

April 21st, 2022

LABLABO
Technosite Altea
269 rue Georges Charpak
74100 Juvigny
France

RE: Hostaform® MT® 24U01 Natural Biocompatibility

To Whom It May Concern:

The following toxicological information is being provided to LABLABO for sole purpose of the evaluation of Hostaform® MT® 24U01 NATURAL as components of a spray insert.

HOSTAFORM® MT® 24U01 NATURAL was submitted for biocompatibility testing. Based on results of that testing we confirm the product complies with the following biocompatibility requirements:

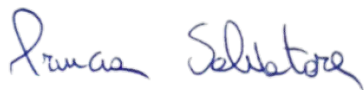
- USP <88> Class VI Plastics
- USP <661> Physicochemical Test
- ISO 10993-5 Cytotoxicity - L929 MEM Elution Test
- ISO 10993-6 Implantation Test
- ISO 10993-11 Systemic Injection Test
- ISO 10993-10 Intracutaneous Reactivity
- ISO 10993-10 Sensitization – Kligman Maximization
- ISO 10993-11 Pyrogen Test
- ASTM F756-08 Hemolysis – Direct and Indirect – Rabbit Blood

We do not recommend or support use of our products in specific medical and sensitive end-use applications without our prior knowledge and approval of the specific applications. HOSTAFORM® MT® 24U01 NATURAL is not intended for medical implant applications or dental implant

applications. Celanese does not make any representations or warranties written, implied, or otherwise concerning the use of HOSTAFORM® MT® products in customer applications. The responsibility for evaluating the processed part and finished article for safety and conformance with applicable requirements lies with the manufacturer of such article. Celanese disclaims any liability for the use of Celanese products in customer applications.

We hope this information proves useful and you will contact us should you require additional information. Thank you for your interest in Celanese products.

Best regards,



Princia Salvatore

Regulatory Compliance Specialist
Celanese Engineered Materials

This assurance is accurate as of the date of issue. We are providing this information at your request, and, as such, nothing in this letter should be deemed to be or construed as an amendment or modification of any terms and conditions of sale under any contract in place between Celanese and you or any representation, guarantee, or warranty regarding such product and its characteristics, uses, suitability, safety, efficacy, hazards or health effects. Any liability or responsibility for such product shall be governed solely by, and any and all representations, guarantees, warranties regarding such product shall be solely as set forth in, the invoice or other contract for such shipments. This information relates only to the above-mentioned material as delivered in its original packaging. It does not relate to any product made of these materials with or without the inclusion of further additives, such as processing aids or colorants. The product mentioned herein is not intended for use in medical or dental implants. To the extent that any hazards may have been mentioned in this publication, we neither suggest nor guarantee that such hazards are the only ones that exist. This information should not be construed as a promise or guarantee of specific properties of the products described or their suitability for a particular application. Any existing intellectual property rights must be observed. 22025-PS.