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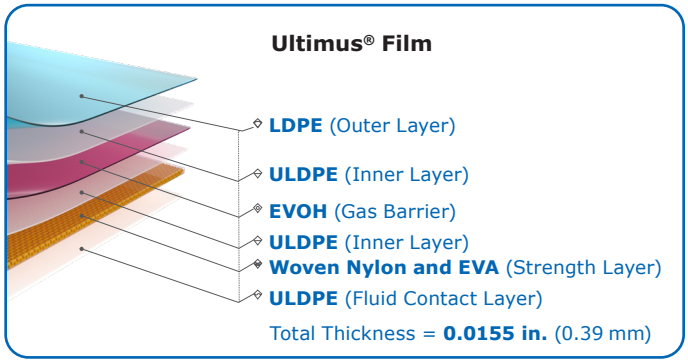
Application Note

Performance of Mobius® Bag Assemblies with Ultimus® Film in Truck Shipping Simulation Test

Introduction

Single-use bags offer many benefits in the bioprocessing world including elimination of the need to clean, store, and sterilize multi-use containers. A key consideration when incorporating these bags into the workflow is their use in transporting solutions such as drug substance from one location to another. It is crucial to maintain bag integrity during the transportation process to ensure safe and efficient delivery. The transport process presents risks, such as the bag abrading against the bin and the potential for it to fold in on itself due to the motion of the transport. In these cases, the bags may leak, resulting in costly product loss.

This application note describes the evaluation of Mobius® single-use bags made with Ultimus® film under strenuous shipping conditions. Ultimus® film was developed to meet the challenges of large volume processing with superior strength and durability[1]. Results of this study demonstrated the ability of bags made with Ultimus® film to safely transport various volumes of liquid and maintain their integrity.



Materials and Methods

A vibration test using a hydraulic shaker table was used to simulate the wave action generated by truck transportation. Several key variables were considered to ensure the test reflected real-world shipping conditions, including a worst-case scenario.

- **Fill Volume:** Three fill levels were evaluated to represent various scenarios for transporting a 1,000 L bin.
- **Bin Packing Materials:** While plastic collapsible bins are not recommended for transportation, this method of transport was tested as a worst-case scenario. A combination of bubble wrap and foam pads were used to fill the void space in the bins after being filled to restrain the bag and minimize sloshing. For this application, which is outside of ideal conditions, a thermoplastic polyurethane (TPU) bin liner was used in four out of the five samples to minimize the friction between the bag and the bin.
- **Test Temperature:** Since the abrasion resistance of plastic materials tends to increase in colder temperatures, testing was performed at room temperature as a worst-case scenario.
- **Vibration Curve:** ISTA 3H is a standardized test method for filled palletized goods. The vibration curve from the ISTA 3H protocol for shipping via truck was chosen to simulate a realistic wave action that the bag might experience.
- **Test Time:** Each filled assembly endured eight hours of vibration testing on a hydraulic shaker table, the equivalent of traveling 2,400 miles. According to the ISTA 3H test procedure, test time duration in minutes equals transport miles divided by five.

Five 1,000 L Mobius® collapsible bin bag assemblies made with Ultimus® film were integrity tested, sterilized with gamma irradiation at 25–40 kGy, then visual inspected to confirm bag integrity prior to vibration testing.

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Bag assemblies were installed in a Mobius® collapsible bin and filled with water and leak detecting dye to various volumes **(Table 1)**. Once filled with water, the Mobius® collapsible bin was packed with bubble wrap and foam pads. The lid was then strapped onto the bin and a crane was used to transfer the filled bin onto the hydraulic shaker. The bin was secured onto the hydraulic shaker, ensuring vertical motion was not restricted during the test. The filled bin was then exposed to eight hours of random vibration on a hydraulic shaker table at room temperature.

Table 1. Test Plan

Variable	Bag 1	Bag 2	Bag 3	Bag 4	Bag 5
Fill Volume (L)	650	650	765	960	960
Bin Liner	Yes	Yes	No	Yes	Yes
Bin Part Number	BIN1000L002	BIN1000L002	BIN1000L002	BIN1000L002	BIN1000L002

Once the testing was completed, a crane was used to transfer the filled bin from the hydraulic shaker. The bin was opened and visually inspected for leaks. The bag assemblies were then drained and removed from the bin. Each bag assembly was then subjected to another round of integrity testing, visual inspection, and a soapy water test.

- **Integrity Test:** The bag assembly was pressurized and allowed to stabilize. If a pressure drop was observed during stabilization, this indicated that the bag assembly had been compromised.
- **Visual Inspection:** The surface of the bag assembly/bin was inspected for any visible leaks or holes.
- **Soapy Water Test:** While the bag assembly was pressurized, soapy water was sprayed onto any visual film markings that were observed on the film surface. If the soapy water on the film marking resulted in the generation of bubbles, this indicated that the bag had been compromised.

Results

Bag Integrity

Each bag was integrity-tested prior to being sent for gamma irradiation; all bags passed the pre-vibration integrity test. Following gamma treatment and prior to vibration testing, bags were visually inspected, and any observed anomalies were marked for traceability. During the vibration testing, the bags were filled with water and pink dye to enhance leak detection. After eight hours of vibration testing, the bags were inspected for leaks and then drained; no leaks were observed at this time. Once the bags were drained, they were visually inspected, and integrity-tested. Each bag passed the post-visual and integrity test and all markings on the bag passed the soapy water test. A summary of these results is shown in **Table 2.**

Table 2. Summary of Results

	Pre-Vibration Test		Post-Vibration Test		
	Integrity Test	**Visual Inspection**	**Visual Inspection**	**Integrity Test**	**Soapy Water Test**
Bag 1	Pass	Pass	Pass	Pass	Pass
Bag 2	Pass	Pass	Pass	Pass	Pass
Bag 3	Pass	Pass	Pass	Pass	Pass
Bag 4	Pass	Pass	Pass	Pass	Pass
Bag 5	Pass	Pass	Pass	Pass	Pass

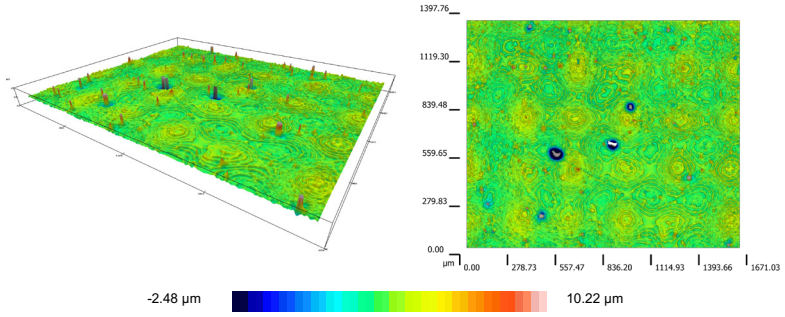
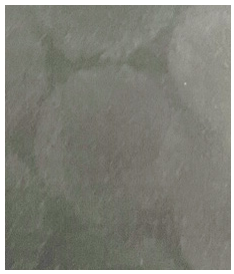
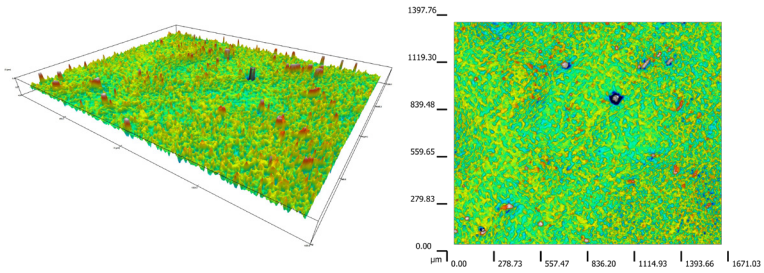
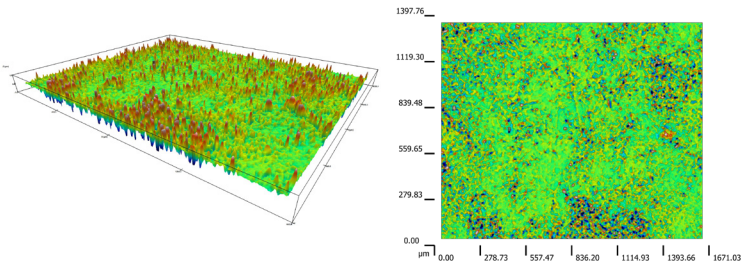
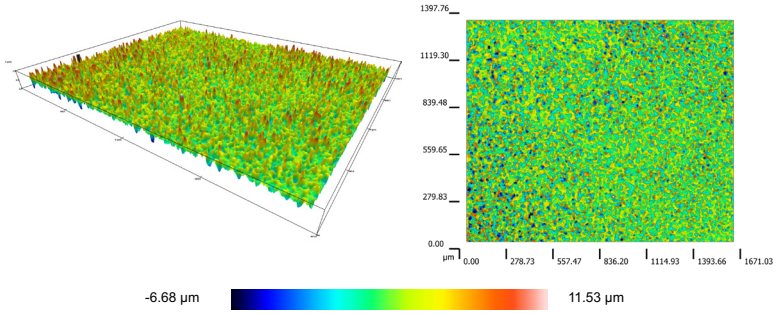
Film Surface Integrity

While no leaks were observed following vibration testing based on the visual, integrity, and soapy water tests, the film surface was further examined to identify the extent of apparent damage on the Ultimus® film assemblies. Many scuff marks were observed post vibration testing; however, these marks were not associated with any leaks. A scuff is a faint rubbed impression in the film that occurs when flat film is rubbed against another surface. To quantify the damage on the film caused by the scuff, a white light interferometry analysis was performed using the Sensofar S-Neox 3-D Optical Profiler. The data was collected following ISO 25178 guidelines.

Three samples with varying degrees of scuff marks created from the vibration testing were analyzed. An untouched Ultimus® film sample was used as a control for comparison of the normal roughness of the Ultimus® film surface. A surface area of 1.67 mm x 1.40 mm was evaluated for each of the samples.

The control Ultimus® film sample had an average surface roughness of 31.5 nm. In comparison, the scuff mark that visually appeared to be most damaged had an average surface roughness of 455 nm (0.000455 mm). Considering that the thickness of Ultimus® film is 0.39 mm, the roughness caused by the scuff mark is only 0.1% of the total film thickness and did not penetrate through the top layer of the film. Although the average surface roughness of the film increased, the level of magnitude of the damage was not significant enough to have caused detrimental damage to the film, as evidenced by successful visual, soapy water, and integrity tests.

Table 3. Surface Roughness Evaluation

Sample	Average Surface Roughness	Visual Marking	Surface Roughness Images
Control (Least Rough)	31.5 nm	Untouched Ultimus® film sample 	
	64.3 nm	Scuff Mark 1 	
	214.0 nm	Scuff Mark 2 	
Most Rough	455.0 nm	Scuff Mark 3 	

Conclusion

- Transport of 1,000 L of liquid in Ultimus® bags in collapsible bins filled to various volumes withstood eight hours of ISTA 3H vibration testing representing 2,400 miles of truck transport, with no leaks observed.
- A single test of a 1,000 L Ultimus® bag in a collapsible bin without a bin liner successfully passed vibration testing – to further demonstrate robust film durability.
- Ultimus® film experienced minimal surface damage after being subjected to eight hours of random vibration testing.

References

1. Demonstrated Strength and Durability of Ultimus® Film, 2022, Lit. no. TB5661EN

2. ISTA 3H, Products or Packaged-Products in Mechanically Handled Bulk Transport Containers, International Safe Transit Association, East Lansing, MI, www.ista.org

3. ISO 25178, Geometrical Product Specifications (GPS), International Organization for Standardization, Geneva, Switzerland, www.iso.org

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Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

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