SAFC Biosciences™
Accelerate Success™

Technical Bulletin

BIOEAZE™ Bags — Polyethylene (PE) Film

BIOEAZE™
Connecting Process to Progress.™

APPLICATIONS			
BIOEAZE™ BAGS	**STERILE SAMPLING**	**FILTRATION**	**FLUID TRANSFER**
• Media storage	• Quality control, retention, pH	• Media	• Media in/out to bioreactors
• Harvest	• During scale-up	• Concentration, buffer exchange	• Inoculation
• Waste collection	• From bioreactor	• Purification	• Feeds
• Water	• During formulation, fill and finish	• Virus removal	• Supplements, reagents
• Buffers	• Concentration/purification		• Product harvest
• Bulk therapeutics	• Harvest		• Buffers, buffer exchange
• Replacement of glass bottles and carboys			• Replace flex lines

BIOEAZE™ DISPOSABLE BIOPROCESS BAGS	
FEATURES	**AVAILABLE BAG CONFIGURATIONS**
• Multi-layer, single-web laminate film	• Standard bag sizes with various port configurations
• Barrier to oxygen, nitrogen and carbon dioxide	♦ PE: 1 L to 1,000 L
• Chlorine free	♦ Custom: 60 mL to 2000 + L
• Translucent material providing excellent clarity	• Designed with or without rigging sets
• Puncture resistant	• Designed with or without filter sets
• Non-leachable, inert plastic	• Sterile, gamma irradiated (irradiation certificate provided)
• Assembly in a Class 10,000 HEPA filtered clean room	• Custom bag sizes available on request
• Complete documentation and traceability	• Non-sterile bags available on request

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.

BIOEAZE™ polyethylene (PE) bags are constructed with two layers (a dual-web) of translucent film, where the fluid contact surface (the innermost layer) is a single layer of Dow ATTANE™ ultra low-density polyethylene (ULDPE). ULDPE offers low temperature flexibility, is non-leachable and inert, making it ideal for containing liquids. The outer layer is a laminate of nylon, polyvinylidene chloride (PVDC) and linear low density polyethylene (LLDPE). These resins provide a barrier to gas transmission and are puncture resistant.

BIOEAZE™ PE 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)

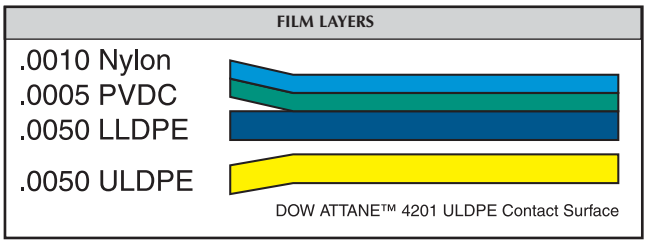
United States
SAFC Biosciences, Inc.
13804 W. 107th Street
Lenexa, Kansas 66215
USA
Phone +1 913-469-5580
Toll free-USA 1 800-255-6032
Fax +1 913-469-5584
E-mail info-na@sial.com

Europe
SAFC Biosciences Ltd.
Smeaton Road, West Portway
Andover, Hampshire SP10 3LF
UNITED KINGDOM
Phone +44 (0)1264-333311
Fax +44 (0)1264-332412
E-mail info-eu@sial.com

Asia Pacific
SAFC Biosciences Pty. Ltd.
18-20 Export Drive
Brooklyn, Victoria 3025
AUSTRALIA
Phone +61 (0)3-9362-4500
Toll free-AUS 1 800-200-404
Fax +61 (0)3-9315-1656
Fax info-ap@sial.com

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
- Japanese Pharmacopoeia Test Methods
- European Pharmacopoeia Monograph Testing Section 3.2.2.1
- European Pharmacopoeia Monograph Testing Section 3.1.5



PE Contact Layer		
Size Liter	Bag Style 2-D (pillow)	Bag Style 3-D
1 L	x	
5 L	x	
10 L	x	
20 L	x	
50 L	x	
100 L	x	
200 L	x	x
500 L	x	x
1000 L		x
1000 - 2000 + L		x
Rocker - 10 L	x	
Rocker - 20 L	x	

Sterility Assurance Level	
	Value
SAL	10^{-6}

PHYSICAL PROPERTIES OF INNER AND OUTER PE BAG FILMS

	LONGITUDINAL DIRECTION (INNER / OUTER FILM)	TRANSVERSE DIRECTION (INNER / OUTER FILM)	METHOD
Tensile strength (psi)	5024 / 4604	5061 / 4420	ASTM D-882-00
Elongation at Break (%)	906 / 518	980 / 580	ASTM D-882-00
Modulus @ 100% Elongation (psi)	1391 / 2100	1300 / 1931	ASTM D-882-00
Initial Tear Resistance (Newtons)	15.34 / 18.32	14.58 / 18.04	ASTM D-1004-03
Initial Tear Resistance (lb)	3.447 / 4.117	3.227 / 4.054	ASTM D-1004-03

	VALUE (INNER / OUTER FILM)	METHOD(S)
Oxygen Transmission Rates (cc/100 in^2/24 hours/atm 0_2)	132.26 / 2.52	ASTM D-1434
Permeance (mol/m^2 • sec • Pa)	1.04E-13 / 1.97E-15	ASTM D-1434
Permeability (mol/m^2 • sec • Pa)	2.15E-17 / 4.80E-19	ASTM D-1434
Carbon Dioxide Transmission Rates (cc/100 in^2/24 hours)	656.7 / 3.02	ASTM D-1434
Permeance (mol/m^2 • sec • Pa)	5.23E-13 / 2.41E-15	ASTM D-1434
Permeability (mol/m^2 • sec • Pa)	1.07E-16 / 5.68E-19	ASTM D-1434
Density (g/cm^3)	0.935 / 1.011	ASTM D-1505, D-792-00
Thickness (mils)	5.26 / 6.20	ASTM D-1434
Slow Rate Puncture Resistance Load @ Rupture (lb)	36.00 / 62.78	FTMS 101-2031
Brittleness at Low Temperature by Impact	< -40 F / < -40 F	ASTM D-746, D-1790

PHYSICAL PROPERTIES OF COMPLETE PE BAGS
(BOTH FILM LAYERS TESTED AS A WHOLE)

	RESULT	METHODS
Puncture Resistance and Elongation Maximum Load (lbf)	22.9	FTMS 101C-2065
Load/Thickness at Max Load (lbf/in)	1990	FTMS 101C-2065
Displacement at Max Load (in)	0.79	FTMS 101C-2065
Water Vapor Transmission Rate (g/100 in^2/24 hours @ 37.8 C, 100% RH)	0.124	F-1249-90
Oxygen Transmission Rate (cc/100 in^2/24 hours @ 23 C, 0% RH)	0.470	D-3985

BIOCOMPATIBILITY AND BIOCHEMICAL PROPERTIES		
	VALUE (INNER / OUTER)	METHOD
Intracutaneous Reactivity Test in Rabbits	Pass / Pass	USP<88>
Acute Systemic Injection Test in Mice	Pass / Pass	USP<88>
Intramuscular Implantation Test in Rabbits	Pass / Pass	USP<88>
Cytotoxicity	Pass / Pass	USP<87>
Non-Volatile Residue	Pass / Pass	USP<661>
Heavy Metals	Pass / Pass	USP<661>
Buffering Capacity	Pass / Pass	USP<661>
Hemolysis (Direct Contact Method)	Nonhemolytic / Nonhemolytic	NIH
Endotoxin (EU/mL)	< 0.025 / < 0.015	LAL

European Pharmacopoeia (4th Edition, 2004) Monograph Testing Section 3.2.2.1, Plastic Containers for Aqueous Solutions for Parenteral Infusion.

TESTING PERFORMED ON FLUID CONTACT FILM		
ANALYSIS	SPECIFICATION	RESULT
Appearance	Clear and colorless	Pass
Initial Color of Solution	The solution was colorless with the addition of phenolphthalein	Pass
Acidity	Solution is pink with addition of sodium hydroxide	Pass
Alkalinity	Solution is orange-red with the addition of hydrochloric acid and methyl red	Pass
UV Absorbance at 231.1 nm	≤ 0.02 units	Pass
Reducing Substances	Difference between titration volumes for test and blank solutions is ≤ 1.5 mL	Pass
Transparency	Cloudiness is perceptible when viewed through the container	Pass

The Japanese Pharmacopoeia 14th Edition, 2001 61 (pages 95 - 101). Test Methods for Plastic Containers. Polyethylene or Polypropylene Containers for Aqueous Injections.

TESTING PERFORMED ON FLUID CONTACT FILM		
ANALYSIS	SPECIFICATION	RESULT
Transparency	The containers have a transmittance of not less than 55%	Pass
Appearance	The containers do not have strips, cracks, bubbles or other faults which cause difficulties in practical use	Pass
Heavy Metals	The turbidity of the test solution is not greater than that of the control solution when the amount of the sample is 1.0 g	Pass
Lead	The absorbance of the sample is not more than that of the standard solution	Pass
Cadmium	The absorbance of the sample is not more than that of the standard solution	Pass
Residue on Ignition	The residue is not more than 0.10%	Pass
Foaming Test	The foam formed almost disappears within 3 minutes	Pass
pH	The difference in the reading between the test solution and the blank solution is not more than 1.5	Pass
Potassium-Permanganate Reducing Substances	The difference between the sample of the blank is not more than 1.0 mL	Pass
UV Spectrum	The maximum absorbance between 220 nm and 240 nm is not more than 0.08, and that between 241 nm and 350 nm is not more than 0.05	Pass
Residue on Evaporation	Not more than 1.0 mg	Pass

Warranty, Limitation of Remedies

SAFC Biosciences is not the manufacturer of the products and their related components. ACCORDINGLY, SAFC BIOSCIENCES MAKES NO WARRANTY OF ANY NATURE WHATSOEVER IN CONNECTION WITH THE PRODUCTS AND THEIR COMPONENTS AND EXPRESSLY DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS, IMPLIED OR OTHERWISE, INCLUDING THE IMPLIED WARRANTIES OF MARKETABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ANY WARRANTY AGAINST CLAIMS BY ANY THIRD PARTY BY WAY OF INFRINGEMENT, PROPERTY DAMAGE OR PERSONAL INJURY. BY ACCEPTANCE OF DELIVERY OF THE PRODUCTS, THE BUYER AFFIRMS THAT IT HAS RELIED ON ITS OWN SKILL AND JUDGMENT IN SELECTING THE PRODUCTS AND DETERMINING THEIR SUITABILITY FOR ITS NEEDS. IN NO EVENT WILL SAFC BIOSCIENCES BE LIABLE FOR ANY SPECIAL, EXEMPLARY, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH OR ARISING OUT OF THE PRODUCT OR ITS USE OR OPERATION, BASED UPON BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, TORT OR OTHER LEGAL THEORY, EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR CLAIMS.

The original product manufacturers may provide certain limited warranties under certain circumstances. For copies of these warranties, you [or the Buyer] should inquire directly of the original product manufacturer. SAFC Biosciences can provide contact information for the original product manufacturer, but is not an agent or representative of the manufacturers in connection with any warranty claims.

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

Issued February 2006 T082
0805 1105
0603/B003

www.safcbiosciences.com

United States

SAFC Biosciences, Inc.
13804 W. 107th Street
Lenexa, Kansas 66215
USA
Phone +1 913-469-5580
Toll free-USA 1 800-255-6032
Fax +1 913-469-5584
E-mail info-na@sial.com

Europe

SAFC Biosciences Ltd.
Smeaton Road, West Portway
Andover, Hampshire SP10 3LF
UNITED KINGDOM
Phone +44 (0)1264-333311
Fax +44 (0)1264-332412
E-mail info-eu@sial.com

Asia Pacific

SAFC Biosciences Pty. Ltd.
18-20 Export Drive
Brooklyn, Victoria 3025
AUSTRALIA
Phone +61 (0)3-9362-4500
Toll free-AUS 1 800-200-404
Fax +61 (0)3-9315-1656
Fax info-ap@sial.com