

# Technical Bulletin

## BIOEAZE™ Bags — Ethyl Vinyl Acetate (EVA) Film



### APPLICATIONS

BIOEAZE™ BAGS	STERILE SAMPLING	FILTRATION	FLUID TRANSFER
<ul style="list-style-type: none"> <li>• Media storage</li> <li>• Harvest</li> <li>• Waste collection</li> <li>• Water</li> <li>• Buffers</li> <li>• Bulk therapeutics</li> <li>• Replacement of glass bottles and carboys</li> </ul>	<ul style="list-style-type: none"> <li>• Quality control, retention, pH</li> <li>• During scale-up</li> <li>• From bioreactor</li> <li>• During formulation, fill and finish</li> <li>• Concentration/purification</li> <li>• Harvest</li> </ul>	<ul style="list-style-type: none"> <li>• Media</li> <li>• Concentration, buffer exchange</li> <li>• Purification</li> <li>• Virus removal</li> </ul>	<ul style="list-style-type: none"> <li>• Media in/out to bioreactors</li> <li>• Inoculation</li> <li>• Feeds</li> <li>• Supplements, reagents</li> <li>• Product harvest</li> <li>• Buffers, buffer exchange</li> <li>• Replace flex lines</li> </ul>

### BIOEAZE™ DISPOSABLE BIOPROCESS BAGS

FEATURES	AVAILABLE BAG CONFIGURATIONS
<ul style="list-style-type: none"> <li>• Multi-layer, single-web laminate film</li> <li>• Barrier to oxygen, nitrogen and carbon dioxide</li> <li>• Chlorine free</li> <li>• Translucent material providing excellent clarity</li> <li>• Puncture resistant</li> <li>• Non-leachable, inert plastic</li> <li>• Assembly in a Class 10,000 HEPA filtered clean room</li> <li>• Complete documentation and traceability</li> </ul>	<ul style="list-style-type: none"> <li>• Range of sizes and capabilities, with various port configurations <ul style="list-style-type: none"> <li>♦ EVA: 75 mL to 30 L</li> </ul> </li> <li>• Designed with or without rigging sets</li> <li>• Designed with or without filter sets</li> <li>• Sterile, gamma irradiated (irradiation certificate provided)</li> <li>• Custom bag sizes available on request</li> <li>• Non-sterile bags available on request</li> </ul>

BIOEAZE™ bags and disposable bioprocessing systems are designed by SAFC Biosciences to address your specific needs and applications. Disposable technology provides many advantages, including the elimination of cleaning and sterilization procedures and the validation of these processes.

BIOEAZE™ disposable bioprocess bags are routinely used as flexible containers for the pharmaceutical and biotechnology industries. BIOEAZE™ bioprocess bags are specifically designed to provide strong seals, extraordinary robustness, superior flex, crack and pin-hole resistance, plus desirable gas and moisture barrier performance.

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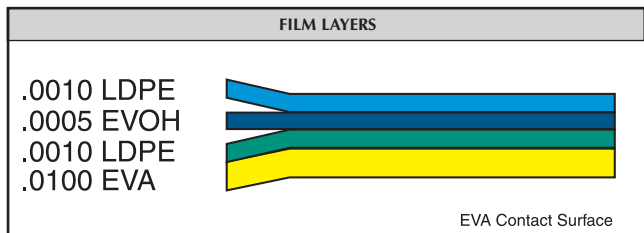
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BIOEAZE™ Ethyl Vinyl Acetate (EVA) bags are constructed from a single-web, medical grade laminate of four different films, with a fluid contact surface of EVA, and two layers of low-density polyethylene (LDPE) enveloping a layer of ethyl vinyl alcohol (EVOH).

EVA bags are assembled in a Class 10,000 HEPA filtered clean room, and all materials and processes are in accordance with Current Good Manufacturing Practices (cGMPs) and meet United States Pharmacopeia (USP) Class VI Plastics Guidelines. In addition, the bags have been tested using the appropriate specifications of the following methods/guidelines:

- American Standards Test Methods (ASTM)
- International Standards Organization (ISO) Quality System Requirements



Sterility Assurance Level	
	Value
SAL	10 <sup>-6</sup>

EVA Contact Layer	
Size Liter	Bag Style 2-D (pillow)
75 - 100 mL	x
350 mL	x
1 L	x
2 L	x
5 L	x
10 L	x
20 L	x
30 L	x

CHEMICAL AND BIOCOMPATIBILITY RESULTS OF EVA FILM MEETS USP CLASS VI MEDICAL GRADE PLASTIC REQUIREMENTS		
	VALUE	METHOD
Intracutaneous Reactivity Test in Rabbits	Pass	ISO 10993-10
Acute Systemic Injection Test in Mice	Pass	ISO 10993-11
Intramuscular Implantation Test in Rabbits	Pass	ISO 10993-6
Cytotoxicity	Pass	USP<87>
Hemolysis	Nonhemolytic	NIH, ISO 10993-4
Endotoxin (EU/mL)	< 0.015	LAL
Nonvolatile Residue	Pass	USP<661>
Heavy metals	Pass	USP<661>
Buffering capacity	Pass	USP<661>
Residue on Ignition	None applicable	USP<661>

## PHYSICAL PROPERTIES OF EVA FILM

	LONGITUDINAL DIRECTION	TRANSVERSE DIRECTION	METHOD
Tensile strength (psi)	2940	2230	ASTM D-882-00
Elongation at Break (%)	565	465	ASTM D-882-00
Modulus @ 100% Elongation (psi)	55	126.9	ASTM D-882-00
Tear Resistance (psi)	831	781	ASTM D-1004-03
		RESULT	METHOD
Puncture Resistance (lbf)		11.3	FSMS 101B
Brittleness Temperature (C)		-77	ASTM D-746-98
Specific Gravity		0.96	ASTM D-792-00
Water Vapor Transmission Rate (g/100 in <sup>2</sup> /24 hours @ 37.8 C, 100% RH)		0.31	ASTM F-1249-90
Oxygen Transmission Rate (cc/100 in <sup>2</sup> /24 hours/atm O <sub>2</sub> @ 23 C, 50% RH)		0.11	ASTM D-3985
Carbon Dioxide Transmission Rate (cc/100 in <sup>2</sup> /24 hours @ 23 C, 0% RH)		3.4	ASTM F-1249-90

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Additional Terms and Conditions are contained in the product Catalog, a copy of which is available upon request.

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