

# PRODUCT REGULATORY INFORMATION SHEET

Print Date: 10/14/2014

Version: 09/26/2014 (00001.00001)

71100831

Eastman Amphora(TM) 3D Polymer AM1800

PRODUCT NAME	
Eastman Amphora(TM) 3D Polymer AM1800	

COMPANY INFORMATION	
Address	Eastman Chemical Company P. O. Box 511 Kingsport, TN 37662

## FOOD CONTACT / FOOD ADDITIVE INFORMATION

### EMEA Region

#### European Union

Declaration of Compliance for Food Contact: Commission Regulation (EU) No. 10/2011 (replaced Directive 2002/72/EC and amendments)

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 ethylene glycol or diethylene glycol (30 mg/kg of food). 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, 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 Regulation (EC) 1935/2004. This product is produced under good manufacturing practices in compliance with EU Regulation 2023/2006.

### North America Region

#### United States

Food Law Compliance

Under regulations administered by the U.S. Food and Drug Administration (FDA), this product may lawfully be used as articles or components of articles intended for use in contact with food subject to provisions of Food Contact Notification Nos. 937 and 1234. This polymer may be used in the manufacture of articles intended for use (1) in contact with aqueous, acidic, low-alcohol (up to 13 percent by volume), and fatty foods under Conditions of Use C ("Hot filled or pasteurized above 150°F") through G ("Frozen storage (no thermal treatment in the container)"), and for use in contact with foods containing up to 50 percent by volume alcohol under conditions of use E ("Room temperature filled and stored (no thermal treatment in the container)") through G ("Frozen storage (no thermal treatment in the container)") as described in Table 2 at website <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/ucm109358.htm>. This product is cleared by the above FCNs and, thus, may be used as intended in full compliance with the Federal Food and Drug, and Cosmetic Act, provided that polymers otherwise meet the limitations set forth

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	in the FCNs ( <a href="http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm">http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm</a> ).
Other Information	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).

### OTHER APPLICABLE REGULATIONS

#### EMEA Region

##### European Union

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 June 2014 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. For further information, refer to our website: <a href="http://www.eastman.com/reach">www.eastman.com/reach</a> .
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.
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, excluding milk or milk derivatives and derivatives of wool and hair of ruminants. The equipment used in the manufacturing process of the product did not come into contact with a substance derived from animal origin.
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.
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.
Regulation (EC) No. 1005/2009	Eastman Chemical does not analyse this product for ozone

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on Substances that Deplete the Ozone Layer	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.
Directive 2011/65/EU (Recast of 2002/95/EC (Restrictions of Hazardous Substances - RoHS)), as amended	To our knowledge, lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE), including decabromodiphenyl ether are not used as raw materials in this product, nor are they added during the production process or the end product. Based on a one-time analysis of this product by an independent laboratory, the listed substances were not detected in this product (method detection limit of 5 mg/kg for PBBs or PBDEs and 2 mg/kg for metals). Further information is available from your Eastman representative.
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	Eastman Chemical Company does not analyse this product for the following epoxy substances: bis(hydroxyphenyl)methane bis (2,3-epoxypropyl) ethers (BFDGE) [and derivatives BFDGEH <sub>2</sub> O, BFDGEHCl; BFDGE <sub>2</sub> HCl; BFDGEH <sub>2</sub> O.HCl]; 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (BADGE) [i.e. Bisphenol-A DiGlycidyl Ether, and derivatives BADGEH <sub>2</sub> O, BADGEHCl; BADGE <sub>2</sub> HCl; BADGEH <sub>2</sub> O.HCl]; Novolac glycidyl ethers (NOGE). However, these substances are not used as a raw material, nor are they added to the manufacturing process or the end product. This product complies with 2005/1895/EC, and amendments, which replaced Directive 2002/16/EC.
Directive 76/769/EEC (Marketing and Use of Certain Dangerous Chemicals), as amended	Based on our knowledge of the raw materials and the manufacturing process, Antimony (Sb), cobalt (Co), copper (Cu), manganese (Mn) and/or zinc (Zn) may be used in the manufacture of this product and may be present at levels below 0.02%. These are considered low volatility metals that are normally removed from incinerators in the ash/particulate fraction. Operators of incinerators or co-incinerators are responsible from complying with applicable limits for these metals in this Directive.
Regulation (EU) No. 528/2012 on Biocidal Products (repealed and replaced Directive 98/8/EC)	This product contains no biocide and is not subject to the provisions of this regulation.
WGK Identification Number:	not available
EU Regulation 208/2005 (Polycyclic Aromatic Hydrocarbons), as amended	Eastman Chemical Company does not analyse this product for the following polycyclic aromatic hydrocarbons (PAH) defined in this amendment or Commission Regulation (EC) No 466/2001: Benzo[a]anthracene; Benzo[b]fluoranthene; Benzo[j]fluoranthene; Benzo[k]fluoranthene; Benzo[ghi]perylene; Benzo[a]pyrene; Chrysene; Cyclopenta[c,d]pyrene; Dibenzo[a,h]anthracene; Dibenzo[a,e]pyrene; Dibenzo[a,h]pyrene; Dibenzo[a,i]pyrene; Dibenzo[a,l]pyrene; Indeno[1,2,3-cd]pyrene; 5-methylchrysene, Benzo[c]fluorene. These substances are not used as a raw material, nor are they added to the manufacturing process or the

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	<p>end product. We have no reason to expect that the listed substances would be present in this product.</p>
<p>Regulation (EC) No. 1881/2006/EC (Maximum levels for certain contaminants in foodstuffs), as amended</p>	<p>Commission Regulation (EC) No. 1881/2006 replaced Regulation 2375/2001 (which amended Regulation (EC) No. 466/2001 and 683/2004/EC). As listed in the Annex to this regulation, the following substances are included: nitrates, aflatoxins, ochratoxin A, patulin, deoxynivalenol, T-2 and HT-2 toxin, lead, cadmium, mercury, tin (inorganic), 3-monochloropropane-1,2-diol (3-MCPD), dioxins (sum of polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans), polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (benzo(a)pyrene). Eastman does not analyze this product for the presence of these substances. However, based on our knowledge of the raw materials and manufacturing process, we have no reason to expect that materials which would produce these substances were used in this product or that this product would have contacted materials that produce these substances.</p>
<p>Directive 2004/42/EC (Volatile Organic Compounds), as amended</p>	<p>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). Also, it is not considered a VOC, nor does it contain one, as defined in the Swiss ordinance on incentive taxes on volatile organic compounds (OVOC): "volatile organic compounds (VOC) are organic compounds with a vapour pressure of at least 0.1 mbar at 20°C or a boiling point of maximum 240°C at 1013.25 mbar".</p>
<b>North America Region</b>	
<b>United States</b>	
<p>21 CFR 189.5; 21 CFR 700.27 (BSE/TSE)</p>	<p>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.</p>
<p>US CSG (CONEG)</p>	<p>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.</p>
<p>California Proposition 65</p>	<p>Eastman has not specifically analyzed this product for the purpose of identifying the presence of the substances listed in Proposition 65. This product contains a chemical known in the State of California to cause cancer or reproductive toxicity. Acetaldehyde is an unavoidable byproduct in polyesters made from ethylene glycol. Acetaldehyde has a high vapor pressure at room temperature, and the rate of migration is slow, especially at low temperatures. Therefore, very little migration should occur during short time periods at room temperature or below. Because Eastman has limited knowledge of your manufacturing processes, products or the circumstances under which potential exposures may arise,</p>

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	<p>Eastman is unable to certify that when our product is used to manufacture your products, no individuals using such products in California will be exposed to any Proposition 65 chemicals in amounts that require a Proposition 65 warning. For this reason, your company must make its own determination that Eastman products are safe, lawful, and technically suitable for use in your company's intended applications. If you have general questions regarding the chemical composition or properties of specific products, please refer to the Material Safety Data Sheet.</p>
GMO (Genetically Modified Organisms)	<p>This product is not derived from plant sources and, therefore, is not produced using genetically modified organisms (GMOs) or recombinant DNA technology.</p>
40 CFR Part 82 Subpart E, ODS	<p>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.</p>
Allergen Information	<p>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.</p>
Consumer Product Safety Improvement Act of 2008	<p>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 (&gt;100 ppm for lead; and concentrations &gt;0.1% for the listed phthalates).</p>

*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](http://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.*