

March 31, 2020

## **Hostaform® FK 2:25 22 (white)**

### **Food Contact Declaration**

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. The suitability of the finished article for the intended application (e. g. with respect to global migration limits) has to be checked by the manufacturer or seller.

When manufacturing above listed products Celanese Engineered Materials complies with the Food Contact Framework Regulation (EC) 1935/2004 and the guidelines laid down in the Regulation (EC) 2023/2006.

A food contact approval is related to the final product and to its intended use. A raw material, such as the above listed Celanese Engineered Materials, is only an ingredient of a final product. Consequently, the Celanese is not in a position to give a general statement regarding the compliance of the final product with the food contact regulations, such assessment being in the field of control and responsibility of the manufacturer of the final article.

### **EU: Regulation (EU) 10/2011<sup>1</sup> and BfR<sup>2</sup>**

The Food Contact Framework Regulation (EC) 1935/2004 sets out the general rules for all classes of food contact materials without giving any specific rule of how to prove the safety of food contact articles. Plastic materials, e.g. polymers compounds as sold by Engineered Materials are regulated by Regulation (EU) 10/2011 and its amendments.

The monomers and additives used for the manufacturing of the above mentioned product are listed in the regulation (EU) 10/2011 from January 14<sup>th</sup>, 2011.

The above mentioned polymer compounds contain monomers and additives which are regulated with a specific migration limit. If required, we will disclose this confidential formulation information to a suitable third party test institute (laboratory) on the basis of a secrecy agreement.

With regard to impurities of traces of heavy metals and the content of primary aromatic amines the colourants employed in the above mentioned colour concentrate comply to the

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<sup>1</sup> including all amendments published before the date of this statement

<sup>2</sup> BfR = Bundesinstitut für Risikobewertung (German Institute for Risk Assessment)

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requirements of the recommendation IX „Colorants for plastics...“ of the BfR (Bundesinstitut für Risikobewertung) and Resolution AP 89/1 of Council of Europe.

Consequently the coloured product made out of the above mentioned colour concentrate and natural Hostaform C-Types in the recommended ratio complies with the recommendation XXXIII „Acetal resins“ of the BfR. **The pure colour concentrate itself is not suitable for food contact due to its high concentration of the colourants.**

To fully comply with food regulations in Europe, the finished plastic article needs to comply with, amongst other things, Overall Migration Limit requirements and Specific Migration Limits as specified in (EU) 10/2011 when tested on the food contact surface with the appropriate food simulants and time/temperature test conditions. **This is the responsibility of the manufacturer of the final article.**

### **USA Regulation: FDA CFR 21**

The colorants employed are listed in 21 CFR § 178.3297 „Colorants for polymers“. Consequently the above mentioned product is in compliance to 21 CFR of the Federal Drug Administration (FDA) of the United States of America.

Therefore the colored product made out of the above mentioned colour concentrate and natural Hostaform C-Types in the recommended ratio complies with the Code of Federal Regulations, title 21, CFR, § 177.2470 "Polyoxymethylene copolymer" and § 178.2010 "Antioxidants and Stabilizers" of the Food and Drug Administration (FDA), revised as of as of April 1, 2015.

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 assurance is accurate as of the date of issue based on the most recent version of any applicable regulations or standards unless otherwise stated above.

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 Engineered Materials 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 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.

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The responsibility for evaluating the finished food contact article for conformance with applicable requirements lies with the manufacturer of such article.

The products mentioned herein are not intended for use in medical or dental implants.