PRODUCT NAME
Eastman Tritan(TM) Copolyester MX711

COMPANY INFORMATION	
Address	Corporate Headquarters: Eastman Chemical Company 200 South Wilcox Drive Kingsport, TN 37660 Eastman Chemical Company P. O. Box 511 Kingsport, TN 37662 Telephone: 1 423 229-2000 or 1 800 EASTMAN

FOOD CONTACT / FOOD ADDITIVE INFORMATION	
EMEA Region	
European Union	
Declaration of Compliance for Food Contact: Commission Regulation (EU) No. 10/2011 (and amendments)	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 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 Regulaton, 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.
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 Food Contact Notification No. 1041, which replaces FCN No. 729. 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/packagingfcs/foodtypesconditionsofuse/ucm109358.htm to access the Food Types and Conditions of Use for Food Contact Substances Tables). 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).

MEDICAL DEVICE / PACKAGING INFORMATION	
ISO 10993/USP Class VI Test Report	The laboratory certificate of compliance is available upon request. Samples made from this product were sterilized (Gamma at 50 kGy dosage and ETO at 130 degrees F), and these samples passed the following FDA-Modified ISO 10993 tests with human tissue contact time of 30 days or less: cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicty (acute), implantation, hemocompatibility, physicochemical (USP).

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product in order to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies. Eastman products have not been designed for nor are they promoted for end uses that would be categorized by either the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1 "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices, or (3) as any critical component in any medical device that supports or sustains human life. For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. Tests are defined in FDA-Modified ISO-10993, Part 1 'Biological Evaluation of Medical Devices'. Limited testing information for certain Eastman products is available upon request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device. The suitability of an Eastman product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements

and to adequately advise and warn purchasers and users thereof.

OTHER APPLICABLE REGULATIONS	
EMEA Region	
European Union	
Regulation (EC) No. 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (REACH)	Eastman confirms its compliance with REACH. Where relevant and required, all substances manufactured in and imported into the European Union by Eastman have been duly registered and/or pre-registered. Polymers are exempt from registration under REACH, however all monomers and additives are pre-registered and registered where relevant, such that our polymer products are REACH compliant.
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 7 July 2017 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 (PFOS) 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.
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	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.
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 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 %); 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 %).
	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 substances: bis(hydroxyphenyl)methane bis (2,3-epoxypropyl) ethers (BFDGE) [and derivatives BFDGEH2O, BFDGEHCl; BFDGE2HCl; BFDGEH2O.HCl]; 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (BADGE) [and derivatives BADGEH2O, BADGEHCl; BADGE2HCl; BADGEH2O.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.
	Regulation (EU) No. 1272/2008 on the classification, labeling, and packaging of substances	Eastman has determined that this product does not contain any substances that have been identified/classified as a carcinogen, mutagen, or reproductive toxicant (CMR; categories 1A and 1B), as defined under this regulation or its amendments.
	Regulation (EU) No. 528/2012 on Biocidal Products (repealed and replaced Directive 98/8/EC)	This regulation entered into force on September 1, 2013 with a transitional time for certain provisions. To discuss in detail the applicable requirements for this product, contact your Eastman representative. (Reference:

	http://ec.europa.eu/environment/biocides/2012/overview.htm).
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 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). 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".
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.
California Proposition 65	Eastman has not specifically analyzed this product for the purpose of identifying the presence of the substances listed in Proposition 65. Based on our knowledge of the raw materials and manufacturing process, we have no reason to expect that this product would contain substances at levels which would require warning as required by Proposition 65. Because Eastman has limited knowledge of your manufacturing processes, products or the circumstances under which potential exposures may arise, 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.
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.
40 CFR Part 60	Eastman has performed no specific testing of this product for VOC content. Based on the physical properties of this material, the VOC content is expected to be negligible when tested using EPA Method 24.
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).
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 5 ppm). Contact your Eastman representative for additional information.

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.