
Regulatory Information Sheet

colorFabb nGen

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



colorFabb nGen printing filament is produced with Eastman Amphora 3D Polymer AM3300, 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 complies with the compositional requirements of this Regulation for plastics used in food-contact applications. The final product must meet the overall migration limit of 60 mg/kg of food or 10 mg/square decimeter of the plastic. There are also specific migration limits for terephthalic acid (7.5 mg/kg of food) and isophthalic acid (5 mg/kg of food) under the Regulation. Based on data obtained by Eastman, articles produced from this polymer should comply with the applicable overall and specific migration limits when tested with 3% acetic acid, 10% ethanol and simulant D under conditions including 2 hours at 70°C followed by 10 days at 40°C. Regarding the dual use additives provision in the 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 may lawfully be used as articles or components of articles for use in contact with food subject to provisions of 21 CFR 177.1240. This product as supplied by Eastman, complies with the compositional requirements of FDA regulations at 21 CFR 177.1240(a). Based on results from testing of representative polymers, we expect that articles made under good manufacturing practices will meet the requirements of 21 CFR 177.1240(e)(1),(2), and (3). It 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).

MERCOSUR Status

Eastman Chemical Company certifies that this product is produced from monomers listed in accordance with Mercosur's Positive List (GMC Res. No. 02/12). One of the monomers used in the manufacture of this product has an SML of 5 mg/kg.

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 16 January 2020 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. Therefore, it also would not contain substances included in Annex XIV.

Regulatory Information Sheet

colorFabb nGen

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



Allergies or intolerances

(Regulation 1169/2011, Annex II (Substances or products causing allergies or intolerances))

In regard to the presence of allergens and products which cause intolerances, this product is not manufactured with the following listed substances or products thereof: cereals containing gluten; crustaceans; eggs; fish; peanuts; soybeans, milk, nuts (almonds, hazelnuts, walnuts, cashews, pecans, Brazil nuts, pistachio nuts, macademia or Queensland nuts), celery, mustard, sesame seeds, sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO₂, lupin, molluscs.

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). 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.

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 Directive states that certain phthalates shall not be used as substances or as constituents of preparations, at concentrations of greater than 0.1% by mass of the plasticised material, in toys and childcare articles. The listed phthalates are as follows: bis(2-ethylhexyl) phthalate (DEHP); dibutyl phthalate (DBP); benzyl butyl phthalate (BBP); di-iso-nonyl phthalate (DINP); di-isodecyl phthalate (DIDP); di-n-octyl phthalate (DNOP). We do not analyse this product for these phthalates. However, these substances are not used as a raw material, nor are they added to the manufacturing process or the end product.

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.

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%.

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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), 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 (DBA_hA) (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.

(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, we expect that the sum of any trace quantities of lead, mercury, cadmium, and hexavalent chromium is below legislation limit of 100 ppm.

(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.

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(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.

(Allergen Information)

This product is not derived from the following materials identified in the Food Allergen Labeling and Consumer Protection Act of 2004 as major food allergens: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts and soybeans.

(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).

(State Legislation on Bisphenol A (BPA))

Connecticut HB 6572: 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.

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.