

Hostaform® FK 2:25 22 (white)

Animal Derived Materials, BSE and GMO Declaration:

EMEA BSE Guideline (EMEA/410/01 rev.3; 2011/C 73/01)

Directives 2001/2/EC and 2003/32/EG, and Regulation (EU) 722/2012

Celanese products (polymer compounds) do not fall under the scope of the EMEA BSE Guideline (medicinal products as described in paragraph 2 of the Guideline). However, to help economic operators in the supply chain to comply with the rules laid down in the above mentioned regulations Celanese, Engineered Materials certifies that based on Celanese manufacturing process and the raw materials used, above listed products comply with this Guideline and Directives.

This is also supported by the assurance of our additive suppliers. They do not use animal materials in a direct way to produce the additive. The production of the waxes may use raw materials that could be derived from animal origin. The suppliers of these materials use appropriate process parameters (pressure, temperature) to eliminate any BSE risk.

Further the processing parameters during the final additive manufacturing process are such (minimum of 200°C during several hours), that the requirements of both guidelines are fulfilled. Therefore, the wax additives used in the above listed Celanese Engineered Materials products can be considered compliant to EMEA-BSE regulation 2004/C24/03, 2001/2/EC and 2003/32/EG.

Celanese Engineered Materials does not use by intention genetically modified organisms (GMO) when manufacturing above listed products. However, we do not on a routine basis test the materials used in the manufacture of the products and do not keep documents from all our raw materials suppliers confirming the absence of GMO materials.

March 31, 2020

Please note that the manufacturer or seller of parts and articles made out of the above mentioned products have to take the full responsibility regarding applicable legal requirements.

Celanese, Engineered Materials Product Safety.

Important: This information relates only to the above mentioned materials as delivered in their 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. 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.

It is the responsibility of any manufacturer of medical devices containing Celanese Engineered Materials resins to determine the necessary steps to ensure the safe and efficacious use of their products/devices and to obtain the necessary regulatory approvals for the intended applications. Insofar as this information relates to sterilization for medical purposes, the data contained herein show the typical effects of sterilization procedures on the nominal physical properties (using standardized test specimens) of the Celanese Engineered Materials resins. The actual sterility of the parts has not been evaluated for either single or multiple use applications. The products mentioned herein are not intended for use in medical or dental implants.