
Regulatory Information Sheet

colorFabb_HT

Date of issue: April 9, 2020
Version: v1.0



colorFabb_HT printing filament is produced with Eastman Amphora 3D Polymer HT5300, which is in compliance with the following legal requirements (in each case including all amendments in their currently valid versions):

European Union Food Contact

(Regulation (EU) 10/2011 Annex IV)

This product is a polymer of dimethyl terephthalate (FCM 288, Ref No. 24970, listed as terephthalic acid, dimethyl ester), 1,4- cyclohexanedimethanol (FCM 210, Ref No. 13390, listed as 1,4- bis(hydroxymethyl) cyclohexane), and 2,2,4,4- tetramethylcyclobutane-1,3-diol (TMCD)(FCM 881, Ref No. 25187). The monomers listed above, except TMCD, are listed without specific migration limits. TMCD has a specific migration limit of 5 mg/kg of food for repeated use articles for long term storage at room temperature or below and hotfill conditions. Specific migration of TMCD from a representative copolymer was tested using a protocol for repeated use applications under test conditions of both 10 days at 40°C and 2 hours at 100°C at a ratio of 10 dm² per 1 kg food using 3% acetic acid, 10% ethanol and olive oil as food simulants. Under these conditions, no migration of TMCD was detected with a detection limit of 25 micrograms/kg for aqueous food simulants and 1.3 microgram/kg for olive oil. Regarding the dual use additives provision in the Plastics Regulation, there are no additives subject to restrictions on concentrations in food as a food additive. This product is intended for use to manufacture materials and articles in compliance with the general requirements of the Framework Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food. This product is produced under good manufacturing practices in compliance with EU Regulation 2023/2006.

US Food and Drug Administration (FDA)

Under regulations administered by the U.S. Food and Drug Administration (FDA), this product, as supplied by Eastman Chemical Company, may lawfully be used on the basis of 21 CFR 174.5(d)(5) as a component in the manufacture of repeated use food-contact articles as described in Food Contact Notification No. 1041. FCN No. 1041 replaces FCN No. 729 and product as supplied by Eastman under FCN No. 729 may lawfully be used under FCN No. 1041. The finished food contact article containing this polymer is intended to contact all types of food at temperatures up to and including 100°C (for definitions of food types, refer to the Food Contact Substances website at <http://www.fda.gov/food/ingredientspackaginglabeling/packagingfc/s/foodtypesconditionsofuse/ucm109358.htm> to access the Food Types and Conditions of Use for Food Contact Substances Tables).

This product is manufactured, stored, handled and transported under conditions adhering to 21 CFR 174.5 on general provisions applicable to indirect food additives (i.e., current good manufacturing practices for food contact substances).

China Food Packaging Materials

This polymer is listed as No. 94 (CAS No. 261716-94-3) on the official "List of 107 Resin Types Used for Food Packaging Materials" published by the Chinese Ministry of Health (MOH) in November 2011.

REACH

(Regulation (EC) No. 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (REACH) - Substances of Very High Concern)

With reference to the SVHC Candidate List, as amended up to and including the 17 December 2015 update, this product placed on the market in the European Union is not known to contain any substances listed on the candidate list of Substances of Very High Concern (SVHC) in concentrations greater than or equal to 0.1% or those otherwise established under paragraph 6(b) of Article 56.

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Packaging waste

(Directive 94/62/EC, Packaging and Packaging Waste (amended by 2004/12/EC, 2005/20/EC, and Regulation (EC) No 219/2009))

This statement covers the following heavy metals (or their compounds): Cadmium (Cd), Hexavalent chromium (Cr (6+)), Lead (Pb), Mercury (Hg). This product complies with the heavy metal content limits of this legislation.

Animal Origin

(Substances of Animal Origin Regulation 999/2001, as amended)

Based on our knowledge of the raw materials and processes used in the manufacture of this product, we have no reason to expect that animal-derived or bovine-derived materials are present in this product. This product is manufactured using non-animal-derived raw materials. Additionally, this product does not contain, and is not derived from, specified risk materials as defined in EU regulations. This product is not derived from any constituent of animal origin, including ruminants. The equipment used in the manufacturing process of the product did not come into contact with a substance derived from animal origin.

Non-GMO

(Directive 2001/18/EC and Regulations 1829/2003 and 1830/2003 (Genetically Modified Organisms), as amended)

Based on our knowledge of the raw materials or based on supplier information, this product is considered not genetically modified or not derived from a genetically modified organism as defined in these regulations.

Phthalates

(Directive 2005/84/EC, Commission Decision 1999/815/EC (Phthalates), as amended)

This product does not contain phthalate esters used as plasticizers (such as di-2-ethylhexyl phthalate (DEHP), diisononyl phthalate (DINP), dibutyl phthalate (DBP), di-n-octyl phthalate (DNOP), benzylbutyl phthalate (BBP), diisodecyl phthalate (DIDP)). The term "phthalates" refers to diesters of phthalic acid (also known as ortho-phthalic acid or 1,2-benzenedicarboxylic acid) that are used to make materials, such as vinyl, more flexible. These are the substances which are the subject of specific regulations and are banned or proposed to be banned in certain consumer products. Phthalate esters are not used in the manufacture of this product. However, there is potential for confusion resulting from the use of dimethyl terephthalate as a monomer to manufacture this polymer. Terephthalates have different physical, chemical, and toxicological properties than the ortho-phthalate esters, and we are not aware of any scientific studies linking terephthalates with endocrine effects. More importantly, dimethyl terephthalate is reacted and becomes part of a high molecular weight polymer. In contrast, low molecular weight plasticizers, such as ortho-phthalates, can be used at high loadings and have a high potential for migration when the plasticized polymer is used in contact with fatty foods.

Ozone Layer

(Regulation (EC) No. 1005/2009 on Substances that Deplete the Ozone Layer)

Eastman Chemical does not analyse this product for ozone depleting substances (ODS) that are classified as such by this legislation. Based on our knowledge of the raw materials and our manufacturing process, we do not expect the listed substances to be present in our product.

ELV

(Directive 2000/53/EC (End of Life Vehicles - ELV), as amended)

This statement covers the following heavy metals (or their compounds): Cadmium (Cd), Hexavalent chromium (Cr (6+)), Lead (Pb), Mercury (Hg). This product complies with the heavy metal content limits of this legislation.

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RoHS

(Directive 2011/65/EU (Restrictions of Hazardous Substances - RoHS2), as amended)

We do not routinely analyze our product for the substances restricted by this regulation. However, we do not expect that these substances would be present in this product above the specified limits: Cadmium (Cd): 0.01%; Mercury: 0.1% (Hg); Lead (Pb): 0.1%; Hexavalent chromium (Cr6+): 0.1%; Polybrominated biphenyls (PBB): 0.1 %; Polybrominated diphenyl ethers (PBDE): 0.1 %; Bis(2-Ethylhexyl) phthalate (DEHP): 0.1%; Benzyl butyl phthalate (BBP): 0.1%; Dibutyl phthalate (DBP): 0.1%; Diisobutyl phthalate (DIBP): 0.1%.

Other EU regulations

(Directive 2003/53/EC (Restricting Nonylphenol and Nonylphenol Ethoxylates), as amended)

Eastman Chemical Company does not analyse this product for nonylphenol and nonylphenol ethoxylates. Emulsifiers are not used as a raw material, nor are they added to the manufacturing process or the end product. Therefore, we have no reason to expect that these substances are present.

(Regulation 2005/1895/EC (Epoxy Derivatives), as amended)

This regulation replaced Directive 2002/16/EC and is applicable to plastics, surface coatings and adhesives. The following substances are prohibited: 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (or BADGE) (CAS No 001675-54-3), [and derivatives BADGE.H2O, BADGE.HCl; BADGE.2HCl; BADGE.H2O.HCl]; bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (or BFDGE (CAS No 039817-09-9) [and derivatives BFDGE.H2O, BFDGE.HCl; BFDGE.2HCl; BFDGE.H2O.HCl]; other novolac glycidyl ethers (NOGE). These substances are not used in the manufacture of this product. Eastman does not conduct specific analysis for these substances.

(EU Regulation 208/2005 (Polycyclic Aromatic Hydrocarbons (PAHs)), as amended)

Regulation (EC) No 208/2005 and Regulation (EC) No 466/2001 are obsolete. Regulation (EC) No. 1272/2013 amended Entry 50 of Annex XVII to REACH Regulation (EC) No. 1907/2006 on the restrictions of polycyclic aromatic hydrocarbons (PAHs). In addition, Regulation 2015/326/EU also amended Regulation (EC) No 1907/2006. Following are the listed PAHs: (1) Benzo[a]pyrene (BaP) (CAS No 50-32-8); (2) Benzo[e]pyrene (BeP) (CAS No 192-97-2); (3) Benzo[a]anthracene (BaA) (CAS No 56-55-3); (4) Chrysen (CHR) (CAS No 218-01-9); (5) Benzo[b]fluoranthene (BbFA) (CAS No 205-99-2); (6) Benzo[j]fluoranthene (BjFA) (CAS No 205-82-3); (7) Benzo[k]fluoranthene (BkFA) (CAS No 207-08-9); (8) Dibenzo[a,h]anthracene (DBAha) (CAS No 53-70-3). These substances are not used as a raw material, nor are they added to the manufacturing process or the end product. We have no reason to expect that the listed substances would be present in this product.

(Directive 2004/42/EC (Volatile Organic Compounds), as amended)

This product is not considered to be a volatile organic compound (VOC), nor does it contain a VOC, as defined in Article 5 of EU Directive 2004/42/EC (an organic substance with an initial boiling point less than or equal to 250 °C at a standard pressure of 101,3 kPa).

Other USA regulations

(21 CFR 189.5; 21 CFR 700.27 (BSE/TSE))

Based on our knowledge of the raw materials and processes used in the manufacture of this product, we have no reason to expect that bovine-derived materials are present in this product.

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(US CSG (CONEG))

This statement covers the following heavy metals (or their compounds): Cadmium (Cd), Hexavalent chromium (Cr (6+)), Lead (Pb), Mercury (Hg). These metals are not intentionally added to this product as supplied by Eastman Chemical Company. We have not specifically analyzed this product for the presence of these substances. Based on our knowledge of the raw materials and the manufacturing process, it is unlikely that any of these elements would be present in this product in concentrations exceeding the legislation limits.

(GMO (Genetically Modified Organisms))

This product is not derived from plant sources and, therefore, is not produced using genetically modified organisms (GMOs) or recombinant DNA technology.

(40 CFR Part 82 Subpart E, ODS)

Eastman Chemical Company products are neither manufactured with nor contain any "ozone depleting substances" listed by the U.S. Environmental Protection Agency for the protection of stratospheric ozone (Title VI of the Clean Air Act, and 40 CFR Part 82, Subparts A and E, including chlorofluorocarbons, halons, carbon tetrachloride, methyl chloroform, hydrochlorofluorocarbons.) However, based on our knowledge of the raw materials and manufacturing process, these substances may be present in trace quantities in our products.

(Consumer Product Safety Improvement Act of 2008)

We have not analyzed this product for the following substances: Lead, Di-iso-nonyl phthalate (DINP); Di(2-ethylhexyl) phthalate (DEHP); Dibutyl phthalate (DBP); Di-iso-decyl phthalate (DIDP); Di-n-octyl phthalate (DNOP); Butylbenzyl phthalate (BBP). However, these substances are not used as a raw material, nor are they added to the manufacturing process or the end product. We have no reason to expect that these substances would be present above the threshold levels in this legislation (>100 ppm for lead; and concentrations >0.1% for the listed phthalates).

(Kosher Status)

Eastman has not sought or received kosher certification for this product, nor do we currently manufacture it under rabbinical supervision. However, Eastman does not use any animal-derived raw materials or additives in the production of this product. Accordingly, it is our understanding that the kosher status of foods packaged in containers made from this product, as supplied from our manufacturing sites, is not adversely affected by the use of this polymer.

(State Legislation on Bisphenol A (BPA))

Connecticut HB 6572; Washington State SB 6248: Based on our current knowledge of the raw materials and manufacturing processes for this product, we have no reason to expect that this product contains Bisphenol-A as supplied by Eastman. Analysis by a third-party laboratory did not detect BPA in representative samples of our Tritan copolyesters (limit of detection 0.01 ppm). Contact your Eastman representative for additional information.

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Liability Limitation

Users should consider this regulatory information provided only as a supplement to other information, such as the Material Safety Data Sheet. It is the responsibility of our customers to determine that their use of our product(s) is safe, lawful, and technically suitable in their intended applications. Because of possible changes in the laws and regulations, as well as possible changes in our products, we cannot guarantee that the status of this product will remain unchanged. Therefore, we recommend that customers continuing to use this product verify its status periodically. For additional information about this product, please contact your Eastman representative or visit our website at www.eastman.com.

Neither Eastman Chemical Company nor its marketing affiliates shall be responsible for the use of this information, or of any product, method or apparatus mentioned, and you must make your own determination of its suitability and completeness for your own use, for the protection of the environment, and for the health and safety of your employees and purchasers of your products. No warranty is made of the merchantability or fitness of any product, and nothing herein waives any of the Seller's conditions of sale.

If further information is required please do not hesitate to contact us.