

Films for **Newsafe™** Contained Powder Transfer Bags



Process Control, Process Traceability, Process Cleanliness

ATMI is a technology leader in the manufacture of single-use bags and consumables for life sciences. The films and contact materials used in Newsafe contained Powder Transfer Bag (cPTB) products represent the culmination of over a decade of experience in ultra-clean polymer film extrusion and bioprocess bag manufacture. As such, they deliver performance to meet or exceed the expectations of the most demanding users in the pharmaceutical industry.

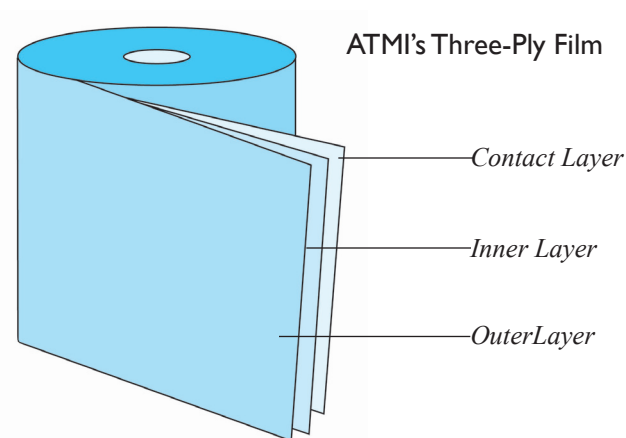
Film Structure and Properties

ATMI offers cPTB products made from three different films: BHN, PSD and BL3. The BHN and PSD films contain FDA-approved additives that dissipate static and

thus improve powder recovery while simultaneously reducing the chance of powder explosions. The BL3 film is made only with pure (additive-free) LDPE resin, and is recommended when damp material is expected, or if a washdown of the bag is necessary.

Each of these films is blow extruded in-house by ATMI under cleanroom conditions (0.2µm filtered nitrogen), ensuring the cleanest possible product-contacting surface. The resulting film has multiple layers of low-density polyethylene (LDPE), a highly flexible polymer which is ubiquitous in the pharmaceutical single-use field due to its purity and broad process compatibility. Each extruded film layer is separated by an air gap that adds extra protection against possible contamination or integrity loss.

The result is a collection of films that are robust, have good optical clarity, are easy to handle, and perform well in a broad range of powder storage and transfer applications. Once extruded, the film is converted into ATMI cPTB products under ISO Class 5 cleanroom conditions.



By performing blow extrusion in-house, ATMI maintains full control and traceability of the contact film composition, from resin through to finished bag product. All resins used in extrusion of cPTB films are traceable by lot.

Table 1 – Film Properties

Property	Test Method	BHN Film	PSD Film	BL3 Film
Thickness	ATMI	150µm	240µm	150µm
Maximum Tensile Strength - MD	ASTM D882-91	>18MPa	>15MPa	>15MPa
Maximum Tensile Strength - TD	ASTM D882-91	>12MPa	>15MPa	>15MPa
Elongation at Break - MD	ASTM D882-91	>500%	>700%	>500%
Elongation at Break - TD	ASTM D882-91	>450%	>800%	>500%
Seal Strength	ASTM D882-91	>25MPa	>20MPa	>25MPa
Surface Resistivity	ASTM D257-66	≤10 ¹² Ohms	≤10 ¹² Ohms	N/A
Static Decay	FED-STD-101-4046	<2 secs	<2 secs	N/A
Cleanliness	ATMI	Class B	Class B	Class B
Shelf Life	ATMI	1 Year	3 Years	3 Years
Gamma Sterilizable	ATMI	Yes	Yes	Yes

Table 2 – Regulatory Compliance

Compliance Test	BHN Film	PSD Film	BL3 Film	
USP<87> In Vitro Biological Reactivity	✓	✓	✓	
USP<88> In Vitro Biological Reactivity	✓	✓	✓	
USP<661> Extractables	✓	✓	✓	
USP<788> Particulates	✓	✓	✓	
EP 2.9.19 Particulates	✓	✓	✓	
EP 3.1.3 Polyolefins	✓	✓	✓	
EP 3.1.5 Parenteral Compatibility	N/A	N/A	✓	
ISO 11137 Sterility	U/R	U/R	U/R	
ISO 11737 Bioburden	✓	✓	✓	
Certified TSE/BSE Safe	✓	✓	✓	
Certified Animal Derived Component Free (ADCF)	X	✓	X	

✓ = Complies
X = Does not comply
N/A = Not Applicable
U/R = Available Upon Request

About ATMI LifeSciences

Advanced Technology Materials Inc. (NASDAQ: ATMI) is the world’s largest manufacturer of ultra-clean flexible containers and packaging. Its experience in the semiconductor and life science industries has driven the company to achieve high standards of product quality and cleanliness. ATMI LifeSciences proprietary films are manufactured in its own facilities and meet applicable industry standards. Every step of the bag manufacturing and assembly process is performed in a controlled environment under ISO Class 5 cleanroom conditions. Contact your local ATMI LifeSciences representative to discuss your particular process needs, and how ATMI can contribute to your success.

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