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Technical Bulletin

International Safe Transit Association Shipping Validation of BIOEAZE™ Polyethylene and Ethyl Vinyl Acetate Bags

A series of shipping validation tests were undertaken by SAFC Biosciences on polyethylene (PE) and ethyl vinyl acetate (EVA) BIOEAZE™ bioprocess bags and shipping containers. All testing was independently performed by International Safe Transit Association (ISTA)-certified laboratories using ISTA test protocols. The purpose of performing the shipping validation tests was to challenge the strength and robustness of BIOEAZE™ bag and packaging configurations and to help determine the capability of the product and packaging to withstand transport hazards.

BIOEAZE™ bags filled with liquid products (e.g. cell culture media or buffers) are packaged and shipped in a variety of configurations. Bags containing less than 50 L of unfrozen product are shipped in rigid plastic totes, whereas bags containing between 50 - 200 L of liquid are shipped in plastic drums. Bags filled with 200 - 500 L of product are packaged in steel pallet tanks. Small volume (<20 L bag size) frozen products are packaged and shipped in insulated corrugated-fiberboard containers.

For the purpose of these tests, all BIOEAZE™ bags were filled with non-sterile water and packaged in the appropriate container according to SAFC Biosciences' Standard Operating Procedures. The containers were delivered to the ISTA laboratory where Series 1A or 1B testing was performed (according to the weight of the package). Series 1A testing included a rotary motion vibration test and a free-fall drop test. Series 1B testing included a rotary motion vibration test, incline-impact test and rotational edge drop test. Containers were assigned a "pass/fail" designation based on maintenance of package functionality and whether or not the bag(s) leaked after any portion of the testing.

Tables that follow summarize the results of the testing.

For more information about this subject or other SAFC Biosciences' products and services, please call our Technical Services department or e-mail us at technicalservices@sial.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
E-mail info-ap@sial.com

ISTA Validation of PE BIOEAZE™ Bags and Shipping Containers Containing Non-Frozen Product (product filled at 100% of total bag volume)				
PE Bag Size	ISTA Test Procedure	Shipping Container Size	Bags Per Container	Result
1 L	1A	Plastic Tote 21.8″ L x 15.2″ W x 9.8″ H	1 - 10	Pass
5 L	1A	Plastic Tote 21.8″ L x 15.2″ W x 9.8″ H	1 - 2	Pass
10 L	1A	Plastic Tote 21.8″ L x 15.2″ W x 9.8″ H	1	Pass
20 L	1A	Plastic Tote 24″ L x 16.5″ W x 6.5″ H	1	Pass
20 L rocker	1A	Plastic Tote 27.5″ L x 22.75″ W x 5.75″ H	1	Pass
50 L	1B	Plastic Drum 17.5″ D x 26.25″ H	1	Pass
100 L	1B	Plastic Drum 20.75″ D x 37.875″ H	1	Pass
200 L	1B	Plastic Drum 24″ D x 36″ H	1	Pass
500 L	1B	Steel Pallet Tank 47.25″ L x 31.675″ W x 41.375 H	1	Pass

ISTA Validation of EVA BIOEAZE™ Bags and Shipping Containers Containing Non-Frozen Product (product filled at 100% of total bag volume)				
EVA Bag Size	ISTA Test Procedure	Shipping Container Size	Bags Per Container	Result
1 L	1A	Plastic Tote 21.8″ L x 15.2″ W x 9.8″ H	1 - 10	Pass
5 L	1A	Plastic Tote 21.8″ L x 15.2″ W x 9.8″ H	1 - 4	Pass
10 L	1A	Plastic Tote 21.8″ L x 15.2″ W x 9.8″ H	1 - 2	Pass
20 L	1A	Plastic Tote 24″ L x 16.5″ W x 6.5″ H	1	Pass

ISTA Validation of EVA BIOEAZE™ Bags and Shipping Containers Containing Frozen Product (product filled at 50% of total bag volume)				
EVA (Frozen) Bag Size	ISTA Test Procedure	Shipping Container Size	Bags Per Container	Result
1 L	1A	Insulated Fiberboard Box 22.75 " L x 15.75" W x 16" H	1 - 10	Pass
5 L	1A	Insulated Fiberboard Box 22.75 " L x 15.75" W x 16" H	1 - 2	Pass
10 L	1A	Insulated Fiberboard Box 22.75 " L x 15.75" W x 16" H	1	Pass
20 L	1A	Insulated Fiberboard Box 22.75 " L x 15.75" W x 16" H	1	Pass

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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
E-mail info-ap@sial.com