

# 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

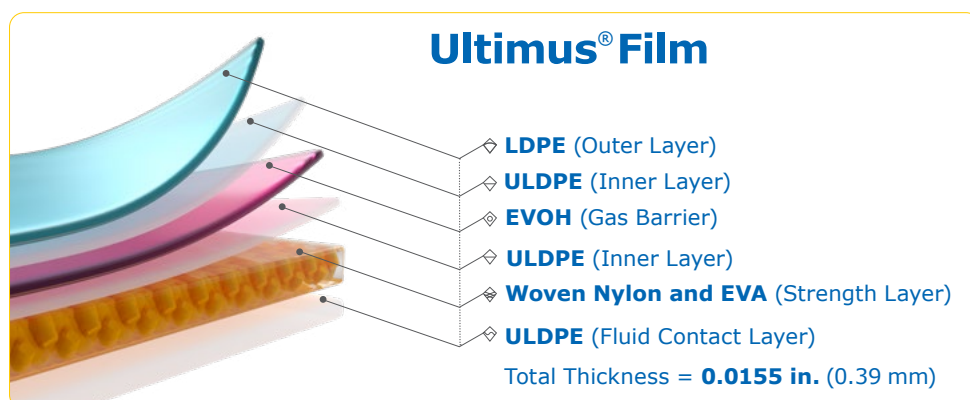
- Extreme durability for superior strength and leak resistance
- Reduced leak rate, minimizing product loss
- Supports healthy cell growth
- Improves operational efficiency and minimizes disruption

## 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

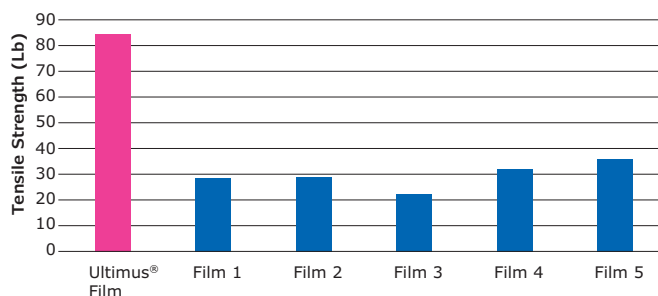
\*Compared to the average results of five commercially available single-use bioprocessing films tested. Refer to TB5661EN Demonstrated Strength and Durability of Ultimus® Film Tech brief for more information.

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

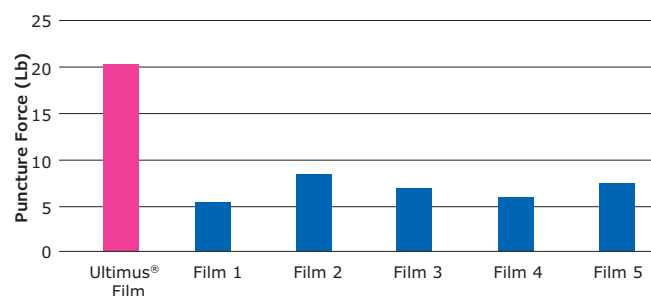


## Comparing Ultimus® Film with Industry Films\*

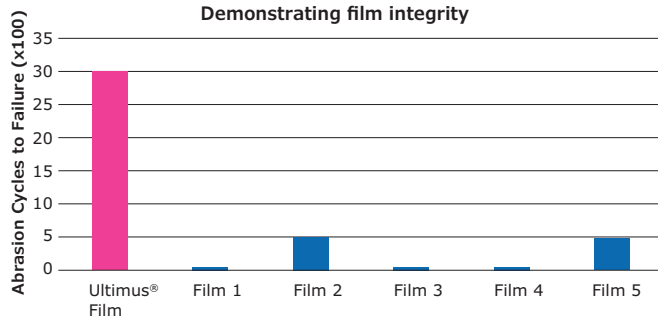
Demonstrating material strength and flexibility



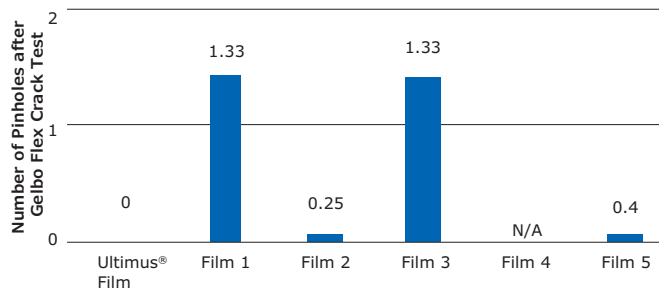
Demonstrating penetration resistance



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](https://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 <sub>2</sub> Transmission Rate        | ASTM F1307 at 23 °C | 0.009 cc/100 in. <sup>2</sup> /24 hrs (0.140 cc/m <sup>2</sup> /24 hrs)                             |
| CO <sub>2</sub> Transmission Rate       | ASTM F2476 at 23 °C | <0.0645 cc/100 in. <sup>2</sup> /24 hrs (1 cc/m <sup>2</sup> /24 hrs)                               |
| Moisture Vapor Transmission Rate (MVTR) | ASTM F1249 at 23 °C | 0.036 g/100 in. <sup>2</sup> /24 hrs (0.558 g/m <sup>2</sup> /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 ( <i>in vivo</i> ), USP<87> ( <i>in vitro</i> ), ISO 10993-5 ( <i>in vitro</i> ).                         |
| Bacterial Endotoxin                         | Aqueous extraction passes the Limulus Amoebocyte 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: <ul style="list-style-type: none"> <li>• Heavy Metals &lt;1 ppm</li> <li>• Buffering Capacity &lt;10 mL</li> <li>• Non-volatile Residuals &lt;15 mg</li> <li>• Residue on Ignition &lt;5 mg</li> </ul> |
| Aqueous Solutions for Parenteral Injections | Ultimus® film meets the requirements for: <ul style="list-style-type: none"> <li>• Appearance</li> <li>• Acidity and Alkalinity</li> <li>• Reducing Substances</li> <li>• Transparency</li> <li>• Absorbancy</li> </ul> per the Ph. EP 3.2.2.1                        |
| Subvisible Particulate Matter               | Ultimus® film meets the requirements for USP <788>.                                                                                                                                                                                                                   |
| Hemolysis                                   | Passed ISO® 10993-4                                                                                                                                                                                                                                                   |

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## For additional information

Please visit [SigmaAldrich.com/singleuseassemblies](https://SigmaAldrich.com/singleuseassemblies)

To place an order or receive technical assistance,  
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