SABIC Innovative Plastics™



## Letter of Authorization

March 26, 2015

Food and Drug Administration Center for Devices and Radiological Health PMA Document Mail Center – WO66-G609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Re: Device Master File MAF-91

Subject:

LEXAN<sup>TM</sup> resin HP6-1H112

Dear Sir or Madam:

SABIC Innovative Plastics hereby authorizes the following company to incorporate by reference SABIC-IP MAF-91 into any 510(K), PMA, or other submissions filed by the company:

TriForest Labware 6 Chrysler Irvine, CA 92618

Authorized reference information: LEXAN<sup>TM</sup> resin HP6-1H112

We hereby authorize the FDA to review the aforementioned specific information in MAF-91 from page 10-18-2013-01 to 10-18-2013-07 and from page 06-02-2010-37 to 06-02-2010-49 when considering any 510(K), PMA, or other submissions filed by TriForest Labware. We request that all information in this file be treated as confidential to the extent possible in accordance with 21 CFR 314.430 and 21 CFR 20.61, and that no information from this file be provided to any third party without our written consent.

SABIC Innovative Plastics 9226 DuPont Road Washington, WV 26181

T: +1 304 863 7956 F: +1 304 863 7156 E: patrick.rodgers@sabic-ip.com www.sabic-ip.com THE MATERIALS, PRODUCTS AND SERVICES OF SABIC INNOVATIVE PLASTICS HOLDING BV, ITS SUBSIDIARIES AND AFFILIATES ("SELLER"), ARE SOLD SUBJECT TO SELLER'S STANDARD CONDITIONS OF SALE, WHICH CAN BE FOUND AT <a href="http://www.sabic-ip.com">http://www.sabic-ip.com</a>. AND ARE AVAILABLE UPON REQUEST. ALTHOUGH ANY INFORMATION OR RECOMMENDATION CONTAINED HEREIN IS GIVEN IN GOOD FAITH, SELLER MAKES NO WARRANTY OR GUARANTEE, EXPRESS OR IMPLIED, (I) THAT THE RESULTS DESCRIBED HEREIN WILL BE OBTAINED UNDER END-USE CONDITIONS, OR (II) AS TO THE EFFECTIVENESS OR SAFETY OF ANY DESIGN INCORPORATING SELLER'S PRODUCTS, SERVICES OR RECOMMENDATIONS. EXCEPT AS PROVIDED IN SELLER'S STANDARD CONDITIONS OF SALE, SELLER SHALL NOT BE RESPONSIBLE FOR ANY LOSS RESULTING FROM ANY USE OF ITS PRODUCTS OR SERVICES DESCRIBED HEREIN. Each user is responsible for making its own determination as to the suitability of Seller's products, services or recommendations for the user's particular use through appropriate end-use testing and analysis. Nothing in any document or oral statement shall be deemed to alter or waive any provision of Seller's Standard Conditions of Sale or this Disclaimer, unless it is specifically agreed to in a writing signed by Seller. No statement by Seller concerning a possible use of any product, service or design is intended, or should be construed, to grant any license under any patent or other intellectual property right of Seller or as a recommendation for the use of such product, service or design in a manner that infringes any patent or other intellectual property right.

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The material furnished will be manufactured in accordance with MAF-91 and in compliance with good manufacturing practices. SABIC-IP states the MAF-91 is current and SABIC-IP will comply with the statements made within. Notification to TriForest Labware and appropriate notification to FDA and this file will be made for significant changes that impact the subject materials of this letter.

Should any additional information on LEXAN\* resin be needed for your review, please contact me by phone at (304) 863-7956, by e-mail at patrick.rodgers@sabic-ip.com, or by mail at the address shown.

Yours sincerely,

Patrick A. Rodgers, Ph. D.

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Product Stewardship

cc: Syed Rehan, TriForest Labware

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