INEOS Styrolution America LLC

4245 Meridian Parkway, Suite 151
Aurora, IL 60504

January 16, 2025

RE: Lustran® 348 replacement nomenclature

Dear Valued Customer,

Following the October 30, 2024 announcement regarding the permanent closure of the Addyston, Ohio facility, INEOS Styrolution has continued the necessary steps to offer our healthcare industry customers an alternative to our renowned Lustran® 348 medical grade of ABS. Throughout this process, the collective feedback from you overwhelmingly indicated the importance of maintaining the same brand and grade nomenclature for the replacement product from our Altamira Mexico ABS production facility.

As a result of your feedback, we are pleased to inform you the previously named Novodur® HD 348 replacement grade will now retain the same Lustran® 348 brand and grade name. The color and packaging codes will also remain unchanged from those used at our Addyston, Ohio facility.

Additionally, testing, certification, and preparation of various regulatory documents is underway. Below are a few of the Altamira-produced Lustran 348 highlights.

- Lustran 348 produced in Altamira, MX is designed to have the same physical performance (e.g. melt volume rate, impact performance) and same basic polymer chemistry as the resin it is replacing from Addyston, OH.

- To account for the differences in manufacturing technologies between Altamira and Addyston, different chemical processing aids and additives are utilized. However, these processing aids and additives are similar in function and are not intended to have any technical effects on the finished ABS resin.

- This Altamira-produced version of Lustran 348 is offered with INEOS Styrolution's Full Service HD Package which is the identical set of regulatory standards as the product produced in Addyston, OH. This package includes compliance to USP Class VI as well as several ISO-10993 and Pharmacopoeia standards. Testing according to these standards are currently underway by third party laboratories and are expected to be complete by end of the first quarter 2025.

- Registration of the corresponding Drug Master File (DMF), filed with the FDA will be completed later in 2025.

More detailed product compositional information and comparisons can be shared upon completion of a Confidentiality Agreement. Furthermore, access to various Technical and Regulatory personnel are available upon request.

As a reminder, each customer, having the expertise and the knowledge in the intended use of an INEOS Styrolution product, must establish, based on his own experience and tests, what is suitable for use in the targeted end application or medical device.

Phone : +1 630 820-9500
E-mail : INSTY.americas@ineos.com

INEOS Styrolution America LLC

4245 Meridian Parkway, Suite 151
Aurora, IL 60504

We appreciate your continued interest in the supply of the Lustran 348 grade of ABS. Your INEOS Styrolution account representative is available to discuss questions you may have regarding this change.

Sincerely,

Ineos Styrolution America LLC

Mohammed Abboud
Business Director,
ABS

Alexander Silvestre
Global Director,
Healthcare

Phone : +1 630 820-9500
E-mail : INSTY.americas@ineos.com