Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Technical Note

Demonstrated Strength and Durability of Ultimus® Film

Protection against leaks, abrasions, tears and material fatigue associated with your toughest large-volume liquid processing

Introduction

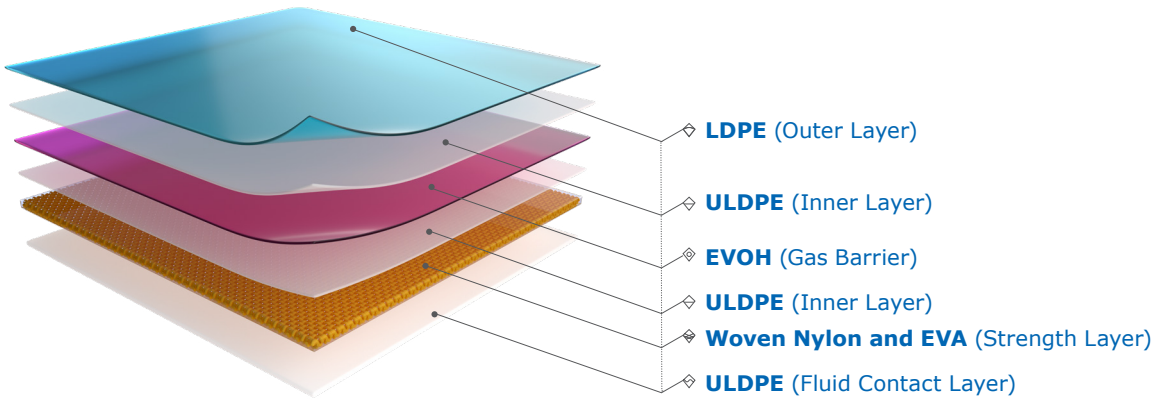
Single-use technology is used for different operations throughout biomanufacturing including mixing, storage and transportation. The integrity of the film used in single-use systems is critical to maintaining product quality and sterility, and reliable manufacturing operations, especially for large volume processing (>200 L). Ultimus® film is an innovative technology with a layered polymer structure which makes it highly resistant to damage and addresses the integrity issues frequently encountered with conventional films.

This Technical Note will outline the development of Ultimus® film and summarize the strength and robustness tests conducted according to the American Society for Testing and Materials (ASTM) standards.

Ultimus® Film Structure

The structure of Ultimus® film provides a clean contact resin, enhanced gas barrier, superior strength, durability, and flexibility. The animal origin-free fluid contact layer is made of ultra-low density polyethylene (ULDPE) and is Irgafos® 168 free to ensure the best cell growth performance. The strength layer is composed of woven nylon, promoting high strength reinforcement, sandwiched between layers of ethylene vinyl acetate (EVA) to ensure flexibility. The gas barrier is made of ethylene vinyl alcohol copolymer (EVOH). The film's outer layer consists of clean low-density polyethylene (LDPE) to increase the film's resistance to leak formation through abrasion, puncture, stretching and tearing.

Ultimus® Film



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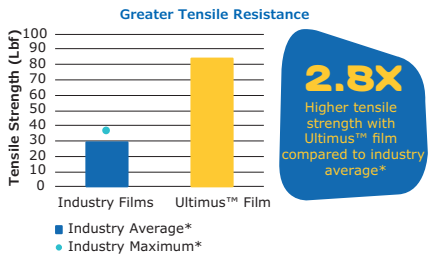
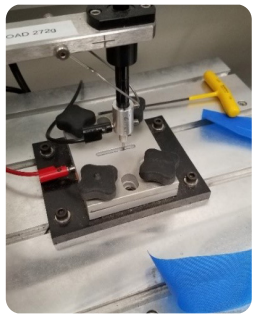
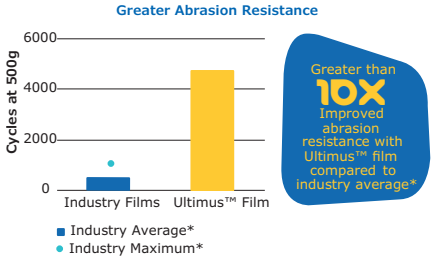
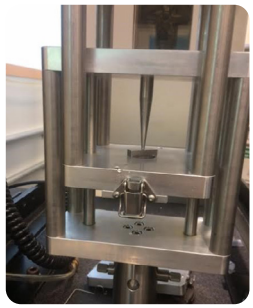
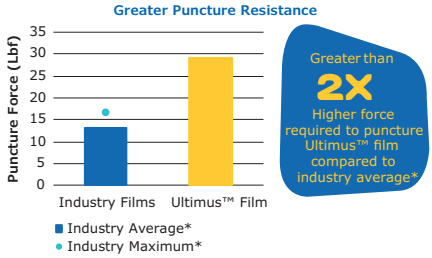
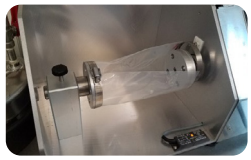
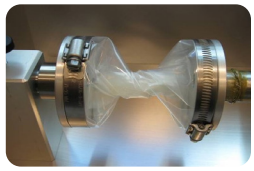
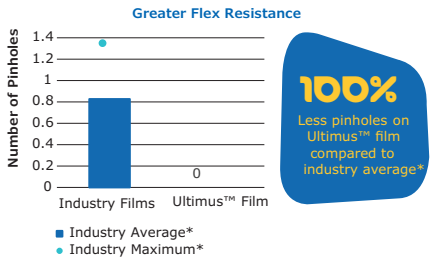
ASTM Test Methods and Results

ASTM defines standard testing methods for various materials including film. Several ASTM test methods were utilized to measure the strength and robustness of Ultimus® film; including tensile strength, number of abrasion cycles to breakthrough, puncture force and number of pinholes after Gelbo flex crack test. In addition, 5 single-use bioprocessing films including our PureFlex™ Plus film were tested following the same ASTM protocols. The average values of these 5 films for each ASTM test were used to benchmark performance of typical films in the industry. The results demonstrated that Ultimus® film has superior tensile strength, abrasion resistance, puncture resistance and flex resistance contributing to the film's resilience during single-use processing.

Table 1. ASTM Test Methods and Results

Test Name	Description	Measurement	Visual	Results
ASTM D882: Tensile Properties of Thin Plastic Sheeting	A sample of Ultimus® film as well as five other films, with known cross-sectional areas, were tested by being aligned and placed in the grips of the testing machine and stretched until the film breaks. From the data collected, a stress-strain curve was plotted and used to calculate the film's tensile properties, including tensile strength (the maximum load/cross sectional area of the sample). Tensile strength is important for material strength and flexibility.	Tensile Strength (Lbf)		
ASTM F3300: Abrasion Resistance of Flexible Packaging Films using a Reciprocating Weighted Stylus	A sample of Ultimus® film as well as five other films with known thicknesses were tested by being secured into a test holder with an opening for exposure to a stylus. A mass of 500 g was placed on the machine. The stylus is then dragged back and forth against the film at a rate of 30 cycles/min. The total number of cycles is captured when the stylus breaks through the film, replicating an integrity failure in a single-use bag. The abrasion of single-use assemblies has been identified as the most common failure mode.	Number of Cycles to breakthrough at 500 g		
ASTM F1306: Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates	A sample of Ultimus® film as well as five other films were secured into a test holder with an open area for a penetration probe. The test machine lowered the probe until perforation of the film occurred. Material strength parameters were collected, including puncture force, which is the force to achieve break. Penetration resistance is important because sharp edged items can puncture film causing leaks.	Puncture Force (Lbf)		
ASTM F392: Standard Practice for Conditioning Flexible Barrier Materials for Flex Durability	A sample of Ultimus® film as well as five other films were secured to a Gelbo flex tester. The secured film was then twisted and compressed by the rotating ends of the machine. After 900 cycles, the film was removed and assessed for pinholes. Flex resistance was measured to represent any potential failures from extreme handleability or use.	Number of pinholes	 	

*Based on 5 commercially available single-use bioprocessing films tested.

Large-Scale Structure and Durability Testing

In addition to ASTM tests, additional tests were performed to further evaluate the integrity of Ultimus® film in Mobius® bag assemblies.

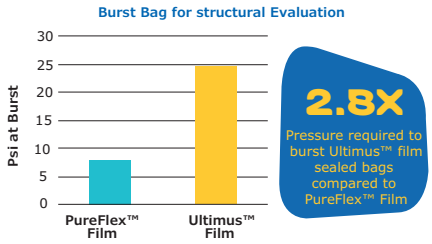
Burst Container for Structure Evaluation

The damage resistance of the film structure as well as the seal strength and container integrity are equally important in bioprocessing applications. To test this application, 2D bags (10 in. x 8 in.) made of Ultimus® film were filled with water and put under pressure until they burst. This test demonstrated that Mobius® bag assemblies made with Ultimus® film withstood 27 psi of pressure. Testing against PureFlex™ film, Ultimus® film demonstrated a 2.8x improvement in bag assembly structure and seal strength.

Large-Scale Multiple Fill and Drain for Robustness Testing

In large-scale applications, extreme over handling of the bags can contribute to leaks. To demonstrate large-scale robustness in the most extreme conditions, a Mobius® bag assembly made with Ultimus® film was filled and drained multiple times to evaluate strength, abrasion and flex resistance. Three 1000 L Mobius® bags used for storage and transportation were subjected to gamma irradiation at 25–40 kGy to mimic customer usage. The results of the studies concluded that Mobius® bag assemblies made with Ultimus® film demonstrated no leaks after 6x filling and draining.

Table 2. Additional Test Methods and Results for Structure and Durability at Full Scale

Test Name	Description	Measurement	Visual	Results
Burst Bag for Structure Evaluation	This test evaluates material structure and seals by measuring the pressure (psi) a bag can withstand before bursting. Bags (10 in. x 8 in.) made of Ultimus® film and PureFlex® film were attached to a gas line, pressure gauge, and water line. Each bag was filled with water and pressurized until it burst. Pressure was measured through testing software and the pressure at burst was recorded. Resistance to burst is important for material structure and seals for integrity of the container and leaks at the bag seams.	Pressure (psi) at burst	 	
Multiple Fill and Drain at 1000 L Scale for Robustness	This test utilized 3x 1000 L Mobius® collapsible bin bags made with Ultimus® film to test durability and ease of handling at large scale. Mobius® bags were filled to 1000 L using a volumetric flow totalizer. After 1 hour of holding time, the bags were checked for leaks. The bags were then drained and the process was repeated six times on a total of three containers. The Multiple Fill and Drain test is an important indication of end-use performance and robustness.	Pass/Fail for Bag Leaks		

Mobius® Collapsible Bin Bags made with Ultimus® Film	Leak Test after 6x Fill and Drain 1000 L
1	Pass
2	Pass
3	Pass

Conclusion

Ultimus® film's novel woven nylon structure provides the strength and robustness needed for single-use applications.

As compared to other commercially available single-use films tested, Ultimus® film demonstrated significant improvement in performance. This superior performance has been demonstrated through ASTM film strength and robustness tests, internal tests for Mobius® bag assembly structure (burst container), and full-size handleability and performance tests. These qualities of the Ultimus® film are essential to support bag installation, handleability, durability, and overall container integrity. This resilient film reduces risk and enables more efficient single-use manufacturing operations.

References

1. ASTM D882-18, Standard Test Method for Tensile Properties of Thin Plastic Sheeting, ASTM International, West Conshohocken, PA, 2018, www.astm.org
2. ASTM F3300-18, Standard Test Method for Abrasion Resistance of Flexible Packaging Films Using a Reciprocating Weighted Stylus, ASTM International, West Conshohocken, PA, 2018, www.astm.org
3. ASTM F1306-16, Standard Test Method for Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates, ASTM International, West Conshohocken, PA, 2016, www.astm.org
4. ASTM F392 / F392M-11(2015), Standard Practice for Conditioning Flexible Barrier Materials for Flex Durability, ASTM International, West Conshohocken, PA, 2015, www.astm.org

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

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