

Ami Polymer

FILMS | TUBING | HOSES | SINGLE USE ASSEMBLIES & BAGS | GASKETS & BELLOWS | INFLATABLE SEALS



POLYMER FILMS FOR LIFE-SCIENCES INDUSTRY



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About Us

Since 1998, APPL has been engaged in the business of polymer products, which ultimately provide solutions to fluid transfers, sealing and contamination controls for the pharma, biopharma, medical, laboratory, food, beverage and engineering sectors worldwide.

APPL has ISO class 7 and 8 cleanroom facilities certified with ISO 9001:2015, ISO 14001:2015, ISO 45001:2018, ISO 27001:2013, ISO 13485:2016 and ISO 15378:2017. We also have a BPOG extractables program for our products for regulatory markets worldwide.

APPL has world-class manufacturing technology with end-to-end process capabilities to fulfill the needs of customers. Our advanced facilities include laser-controlled extrusion, automated hose production lines, thermoplastic extrusion lines, automatic hydraulic presses for elastomers and polymeric components, a cutting-edge laboratory equipped with R&D machinery, in-house tooling and mold-making machinery, laser cutting machines and online printing and marking systems.

The company believes in "Be in business with ethics" and assure quick development, fastest delivery, ultimate quality and also very competitive rates.

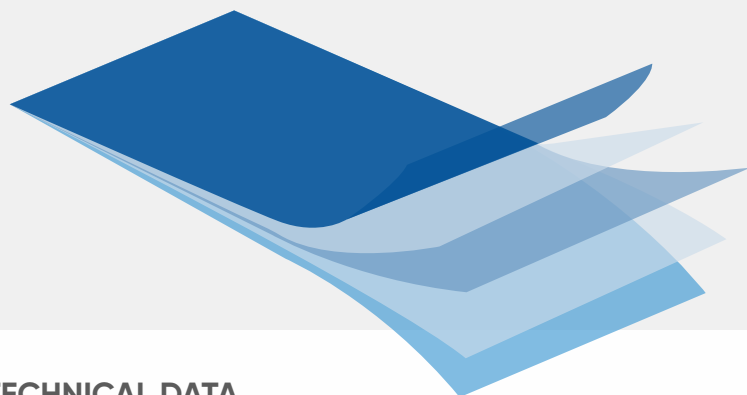
Certification and Compliance



Imaflexell™ B01

Aseptic Processing Film with ULDPE as contact layer & EVOH as barrier layer

The Imaflexell™ B01 features a five-layer structure with an inner contact layer of Ultra Low-Density Polyethylene (ULDPE) resists a wide range of chemicals, while enhancing mechanical strength and an outer layer of Low-Density Polyethylene (LDPE) that provides durability by resisting abrasions, punctures and tearing to prevent leaks. The core layer made of EVOH is barrier against oxygen, which helps in preserving the integrity and shelf life of sensitive products.



FILM COMPOSITION

- 50 µm LDPE - Outer Layer
- 10 µm TIE - Bonding Layer
- 20 µm EVOH - Gas Barrier Layer
- 10 µm TIE - Bonding Layer
- 230 µm ULDPE - Contact Layer

TECHNICAL DATA

Appearance	Transparent
Available Width	1400mm
Available Thickness	320 µm
Recommended Sealing Method	Heat Sealing
Recommended Sterilization Method	Gamma, E-Beam
Manufactured Environment	Cleanroom ISO Class 7

PHYSICAL PROPERTIES

Technical Data	Test Method	Unit of Measure	Values
Tensile Strength at Break	ASTM D882	MPa	13 /13
Elongation at Break (MD/TD)	ASTM D882	%	509/662
Haze	ASTM D1003	%	4.3
Transmittance	ASTM D1003	%	91.5
Density	ASTM D792	gm/cm ³	0.91
Water Vapour Transmission Rate (23° C, 100% RH)	ASTM F1249	g/m ² /24h	0.25
Carbon Dioxide Permeability (23°C, 0%RH)	ASTM F2476	cm ³ /m ² /day/bar	0.25
Oxygen Permeability (23°C, 0%RH)	ASTM D3985	cm ³ /m ² /day/bar	0.07

Gamma Irradiation Sterilization: It can be sterilized by Gamma Radiation at 25 kGy to 40 kGy.

PHARMACOPOEIA AND BIOCOMPATIBILITY TEST

Ami Polymer Pvt. Ltd. certifies that the product mentioned in this catalogue complies as per below listed testing requirements. Described here in;	
Biological Reactivity, in vitro (Cytotoxicity Test)	USP<87>
Biological Reactivity, in vivo (Acute Systemic Toxicity, Intracutaneous and Implantation Test)	USP <88>
Bacterial Endotoxins - LAL Test	USP<85>
Extractable Study as per BPOG Guidelines	24 hours, 21 days, *70 days
Physicochemical Test	USP <661.1>
Hemocompatibility Test	ISO 10993-4
Skin Sensitization Test	*ISO 10993-10
Skin Irritation Test	ISO 10993-23
Food grade test	FDA 21 CFR 177. 1520
ROHS Complied (Restriction of hazardous substance)	Directive (EU) 2015/863
REACH (SVHC) Complied	(EC) No 1907/2006
TSE/BSE Declaration (ADI -Animal Derived Ingredients free)	
Phthalate Content Free	
Bisphenol A (BPA) Content Free	

*Note: Test Certifications provided above are under testing

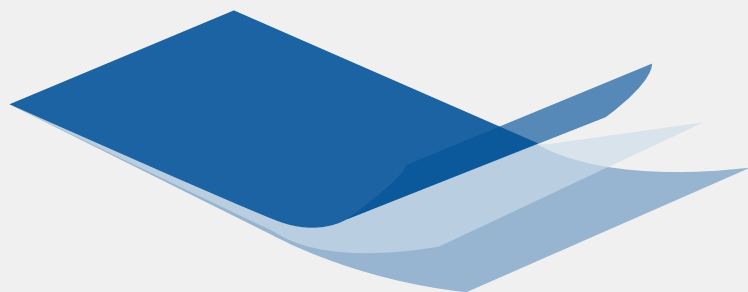
APPLICATION

The Imaflexell™ B-01 Film is designed for biopharma applications, such as liquid single-use bags and containers for transferring and storing liquids. It offers a low oxygen transmission rate and provides excellent flexibility, mechanical strength and good puncture resistance. It is commonly used in mixing systems, media storage, bioreactor sampling and product storage containers.

Imaflexell™ L01

Aseptic Processing Film with ULDPE as contact layer for liners.

The Imaflexell™ L01 features a three-layer design with an inner contact layer of Ultra Low-Density Polyethylene (ULDPE), enhancing mechanical strength, flexibility and toughness. The outer layer is made of Low-Density Polyethylene (LDPE), providing resistance to abrasions, punctures and tears, effectively preventing leaks. The core layer, made of Linear Low-Density Polyethylene (LLDPE) for flexibility with enhanced toughness, improving puncture resistance.



FILM COMPOSITION

- 50 µm LDPE – Outer Layer
- 60 µm LLDPE – Core Layer
- 140 µm ULDPE – Contact Layer

TECHNICAL DATA

Appearance	Transparent
Available Width	1400mm
Available Thickness	250 µm
Recommended Sealing Method	Heat Sealing
Recommended Sterilization Method	Gamma, E-Beam
Manufactured Environment	Cleanroom ISO Class 7

PHYSICAL PROPERTIES

Technical Data	Test Method	Unit of Measure	Values
Tensile Strength at Break	ASTM D882	MPa	23/19
Elongation at Break (MD/TD)	ASTM D882	%	732/1189
Haze	ASTM D1003	%	5.9
Transmittance	ASTM D1003	%	85.6
Density	ASTM D792	gm/cm ³	0.89

Gamma Irradiation Sterilization: It can be sterilized by Gamma Radiation at 25 kGy to 40 kGy.

PHARMACOPOEIA AND BIOCOMPATIBILITY TEST

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Biological Reactivity, in vitro (Cytotoxicity Test)	USP<87>
Biological Reactivity, in vivo (Acute Systemic Toxicity, Intracutaneous and Implantation Test)	USP <88>
Bacterial Endotoxins – LAL Test	USP<85>
Extractable Study as per BPOG Guidelines	24 hours, 21 days, *70 days
Physicochemical Test	USP <661.1>
Hemocompatibility Test	ISO 10993-4
Skin Sensitization Test	*ISO 10993-10
Skin Irritation Test	ISO 10993-23
Food grade test	FDA 21 CFR 177.1520
ROHS Complied (Restriction of hazardous substance)	Directive (EU) 2015/863
REACH (SVHC) Complied	(EC) No 1907/2006
TSE/BSE Declaration (ADI – Animal Derived Ingredients free)	
Phthalate Content Free	
Bisphenol A (BPA) Content Free	

*Note: Test Certifications provided above are under process of testing
Note: Certification provided above are mentioned as per Imaflexell™ B01 film, as the contact layer of film is similar

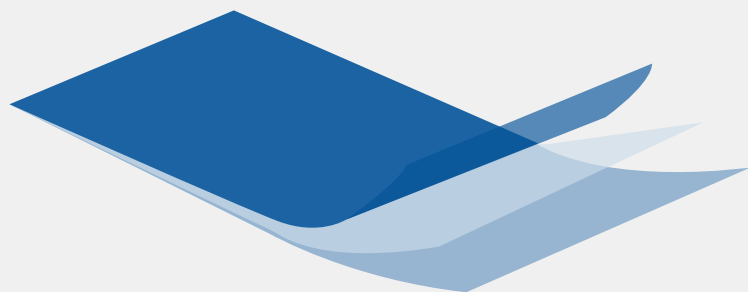
APPLICATION

Designed for safe handling and sterile containment, this three-layer Imaflexell™ L01 liner film offers high strength, excellent flexibility, elongation and puncture resistance. It is ideal for storage, filling, mixing, waste collection, batch handling in biopharma processing.

Imaflexell™ A01

Aseptic Processing Film with Antistatic LLDPE as product contact layer.

The Imaflexell™ A01 features a three-layer design. The inner layer is made of low-density polyethylene combined with an antistatic agent, providing a permanent antistatic property. The core layer is composed of Metallocene linear low-density polyethylene, offering excellent tensile strength, transparency and durability. The outer layer is made of linear low-density polyethylene, providing excellent flexibility and resistance to punctures and tears.



FILM COMPOSITION

- 50 µm LLDPE – Outer Layer
- 50 µm mLDPE – Core Layer
- 150 µm LLDPE + Antistatic – Contact Layer

TECHNICAL DATA

Appearance	Transparent
Available Width	1400mm
Available Thickness	250 µm
Recommended Sealing Method	Heat Sealing
Recommended Sterilization Method	Gamma, E-Beam
Manufactured Environment	Cleanroom ISO Class 7

PHYSICAL PROPERTIES

Technical Data	Test Method	Unit of Measure	Values
Tensile Strength at Break	ASTM D882	MPa	26/ 13
Elongation at Break (MD/TD)	ASTM D882	%	472/1103
Haze	ASTM D1003	%	23
Transmittance	ASTM D1003	%	90.2
Density	ASTM D792	gm/cm ³	0.9
Water Vapour Transmission Rate (23° C, 100% RH)	ASTM F1249	g/m ² /24h	0.26
Oxygen Permeability (23°C, 0%RH)	ASTM D3985	cm ³ /m ² /day/bar	0.002

Gamma Irradiation Sterilization: It can be sterilized by Gamma Radiation at 25 kGy to 40 kGy.

PHARMACOPOEIA AND BIOCOMPATIBILITY TEST

Ami Polymer Pvt. Ltd. certifies that the product mentioned in this catalogue complies as per below listed testing requirements. Described here in;

Biological Reactivity, in vitro (Cytotoxicity Test)	*USP<87>
Biological Reactivity, in vivo (Acute Systemic Toxicity, Intracutaneous and Implantation Test)	*USP <88>
Bacterial Endotoxins – LAL Test	USP<85>
Extractable Study as per BPOG Guidelines	*24 hours, 7 days
Physicochemical Test	USP <661.1>
Hemocompatibility Test	*ISO 10993-4
Skin Sensitization Test	*ISO 10993-10
Skin Irritation Test	*ISO 10993-23
Food grade test	FDA 21 CFR 177. 1520
ROHS Complied (Restriction of hazardous substance)	Directive (EU) 2015/863
REACH (SVHC) Complied	(EC) No 1907/2006
TSE/BSE Declaration (ADI –Animal Derived Ingredients free)	
Phthalate Content Free	
Bisphenol A (BPA) Content Free	

*Note: Test Certifications provided above are under testing

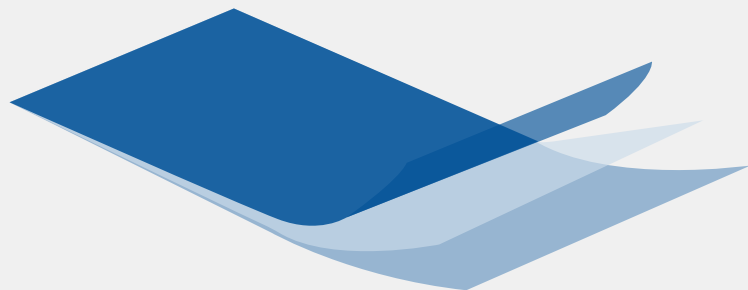
APPLICATION

The One-Sided Antistatic Imaflexell™ A01 Film is developed for biopharma and pharmaceutical applications, ensuring electrostatic protection, cleanroom compatibility and contamination control. It is ideal for sterile packaging and sensitive drug formulations. The film is also used in optimal powder handling, preventing static buildup and ensuring smooth material flow with its static dissipative properties.

Imaflexell™ A02

Aseptic Processing Film with both side (inner/outer) Antistatic LLDPE layers.

The Imaflexell™ A02 features a three-layer structure with antistatic properties on both sides. The inner layer is made of linear low-density polyethylene combined with an antistatic agent, ensuring product cleanliness and providing a permanent antistatic effect. The core layer is composed of Metallocene linear low-density polyethylene, offering excellent tensile strength, transparency, and durability. The outer layer also consists of linear low-density polyethylene mixed with a long-lasting antistatic agent.



FILM COMPOSITION

- 50 µm LLDPE + Antistatic – Outer Layer
- 50 µm mLDPE – Core Layer
- 150 µm LLDPE + Antistatic – Contact Layer

TECHNICAL DATA

Appearance	Transparent
Available Width	1400mm
Available Thickness	250 µm
Recommended Sealing Method	Heat Sealing
Recommended Sterilization Method	Gamma, E-Beam
Manufactured Environment	Cleanroom ISO Class 7

PHYSICAL PROPERTIES

Technical Data	Test Method	Unit of Measure	Values
Tensile Strength at Break	ASTM D882	MPa	24/ 14
Elongation at Break (MD/TD)	ASTM D882	%	1368/ 1278
Haze	ASTM D1003	%	29
Transmittance	ASTM D1003	%	61.2
Density	ASTM D792	gm/cm ³	0.89
Water Vapour Transmission Rate (23° C, 100% RH)	ASTM F1249	g/m ² /24h	0.26*
Oxygen Permeability (23°C, 0%RH)	ASTM D3985	cm ³ /m ² /day/bar	0.002*

*Above Test Results mentioned are as per Imaflexell™ A01 film, as the contact layer of film is similar Gamma Irradiation Sterilization: It can be sterilized by Gamma Radiation at 25 kGy to 40 kGy.

PHARMACOPOEIA AND BIOCOMPATIBILITY TEST

Ami Polymer Pvt. Ltd. certifies that the product mentioned in this catalogue complies as per below listed testing requirements. Described here in;

Biological Reactivity, in vitro (Cytotoxicity Test)	*USP<87>
Biological Reactivity, in vivo (Acute Systemic Toxicity, Intracutaneous and Implantation Test)	*USP <88>
Bacterial Endotoxins – LAL Test	USP<85>
Extractable Study as per BPOG Guidelines	*24 hours, 7 days
Physicochemical Test	USP <661.1>
Hemocompatibility Test	*ISO 10993-4
Skin Sensitization Test	*ISO 10993-10
Skin Irritation Test	*ISO 10993-23
Food grade test	FDA 21 CFR 177.1520
ROHS Complied (Restriction of hazardous substance)	Directive (EU) 2015/863
REACH (SVHC) Complied	(EC) No 1907/2006
TSE/BSE Declaration (ADI – Animal Derived Ingredients free)	
Phthalate Content Free	
Bisphenol A (BPA) Content Free	

*Note: Test Certifications provided above are under process of testing
Note: Certification provided above are mentioned as per Imaflexell™ B01 film, as the contact layer of film is similar

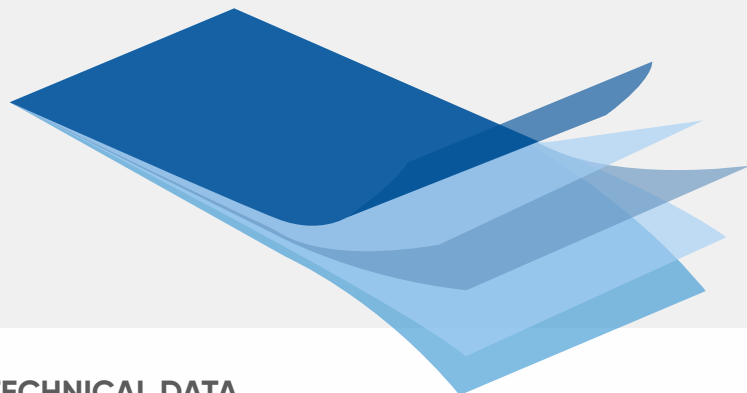
APPLICATION

The Imaflexell™ A02 can be utilised in flexible enclosures and isolators, offering permanent antistatic properties with a surface resistivity of $10^{11} \Omega$ per square. Both sides of the film are treated with antistatic agents, providing effective electrostatic control in cleanrooms, sterile packaging and pharmaceutical applications. It's ideal for powder handling, material flow and protecting sensitive material.

Imaflexell™ C01

Freezing Application Film with EVA as Contact Layer

The Imaflexell™ C01 features a five-layer structure, with an inner contact layer made from Ethylene-Vinyl Acetate (EVA), providing mechanical strength and high flexibility in low-temperature environments. The outer layer is constructed from Low-Density Polyethylene (LDPE), providing transparency and flexibility. EVA ensures the film maintains its integrity in cryogenic conditions by resisting abrasions, punctures, stretching, and tearing, while staying flexible and not becoming brittle in low temperatures. The film enhance the product's lifespan in demanding cold storage environments.



FILM COMPOSITION

- 50 µm LDPE - Outer Layer
- 10 µm TIE - Bonding Layer
- 20 µm EVOH - Gas Barrier Layer
- 10 µm TIE - Bonding Layer
- 230 µm EVA - Contact Layer

TECHNICAL DATA

Appearance	Transparent
Available Width	1400mm
Available Thickness	320 µm
Recommended Sealing Method	Heat Sealing
Recommended Sterilization Method	Gamma, E-Beam
Manufactured Environment	Cleanroom ISO Class 7

PHYSICAL PROPERTIES

Technical Data	Test Method	Unit of Measure	Values
Tensile Strength at Break	ASTM D882	MPa	16/8
Elongation at Break (MD/TD)	ASTM D882	%	380/ 482
Haze	ASTM D1003	%	3.57
Transmittance	ASTM D1003	%	93.4
Density	ASTM D792	gm/cm ³	0.95
Water Vapour Transmission Rate (23° C, 100% RH)	ASTM F1249	g/m ² /24h	0.46
Oxygen Permeability (23°C, 0%RH)	ASTM D3985	cm ³ /m ² /day/bar	0.002

Gamma Irradiation Sterilization: It can be sterilized by Gamma Radiation at 25 kGy to 40 kGy.

PHARMACOPOEIA AND BIOCOMPATIBILITY TEST

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Biological Reactivity, in vitro (Cytotoxicity Test)	*USP<87>
Biological Reactivity, in vivo (Acute Systemic Toxicity, Intracutaneous and Implantation Test)	*USP <88>
Bacterial Endotoxins - LAL Test	USP<85>
Extractable Study as per BPOG Guidelines	*24 hours, 21 days, 70 days
Physicochemical Test	*USP <661.1>
Hemocompatibility Test	*ISO 10993-4
Skin Sensitization Test	*ISO 10993-10
Skin Irritation Test	*ISO 10993-23
ROHS Complied (Restriction of hazardous substance)	Directive (EU) 2015/863
REACH (SVHC) Complied	(EC) No 1907/2006
TSE/BSE Declaration (ADI - Animal Derived Ingredients free)	
Phthalate Content Free	
Bisphenol A (BPA) Content Free	

*Note: Test Certifications provided above are under testing

APPLICATION

The single-sided EVA Imaflexell™ C01 film offers excellent flexibility, making it ideal for bioprocessing, storage and pharmaceutical packaging. Designed for low-temperature applications, it provides good moisture and oxygen barrier properties, preserving the stability of critical products like stem cells during storage. It is commonly used in freezing bags, ensuring safe and secure containment in cryogenic conditions.



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MANUFACTURING UNIT- II

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