Millipore®
Expert Pharm/BioPharm
Products & CTDMO Services

Specification Sheet

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 fluid contact layer supports healthy cell growth and does not contain Irgafos® 168. This ultra-low density polyethylene (ULDPE) fluid contact layer is free of animal origin components and demonstrates a low extractables profile. 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

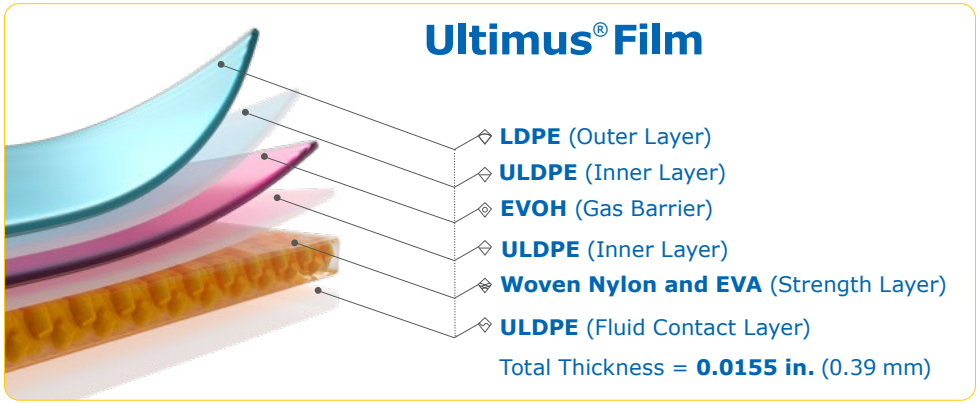
- Extreme durability for superior strength and leak resistance
- Reduced leak rate, minimizing product loss
- Supports healthy cell growth
- Improves operational efficiency and minimizes disruption

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



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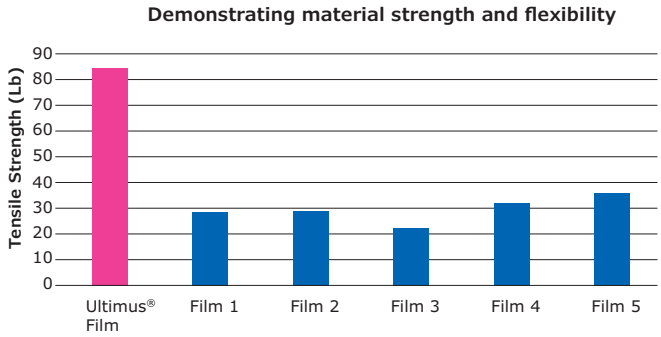
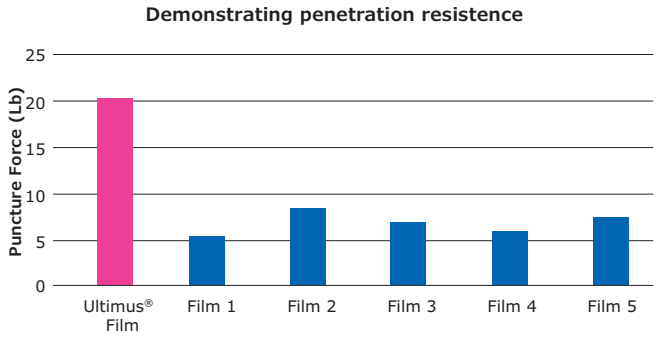
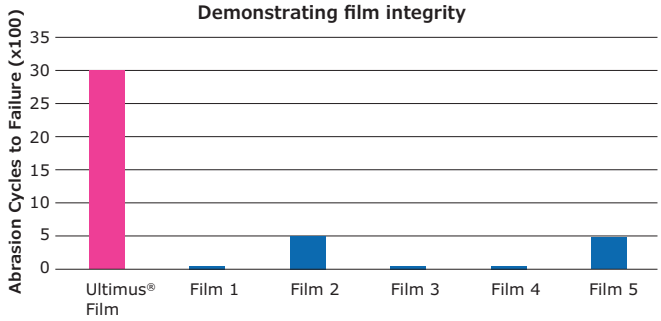
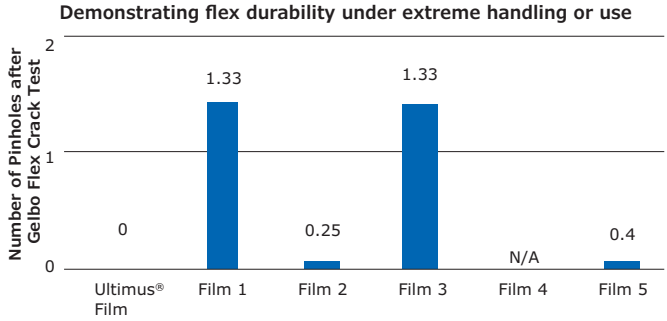
Comparing Ultimus® Film with Industry Films*









*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 (139.23N)
Flex Durability	ASTM F-392	No holes at 900 cycles
Tensile Strength at Break (psi)	ASTM D882	5200psi (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

Properties	Values
Biological Reactivity	Ultimus® Film meets the criteria for Biological Reactivity Testing. These tests can be any or a combination of the following test methods: USP<88> Class VI (*in vivo*), USP<87> (*in vitro*), ISO 10993-5 (*in vitro*).
Bacterial Endotoxin	Aqueous extraction passes the Limulus Ametocyte Lysate (LAL) Test per USP <85>, also meeting the requirements of Ph. Eur. 2.6.14 and JP 4.01.
Physiochemical Test for Plastics	Ultimus® film meets the requirements for USP <661> as follows: • 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 for: • Appearance • Acidity and Alkalinity • Reducing Substances • Transparency • Absorbancy per the Ph. EP 3.2.2.1
Subvisible Particulate Matter	Ultimus® film meets the requirements for USP <788>.
Hemolysis	Passed ISO® 10993-4

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

For additional information

Please visit **SigmaAldrich.com/singleuseassemblies**

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

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