

PRODUCT REGULATORY INFORMATION SHEET

EASTMAN

Print Date: 4/14/2024

Version: 03/20/2024 (00,001.00,091)

71070312

Eastman Tritan(TM) Copolyester TX1001

PRODUCT NAME	
Eastman Tritan(TM) Copolyester TX1001	
COMPANY INFORMATION	
Address	Eastman Chemical Company 200 South Wilcox Drive Kingsport TN 37660-5147 (0001)
PRODUCT INFORMATION	
Substances of Concern	Eastman Chemical Company has not analyzed this product for the presence of the substances listed below. Based on our knowledge of the raw materials and manufacturing processes, we have no reason to expect any of these substances to be present in the final product or to be formed during manufacturing or under normal handling, storage and use conditions:
	natural rubber latex
	melamine
	polyvinyl chloride
	nitrosamines
Food Allergen Information including the US FALCPA and FASTER Act, and EU Regulation 1169/2011 (FIC's Annex II)	Eastman Chemical Company has not analyzed this product for the presence of the substances listed below. Based on our knowledge of the raw materials and manufacturing processes, we have no reason to expect any following materials identified as major food allergens to be present in the final product or to be formed during manufacturing or under normal handling, storage and use conditions: celery, cereals containing gluten (e.g. wheat), crustacean shellfish, eggs, fish, lupin, milk, peanuts, mustard, sesame, soybeans, sulphur dioxide and sulphites, tree nuts, and molluscs.
FOOD CONTACT / FOOD ADDITIVE INFORMATION	
Asia Pacific Region	
China	This product complies with the provisions in the National Standard for Food Safety General Safety Requirements for Food Contact Materials and Articles (GB 4806.1-2016). The resin is listed as No. 78 (CAS No. 261716-94-3) on GB4806.7-2023 (Food Contact Plastic materials and articles) with a specific migration limit and restrictions: 5.0 mg/kg (2,2,4 ,4-tetramethyl -1,3-cyclobutanediol: SML), 7.5 mg/kg (terephthalic acid: SML(T)), use temp not to exceed 100°C. This product contains a proprietary additive which complies with the provisions in GB 9685-2016 (Standard for Uses of Additives in Food Contact Materials and Products) without specific migration limits and/or restrictions.
Japan	The Japan Ministry of Health, Labour, and Welfare (MHLW) published Notification No. 323 of 2021 to amend MHLW

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Eastman Tritan(TM) Copolyester TX1001

	<p>Notification No. 370 which includes a positive list for food-contact synthetic resins and related additives. As of the most recent publish date, the composition of this product is included in the positive lists. This product may be safely used in contact with all food types at up to 100°C.</p> <p>This product contains a proprietary additive with a specific migration limit.</p>
EMEA Region	
European Union	
Declaration of Compliance for Food Contact: Commission Regulation (EU) No. 10/2011 (and amendments up to and including 2023/1627)	<p>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), and a proprietary additive. The additive and 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 hot-fill conditions. Based on testing of a representative sample, articles produced from this product should comply with the applicable overall and specific migration limit for TMCD when tested with food simulants A (10% Ethanol), B (3% Acetic Acid), D1 (50% Ethanol), and D2 (olive oil) under test conditions including both 10 days at 40°C and 2 hours at 100°C. This testing covers use for contact with all food types including foods with an alcohol content above 20%. 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.</p>
Latin America Region	
Brazil	<p>Eastman Chemical Company certifies that the base polymer is listed in accordance with Brazil's National Health Surveillance Agency (ANVISA) Resolution RDC No 56/2012 Part V: Positive list of monomers, other starting substances and polymers authorized for the manufacture of food contact plastic packaging and equipment at temperatures below or equal to 100°C. Additionally, this product contains a proprietary additive which is listed in Resolution No RDC 326/19 (Repeal of RDC 17/2008): Positive List of Additives for Preparation of Plastic Materials and Coatings Polymers for Food Contact with no restrictions or SML.</p>
MERCOSUR Status	<p>Eastman Chemical Company certifies that the base polymer is listed in accordance with Mercosur's Positive List (GMC Res. No. 02/12) Part V - List of Authorized Polymers for use as a</p>

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	component in the manufacture of repeated use articles in contact with all types of food at temperatures below or equal to 100°C. Additionally, this product contains a proprietary additive which is listed in GMC/Res No. 39/19 (Repeal of GMC Res. No. 32/07): Positive List of Additives for Preparation of Plastic Materials and Coatings Polymers for Food Contact with no restrictions or SML.
North America Region	
United States	
Food Law Compliance	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 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. This formulation contains a proprietary additive which complies with the regulations for indirect food additives published by the U.S. Food and Drug Administration.
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

Asia Pacific Region

China ROHS	The Ministry of Information Industry published "Administrative Measure on the Control of Pollution Caused by Electronic Information Products," and the law was signed as Decree No. 39. Some materials used in electronic information products should not contain lead, mercury, cadmium, hexavalent chromium, PBB and PBDE. While Eastman does not specifically analyze our product, these substances are not used in the manufacture of this product.
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EMEA Region

European Union

Regulation (EC) No. 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (REACH)	Eastman confirms its compliance with REACH. This product is either a polymer or contains a polymer according to the REACH definition art 3.5. Polymers are exempt from registration according to REACH Article 2.9. For this reason, you will not find a registration number or eSDS with exposure scenarios in the annex for this product. However, REACH dictates that the monomer(s) of the polymer need to be registered instead. Eastman confirms that all monomers used in the manufacturing of this polymer are either registered or exempt from registration. In case of a product which contains a polymer, the other substances used, like solvents or additives, are either registered or exempt from registration. When required to mention these substances in the SDS and registered, the corresponding REACH
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	registration number can be found in section 3.2 of the SDS.
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 23 January 2024 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.
Directive 2006/122/EC (Relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations (perfluorooctane Sulfonates), as amended	This directive is superseded by amendments to Regulation (EC) No. 1907/2006 Annex XVII (Restrictions on the Manufacture, placing on the market and use of certain dangerous substances, preparations and articles). Perfluorooctane sulfonates & salts & esters are listed with a restriction of <0.005%. We do not analyse this product for these substances. We do not add these substances to the end product, and we do not expect that these substances will be formed during manufacturing or under normal handling, storage and use conditions. Based on our knowledge of our raw materials and manufacturing processes, we have no reason to expect that these substances would be present.
Registration, Evaluation and Authorisation of Chemicals (REACH) Annex XVII - Substances restricted under REACH	Regulation (EC) No. 1907/2006 Annex XVII Restrictions on the Manufacture, placing on the market and use of certain dangerous substances, preparations and articles (updated 17 January 2022). From 4 July 2020 PFOA (Entry 68; CAS# 335-67-1; EC# 206-397-9) including "its salts and polymers" such as Per- and polyfluoroalkyl substances (PFAS) shall not be placed on the EU market in concentration equal to or above 25 ppb of PFOA including its salts or 1000 ppb of one or a combination of PFOA-related substances. With reference to this condition of restriction this product placed on the market is not known to contain Perfluorooctanoic acid (PFOA) including its salts and polymers exceeding the specified limits.
Commission Recommendation 2011/696/EU – Nanomaterials as revised under Commission Recommendation of 10 June 2022	The European Commission under Commission Recommendation of 10 June 2022 defines nanomaterials as "A natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable aggregates or agglomerates, where 50 % or more of the particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions is in the size range 1 nm - 100 nm (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimension is larger than 100 nm"

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71070312

Eastman Tritan(TM) Copolyester TX1001

	Eastman Chemical Company does not intentionally use nanomaterials or apply nanotechnology as defined above in the manufacture of this product.
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.
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.
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.
Regulation (EC) No. 1005/2009 on Substances that Deplete the Ozone Layer	Eastman Chemical Company 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.
Directive 2011/65/EU (Restrictions of Hazardous Substances - RoHS), as amended by Commission Delegated Directive (EU) 2015/863	To our knowledge, the following substances are not used as raw materials in this product, nor are they added during the production process or the end product. Although we do not routinely analyse our product for these substances, we have no reason to expect that these substances would be present above the stated limits: Lead (0,1 %); Mercury (0,1 %); Cadmium (0,01 %); Hexavalent chromium (0,1 %); Polybrominated biphenyls (PBB) (0,1 %);

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	<p>Polybrominated diphenyl ethers (PBDE) (0,1 %); Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %); Butyl benzyl phthalate (BBP) (0,1 %); Dibutyl phthalate (DBP) (0,1 %); Diisobutyl phthalate (DIBP) (0,1 %).</p> <p>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.</p>
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.
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.
EN71-3 (Safety of Toys - Specification for Migration of Certain Elements); Directive 2009/48/EC (replaced 88/378/EEC)	This statement covers the following elements listed in Directive 2009/48/EC, Annex II (Particular Safety Requirements), Part III (Chemical Properties): Aluminum (Al); Antimony (Sb), Arsenic (As), Barium (Ba), Boron (B), Cadmium (Cd), Chromium (Cr III), Chromium (Cr VI), Cobalt (Co), Copper (Cu), Lead (Pb), Manganese (Mn), Mercury (Hg), Nickel (Ni), Selenium (Se), Strontium (Sr), Tin (Sn), organic Tin, Zinc (Zn). Based testing of representative samples and our knowledge of the raw materials and the manufacturing process, it is unlikely that the elements defined above would migrate from this product in concentrations exceeding the limits defined for Category I (dry, brittle, powder-like or pliable toy materials).
Regulation (EU) 2019/1021 on persistent organic pollutants (previously Regulation (EU) 850/2004, as amended by Commission Delegated Regulation (EU) 2023/1608	Eastman Chemical Company has not analyzed this product for the presence of the substances listed below. Based on our knowledge of the raw materials and manufacturing processes, we have no reason to expect any of these substances to be present in the final product or to be formed during manufacturing or under normal handling, storage and use conditions: The amended Annexes (including Regulation 2021/277) list the following persistent organic

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	<p>pollutants: [alkanes C10-C13 chloro (short-chain chlorinated paraffins or SCCPs), endosulfan, tetrabromodiphenyl ether, pentabromodiphenyl ether, hexabromodiphenyl ether, hexabromocyclododecane, 1,2,5,6,9,10-hexabromocyclododecane [and its main diastereoisomers: alpha- hexabromocyclododecane; beta-hexabromocyclododecane; and gamma-hexabromocyclododecane]; hexachlorobutadiene, heptabromodiphenyl ether, perfluorooctane sulfonic acid and its derivatives (PFOS), DDT, chlordane, hexachlorocyclohexanes, aldrin, dieldrin, endrin, heptachlor, hexachlorobenzene, hexabromobiphenyl, chlordecone, pentachlorobenzene, mirex, polychlorinated biphenyls, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, polychlorinated naphthalenes, toxaphene; pentachlorophenol and its derivatives.</p>
Regulation on Polycyclic Aromatic Hydrocarbons (PAHs)	<p>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.</p>
North America Region	
United States	
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, it is unlikely that any of these elements would be present in this product in concentrations exceeding the legislation limits.
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

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	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.
National Sanitation Foundation (NSF)	This product is certified to ANSI/NSF Standard 51. This product is certified to ANSI/NSF Standard 61.
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); Diisobutyl phthalate (DIBP); Dipentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP); Dicyclohexyl phthalate (DHCP). 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.
Washington Department of Ecology Chemicals of High Concern to Children - Children's Safe Product Act (CSPA)	We do not specifically analyze our product for the presence of the CHCC-listed substances. Based on our knowledge of the raw materials and manufacturing process for our product, the substances listed as of the date of this document by the Children's Safe Products Act as CHCCs at website https://ecology.wa.gov/Regulations-Permits/Reporting-requirements/Reporting-for-Childrens-Safe-Products-Act/Chemicals-of-high-concern-to-children are not expected to be present in this product in the form supplied by Eastman Chemical Company.
Regulation of Persistent Bioaccumulative and Toxic (PBT) Chemicals under US TSCA section 6(h)	Eastman Chemical Company has not analyzed this product for the presence of Persistent Bioaccumulative and Toxic (PBT) Chemicals substances listed under US TSCA section 6(h). Based on our knowledge of the raw materials and manufacturing processes, we have no reason to expect any of these substances

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EASTMAN

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Version: 03/20/2024 (00,001.00,091)

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Eastman Tritan(TM) Copolyester TX1001

	to be present in the final product or to be formed during manufacturing or under normal handling, storage, and use conditions.
US EPA action plan on PFAS	The U.S. Environmental Protection Agency (EPA) issued a final ruling on the safe use of per- and polyfluoroalkyl substances (PFAS) recently. Eastman Chemical Company has not specifically analyzed this product for the presence of per- and polyfluoroalkyl substances (PFAS) especially PFOA, PFOS. However, based on our knowledge of the raw materials and manufacturing processes, we have no reason to expect any of these substances to be present in the final product or to be formed during manufacturing or under normal handling and storage.

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 web site 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.