs (0.140 cc/m ² /24 hrs)
CO ₂ Transmission Rate	ASTM F2476 at 23 °C	<0.0645 cc/100 in. ² /24 hrs (1 cc/m ² /24 hrs)
Moisture Vapor Transmission Rate (MVTR)	ASTM F1249 at 23 °C	0.036 g/100 in. ² /24 hrs (0.558 g/m ² /24 hrs)
Glass Transition Temperature	ASTM D5026	Measurement is not meaningful due to composite structure.*
Film Thickness	ASTM D374	0.0155 in. (0.39 mm)
Operating Temperature Range		2–60 °C

*Some physical properties impacted by stretch do not apply to Ultimus® film. Ultimus® film does not stretch before failure because of its reinforced structure.

Biocompatibility Data

Properties	Values
Biological Reactivity	Ultimus® film meets the criteria for Biological Reactivity testing in accordance with the requirements of USP <87> and USP <88>.
Hemolysis	Passed ISO 10993-4
Bacterial Endotoxin	Aqueous extraction passes the Limulus Amebocyte Lysate (LAL) Test per USP <85>, also meeting the requirements of Ph. Eur. 2.6.14 and JP 4.01.
Subvisible Particulate Matter	Ultimus® film meets the requirements for USP <788>.

Chemical Characterization Data

Properties	Values
Physiochemical Test for Plastics	Ultimus® film meets the requirements for USP <661> as follows: <ul style="list-style-type: none"> • Heavy Metals <1 ppm • Buffering Capacity <10 mL • Non-volatile Residuals <15 mg • Residue on Ignition <5 mg
Aqueous Solutions for Parenteral Injections	Ultimus® film meets the requirements per Ph. Eur. 3.2.2.1: <ul style="list-style-type: none"> • Appearance • Acidity and Alkalinity • Reducing Substances • Transparency • Absorbance

Ordering Information

Mobius® Plastic and Collapsible Bin Single-Use assemblies with Ultimius® film

Volume	Film	Part Code	Compatible Bin	Certification	Top Ports			Bottom Ports		Side Ports
					1	1	1	1	1	
100 L	Ultimius®	USBA0100LC1S1	BIN0100L002	Silver	1	1	1	1		
100 L		USBA0100LC2S1	BIN0100L002		1	1	1		1	
250 L		USBA0250LA1S1	BIN0250L001		1	1	1			1
250 L		USBA0250LA2S1	BIN0250L001		1	1	1			
250 L		USBA0250LC1S1	BIN0250L002		1	1	1	1		
250 L		USBA0250LC2S1	BIN0250L002		1	1	1		1	
500 L		USBA0500LC1S1	BIN0500L002		1	1	1	1		
500 L		USBA0500LC2S1	BIN0500L002		1	1	1		1	
1000 L		USBA1000LC1S1	BIN01000L002		1	1	1	1*		
1000 L		USBA1000LC2S1	BIN01000L002		1	1	1		1*	

*1000 L scale bottom ports consists of 3/4" ID pharma-50 tubing and 3/4" ID C-Flex® 374 tubing at same lengths as described 1/2" ID tubing; there is no 3/4" ID Pharma-50 tubing 4" used for step down.

Mobius® Stainless-Steel Bin Single-Use assemblies with Ultimius® film

Volume	Film	Part Code	Compatible Bin	Certification	Top Ports			Bottom Ports		
					1	1	1	1	1	1
200 L	Ultimius®	USBA0200LM1S1	200 L Millitote	Silver	1	1	1			
200 L		USBA0200LM2S1	200 L Millitote		1	1		1		
1500 L		USBA1500LM1S1	1500 L Millitote			4			1	1
1500 L		USBA1500LM2S1	1500 L Millitote			4				1
2000 L		USBA2000LM1S1	2000 L Millitote			4			1	1
2000 L		USBA2000LM2S1	2000 L Millitote			4				1

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

For additional information,

Please visit SigmaAldrich.com/singleuseassemblies

To place an order or receive technical assistance, please visit SigmaAldrich.com/offices

