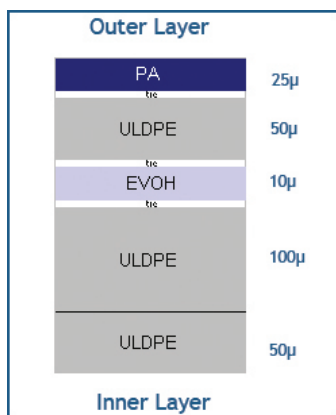


# TK8 Film

## Process Control - Process Traceability - Process Cleanliness

ATMI is a technology leader in the manufacture of single-use bags and consumables for the life science industry. Our TK8 film represents the culmination of over a decade of experience in ultra-clean polymer film extrusion and bioprocess bag manufacture, and delivers performance to meet or exceed the expectations of the most demanding users. TK8 embodies ATMI's "one film" philosophy, giving users access to a single film capable of serving in the full range of bioprocess single-use bag applications, from storage bags through to mixing bags and even bioreactor bags. This approach can yield significant savings in validation effort, time and cost.

## TK8 Film Structure



The TK8 film is constructed from laminated layers of PA (polyamide), EVOH (ethylene vinyl alcohol polymer) and ULDPE (ultralow density polyethylene). The outer PA layer provides robust puncture resistance, strength, and excellent thermal stability. The EVOH layer minimizes gas diffusion across the film while maintaining a very good flex crack resistance. The ULDPE layers provide flexibility, integrity and an ultra-clean, ultra-pure, low-extractables product contacting layer.

The combination of these layers results in a film that has outstanding optical clarity, is easy to handle, and performs well in a broad range of bioprocess applications. The inner ULDPE layer used in TK8 is blow extruded in-house by ATMI under cleanroom conditions (0.2µm filtered air), ensuring the cleanest possible product-contacting surface. Lamination is also performed under controlled, ultra-clean conditions. Lastly, TK8 film is converted into ATMI bag products in our ISO Class 5 cleanroom.

## Traceability & Compliance

All of the layers in TK8 are made from "medical grade" materials, meaning that they comply with industry standards and are subject to strict change controls. The entire structure of TK8 is totally free of any animal derived components (ADCF). ATMI has also created TK8 with dual sourcing and contingency planning in mind, to ensure security of supply.

- TK8 film complies with USP Class VI (USP<87>, USP<88>, and USP<661>)
- ULDPE resin complies with EP 3.1.3. and USP 28
- Shelf life is supported by accelerated aging validation study.
- Certified ADCF.
- Bioburden evaluation available (ISO 11737)
- Particle count data available (EP 2.9.19 or USP<788>)
- By performing blow extrusion in-house, ATMI maintains full control and traceability of the contact film composition, from resin through to finished bag product.

## Leachables/Extractables & Chemical Compatibility Data

An extensive dossier of leachables/extractables data is available upon request. Tests were performed at 40°C, over durations up to 4 weeks.

Extraction solvents include:

- WFI
- Ethanol
- HCl (pH<2)
- NaOH (pH>12)
- Saline (1M NaCl)
- DMSO (10%) (tested at -20°C)
- Tween (0.1%)
- DCM

Additional studies have demonstrated chemical compatibility with the following common bioprocess materials under various, process-typical conditions:

- MgSO4.7H2O
- MnSO4.7H2O.
- Ethanol (55%)
- Riboflavine
- Kanamycine sulfate
- Caseine hydrolysate
- Tromethamine
- Diethanolamine
- Guanidine HCl
- Yeast extract
- Bleach (15%)
- NaOH (0.5M-50%)
- Acetic acid

## Biocompatibility Data (Tested on 50kGy gamma irradiated film)

	Biological Reactivity Test In Vitro	Biological Reactivity Test In Vivo	Systemic Injection Test	Intracutaneous Reactivity Test	Implantation test
<b>Test Protocol</b>	USP <87> ISO10993 part 5	USP <88>	ISO10993, part 11	ISO10993, part 10	ISO10993, part 6
<b>Result</b>	Pass	Pass- Class VI - 70°C	Pass	Pass	Pass

## Physicochemical Data (Tested on 50kGy gamma irradiated film)

	Non Volatile Residue	Heavy Metals	Buffering Capacity	Appearance of Solution	Acidity or Alkalinity	Reducing Substances	Transparency
<b>Test Protocol</b>	USP <661>	USP <661>	USP <661>	EP3.2.2.1	EP3.2.2.1	EP3.2.2.1	EP3.2.2.1
<b>Result</b>	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Recommended Minimum pH (application dependent): 2

Recommended Maximum pH (application dependent): 12

## Physical Properties

Parameter	Test Method	Mean Value
Thickness	ATMI LifeSciences	250µm
Barrier properties		
O <sub>2</sub> transmission rate	ASTM D3895 23°C, 50% RH outside 90% RH inside	0.37 cc/m <sup>2</sup> /day
Water vapor transmission rate	ASTM F1249 23°C, 0% RH outside 100% RH inside	0.41 g/m <sup>2</sup> /day
CO <sub>2</sub> transmission rate	MOCON - 23°C, 0% RH	<1cc/m <sup>2</sup> /day (below detection limit)
Tested on 50kGy gamma irradiated film:		
Strength and Elongation	ASTM D882-91	
Strength ( <i>machine direction</i> ) MD		25 MPa
Strength ( <i>transverse direction</i> ) TD		25 MPa
Elongation MD		125 MPa
Elongation TD		100 MPa
Young Modulus	ASTM D882-91	590 MPa 500 MPa
Puncture resistance		
Max load	FTMS 101B	130 N
Deflection at max load		9 mm
Dart drop (method B)		1100g
Seal behavior	ASTM D1709-01	
Seal strength	ASTM D882-91	90 N/15 mm
Elongation		59 %
Tear resistance	ISO 6383/1	
Avg force MD		17 N
Avg force TD		29 N
Initial Max Force MD		18N
Initial Max Force TD		32N
Sterilizable		at 25kGy
Shelf life		3 years

Recommended Minimum Operating Temperature (application dependent): -20°C

Recommended Maximum Operating Temperature (application dependent): +80°C

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ATMI LifeSciences is known for its development of engineered solutions that help customers with their handling of critical materials and critical active ingredients. The company's knowledge of advanced materials is one of their core competencies. ATMI LifeSciences proprietary films are manufactured in its facilities and meet approval standards for each application. Every step of the bag manufacturer process, as well as package assembly, is done in a controlled environment under cleanroom ISO Class 5 conditions at rest.

