

## Hostaform® MT® 24U01 Natural

### Food Contact Declaration

The above-mentioned Celanese Engineered Materials product might be used as an ingredient of a finished food contact material or article (FCMA). Please note that Celanese Engineered Materials does not make any statement about whether a finished FCMA will be compliant with the applicable food contact regulations. It is responsibility of the producer or the seller of the finished FCMA to ensure that their product meets all the requirements of the below-mentioned regulations.

### EU: Food Contact Regulations

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

The above-referenced product is in compliance with:

- Framework Regulation (EC) No 1935/2004
- Regulation (EC) No. 2023/2006 (GMP)
- Commission Regulation (EU) No 10/2011 and its most recent amendment Regulation (EU) 2020/1245

Some monomers and additives are regulated with a specific migration limit (SML) as specified in Commission Regulation (EU) 10/2011. If required, we will disclose this confidential formulation information to a suitable third-party test institute (laboratory) on a basis of a secrecy agreement.

Please note, that to fully comply with food contact regulations in Europe, the finished plastic article or packaging material need to fulfill all relevant legal requirements. This includes also Overall Migration Limit and Specific Migration Limits requirements when tested for the relevant conditions of use as specified in Commission Regulation (EU) 10/2011. **This is the responsibility of the manufacturer of the final article.**

**USA: FDA CFR21**

This product is formulated using polyacetal base resin that is compliant for use in food contact applications according to (CFR), Title 21, 177.2470. Any additives, that may be present, comply with appropriate, specific FDA Regulations.

Restrictions:

Types of food	All food types except foods containing 15% or more alcohol
Conditions of Use	A through H as listed in Table 2 of 21 CFR 175.300(d); use temperature not to exceed 250 deg F per 177.2470
Application	Repeat Use Articles only

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.

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.