

April 21<sup>st</sup>, 2022

## **Hostaform® MT® 24U01 Natural**

Dear Customer,

Based on the information provided by our raw material suppliers and our manufacturing process, Celanese Engineered Materials declares that the following information is true and accurate to the best of our knowledge.

### **1. Animal Derived Ingredients**

#### **Animal Derived Materials, BSE and GMO Declaration:**

#### **EMEA BSE Guideline (EMEA/410/01 rev.3; 2011/C 73/01) and Directives 2001/2/EC and 2003/32/EG.**

Celanese Engineered Materials 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 Guideline and also in Directive 2003/32/EC, Celanese Engineered Materials certifies that, based on our manufacturing processes and the raw materials used, the above listed product complies with this Guideline and Directive.

We confirm that the above-mentioned product neither contains additives of animal origin nor of human origin.

We also confirm that when manufacturing the above-mentioned Celanese Engineered Materials product we do not use, as intentional ingredients, materials that contain Genetically Modified Organisms (GMO).

### **2. EU Medical Device Regulation**

#### **MDR (EU) 2017/745**

For the above listed Celanese Engineered Materials product we confirm that it does not contain substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B in concentration equal or greater than 0.1% (w/w), according to Part 3 of Annex VI of CLP Regulation (EC) No 1272/2008.

We also confirm that the above listed product does not contain substances in concentrations equal or greater than 0,1% (w/w) having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

When manufacturing the above listed product we do not use:

- biological substances, including derivatives of tissues or cells of human origin and tissues or cells of animal origin or their derivatives,
- latex,
- phthalates (derivatives of 1,2-benzenedicarboxylic acid).

### 3. CMR (Carcinogenic, Mutagenic and Reprotoxic substances)

#### Part 3 of Annex VI of CLP Regulation (CMR substances of category 1A and 1B)

Celanese Engineered Materials confirms that the substances and substance classes listed in Part 3 of Annex VI of the Regulation 1272/2008/EC as carcinogenic, mutagenic or toxic to reproduction ('CMR') of category 1A or 1B are not an intentional part of the formulation of the above listed product. In cases where classified products are contained in our products above the maximum limits allowed, this information is provided in our Safety Data Sheets.

#### Formaldehyde:

Hostaform® are polyacetal (POM) based products containing traces of formaldehyde, a classified chemical (carcinogen category 1B). Formaldehyde is a degradation product of acetal copolymers, the base resin used in POM products. All POM materials contain a low level of formaldehyde as manufactured. When processed (e.g. injection moulded) according to Celanese Engineered Materials processing guidelines, the level of formaldehyde is typically below 100 ppm.

### 4. Allergens

#### Regulation EU 1169/2011 (food information to consumers)

##### Substances or Products Causing Allergies or Intolerances

Celanese Engineered Materials, a producer of polymer compounds, does not fall under the scope of the regulation EU 1169/2011. However, to help economic operators in the supply chain to comply with the rules laid down in EU 1169/2011, we confirm that the substances or products listed in Annex II of EU 1169/2011 are not used when manufacturing the above-mentioned product.

We do not use the following raw materials:

Nuts (all types)	Lactose
Milk (lactose and casein)	Casein
Eggs	Barley, rye, oats
Fish or crustaceans	Sulfur dioxide and/or Sulfites
Soybean oil	Corn or maize
Soybeans (not including oil)	Iodine
Wheat, spelt, kamut®	Latex
Gluten	Sugar (sweet, short-chain, soluble carbohydrates)
Alcohol (ethanol)	Preservatives other than stabilizers

## 5. Phthalates

When manufacturing the above listed Celanese Engineered Materials product, we do not use phthalate softeners (monomeric organic compounds), including those listed in Annex XIV of REACH Regulation (EU) No 1907/2006 and Annex VI of CLP Regulation (EC) No 1272/2008. This product does not contain by constitution the following substances:

Substance	
DEHP	Diethylhexylphthalate (CAS 117-81-7)
DINP	Diisononylphthalate (CAS 28553-12-0, 68515-48-0)
DIDP	Diisodecylphthalate (CAS 26761-40-0)
DBP	Dibutylphthalate (CAS 84-74-2)
BBP	Benzylbutylphthalate (CAS 85-68-7)
DMEP	Bis-(methoxyethyl)-phthalate (CAS 117-82-8)
DnPP	Di-n-pentylphthalate (CAS 131-18-0)
DNOP	Di-n-octylphthalate (CAS 117-84-0)
DiPP	Diisopentylphthalate (CAS 605-50-5)
DIBP	Diisobutylphthalate (CAS 84-69-5)
PIPP	N-pentyl-isopentylphthalate (CAS 776297-69-9)

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

This document has been prepared by Celanese Product Stewardship group. We trust this information proves useful and you will contact us should you require additional information. Celanese does not make any representations or warranties concerning the above-mentioned product in your end-use. The responsibility for evaluating a finished article for conformance with applicable requirements lies with the manufacturer of such article.

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.

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February 1<sup>st</sup>, 2022

## **Celanese Engineered Materials Hostaform® Products**

Products produced in the Celanese European manufacturing facilities

### **SAFETY DATA SHEETS (SDS)**

For information on hazard communication please refer to our safety data sheets available from our website: <https://www.celanese.com/msds>

### **Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**

Celanese is aware of the obligations imposed by REACH on EU manufacturers and importers as well as on downstream users. We are obliged to comply with the requirements of the REACH legislation relating to our EU-based manufacturing facilities, our own imports as well as our obligations as a downstream user in the European chemical industry.

Should you require additional information on REACH and SVHC, please contact Celanese at [Ticona-REACH@celanese.com](mailto:Ticona-REACH@celanese.com).

### **CONFLICT MINERALS**

Information on Conflict Minerals is available on our Engineered Materials Quality and Certification web-page: <https://www.celanese.com/en/Conflict-Minerals-Policy-And-Disclosure>

### **SELF-DECLARATION**

General information on Quality Management, Environmental, Health and Safety (EHS) Management, Hygiene, Product information, Compliance, Ethics, and Sustainability is available on our Engineered Materials Quality and Certification web-page: [Self-Declaration For Customers \(celanese.com\)](#)

## **PACKAGING (HEAVY METALS)**

Our Hostaform® products by constitution do not contain the heavy metals Cadmium, Lead, Mercury and Chromium-VI. Thus, they are compliant with the relevant heavy metals' requirements of the following regulations. As we do not systematically perform specific tests to verify the potential presence of heavy metals, we cannot guarantee that there are no trace amounts present as impurities.

### **CONEG Legislation (Coalition of North-Eastern Governors)**

#### **Packaging and Packaging Waste Directive – EU Directive 94/62/EC**

In our Hostaform® products, if present at all, the total sum of concentration levels of Cadmium, Lead, Mercury and Chromium-VI is below the 100 ppm threshold.

## **AUTOMOTIVE**

### **GADSL (Global Automotive Declarable Substance List, 2020-02-01)**

GADSL is fully incorporated into the IMDS (International Material Data System) and we would recommend that product compliance with GADSL is directly verified in IMDS.

### **End-of-Life Vehicle (ELV) – EU Directive 2000/53/EC**

In our Hostaform® products, if present at all, the concentrations of Lead, Mercury and Chromium-VI do not exceed 0.1 % by weight and the concentration of Cadmium does not exceed 0.01% by weight.

## **ELECTRICAL and ELECTRONIC EQUIPMENT**

Our Hostaform® products are not in the scope of the Directives mentioned below. However, we provide information according to specific requirements to support our customers in their compliance with the rules laid down in these Directives. Please note that the manufacturer or seller of parts and articles made of our Hostaform® products has to take the full responsibility regarding applicable legal requirements.

### **Restriction of Hazardous Substances (RoHS) – EU Directive 2011/65/EU**

In our Hostaform® products, if present at all, the concentration levels of the RoHS substances is below the reporting thresholds.

Lead, Mercury, Hexavalent chromium, Polybrominated biphenyls (PBB), Polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP) – reporting threshold of 0.1%

Cadmium – reporting threshold of 0.01%

### Waste Electrical and Electronic Equipment (WEEE) – EU Directive 2012/19/EC

In our Hostaform® products, if present at all, the concentration levels of the WEEE prohibited substances is below the reporting thresholds.

### Sweden tax (Finances Ministry Act 2016:1067)

Chlorine, Bromine and Phosphorous containing substances are not intentional ingredients of our Hostaform® products. Therefore, if present at all, their content is lesser than 1000 ppm each.

### Flame Retardants

During the manufacturing process of our Hostaform® products no flame retardants are used.

## SUBSTANCES of CONCERN

### Ozone Depleting Substances (ODS)

No ozone depleting substances as defined in the European Regulation (EC) No 1005/2009 are used in the manufacturing process of our Hostaform® products.

### Persistent Organic Pollutants (POP) – Regulation (EU) 2019/1021

No substances subject to the Stockholm Convention on Persistent Organic Pollutants and defined in the Regulation (EU) 2019/1021 are used in the manufacturing process of our Hostaform® products.

### Prior Informed Consent (PIC) – Regulation (EU) No 649/2012

No substances subject to the Rotterdam Convention on the Prior Informed Consent procedure for certain hazardous chemicals and pesticides and defined in the Regulation (EU) No 649/2012 are used in the manufacturing process of our Hostaform® products.

### Often Asked Substances of Concern

During the manufacturing of our Hostaform® products we do not use or intentionally incorporate the substances or class of substances as listed below. This information is to the best of our knowledge and based on the information given by our raw material suppliers at the date hereof. As we do not systematically perform specific tests to verify the potential presence of these substances, we cannot guarantee that there are no trace amounts present as impurities.

<b>Substances or Group of Substances</b>
2-(2H-1,2,3-benzotriazole-2-yl)-4,6-di-tertbutylphenol
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol
2,4,6-Tri-tert-butylphenol
Acrylamide
Acrylonitril
Aldrin
Alkylphenols (AP) and Alkylphenol-ethoxylates (APEO)
Alkylphenol phosphites
Asbestos
Benzene
Benzophenone
Bisphenol A
Bisphenol F
Bisphenol S
Chlorinated paraffin (Short chained: C10-13) (SCCP)
Chlorinated paraffins
Chlorofluoro-carbons (CFCs)
Decabromodiphenyl Ether (DecaBDE)
Dimethylfumarate (DMF)
Fluorinated greenhouse gases (PFCs, SF6, HFCs)
Halogenated Dioxins and Furans
Hexabromocyclododecane (HBCDD)
Hexachlorobenzene
Hexachlorobuta-1,3-diene
Hexavalent chromium (Cr-VI) compounds
Hydrochloro-fluorocarbons (HCFCs)
Lead and its compounds
Lindane
Mercury and its compounds
Methyl 4-hydroxybenzoate
Mirex
N,N'-bis(2-methylphenyl)benzene-1,4-diamine
N-Nitrosamines
Organotin compounds (Dibutyltin, Tributyltin, Triphenyltin, Dioctyltin)

Pentachloro-phenol (PCP) including salts and esters of PCP
Pentachlorothiophenol
Phenol, Isopropylated Phosphate 3:1 (PIP 3:1, CAS No. 68937-41-7)
Phthalates (Bis (2-ethylhexyl)phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP))
Polybrominated biphenyls (PBBs)
Polybrominated diphenyl ethers (PBDEs)
Polychlorinated biphenyls (PCBs)
Polychlorinated naphthalenes (PCN)
Polychlorinated terphenyls (PCTs)
Polyvinyl chloride (PVC) and polyvinylidene chloride (PVDC)
Thiuram E (Disulfiram)

## Formaldehyde

Our Hostaform® products are polyacetal resins (POM). Due to their intrinsic nature all polyacetal products may contain traces of formaldehyde. In our Engineered Materials products, the level of formaldehyde might vary, with max level of 1000 ppm.

## Volatile Organic Compounds (VOC)

Our Hostaform® products are solid polymer compounds which do not contain VOC according to the definition in the European Directive 2010/75/EC and in the Swiss regulation, SR 814.018. Residual amounts of monomers which cannot be totally avoided are very low, typically in the range of ppm. In any case the content of VOC in the above listed Celanese products is well below 3%.

## FOOD SAFETY

### Genetically Modified Organism (GMO)

During the manufacturing of our Hostaform® products we do not use or intentionally incorporate GMO based raw materials. This information is to the best of our knowledge and based on the information given by our raw material suppliers at the date hereof.

### Food Allergens – Regulation (EC) 1169/2011

Our Hostaform® products are not intended for consumption as a food and do not fall in the scope of the Food Information to Consumers Regulation (FIC, also known as EU 1169/2011). However, to support our customers in their compliance with the rules laid down in the EU FIC regulation we confirm that to the best of our knowledge and based on the data from our raw material



suppliers, the substances or products listed in EU FIC, Annex II are not used during the manufacturing process of our Hostaform® products.

## OTHER

### Nanomaterials

Our Hostaform® products are in granulate form and thus not considered as nanomaterials as defined by the European Commission under Recommendation 2011/696/EU. No material of nanoscale is added to our products for its specific nanoscale properties during the manufacturing process. Some Hostaform® products contain raw materials, e.g. pigments and fillers, which might fall under the definition proposed by the European Commission. However, they are dispersed and embedded in the polyacetal polymer matrix and thus not available anymore in nanoform.

### Biocidal Products Regulation

Our Hostaform® products are neither considered biocidal products nor treated articles as defined in Regulation (EU) No 528/2012. During the manufacturing, handling and storage of these products we do not use or intentionally incorporate any biocidal products.

### Latex

The term latex refers to the natural rubber latex made from plant sources such as the sap of the Brazilian rubber tree (*Hevea brasiliensis*). Some synthetic rubber materials may be referred to as "latex" but they do not contain the protein of the *Hevea brasiliensis* that produces the latex allergy.

During the manufacturing of our Hostaform® products we do not use or intentionally incorporate natural rubber latex.

Celanese, Engineered Materials Product Safety.

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