EASTMAN

PRODUCT NAME
Eastman(TM) 168 Plasticizer

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

FOOD CONTACT / FOOD ADDITIVE INFORMATION	
Asia Pacific Region	
China	Listed in GB 9685-2008, Hygienic standards for uses of additives in food containers and packaging materials (CAS No. 6422-86-2)
EMEA Region	
European Union	
Directive 2002/72/EC Declaration of Compliance for Food Contact	(including amendments 2004/19/EC, 2004/1/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC and Commission Regulation (EC) No 975/2009) This product complies with the compositional requirements of this regulation for food-contact applications. The final article must meet the overall migration limit of 60 mg/kg of food or 10 mg/square decimeter of the plastic. This product complies under Ref. No. 92200 for terephthalic acid, bis(2-ethylhexyl)ester with a specific migration limit of 60 mg/kg food. Regarding the dual use additives provision in Directive 2004/19/EC, there are no additives subject to restrictions on concentrations in food as a food additive. This product is intended for use in the manufacture materials and articles in compliance with the general requirements of Regulation (EC) 1935/2004.
North America Region	
United States	
21 CFR Compliance	This product may lawfully be used according to Food Contact Notification 770 [1,4-bis(2-ethylhexyl) benzenedicarboxylate] as follows: (1) At a level not to exceed 35 percent by weight of finished plasticized vinyl chloride polymer formulations used in repeated-use food contact applications at temperatures no greater than 100 degrees C; (2) As a component of a paper or paperboard, or coatings for such paper and paperboard intended for use in contact with dry foods with no free surface fats or oil in compliance with 21 CFR 176.180 Components of paper and paperboard in contact with dry food; (3) As a component of adhesives complying with the provisions of 21 CFR 175.105 Adhesives; and, (4) As a component of pressure sensitive adhesives complying with the provisions of 21 CFR 175.125 Pressure-sensitive adhesives. It is also permitted as a component of closure-sealing gaskets for food containers subject to the provisions and limitations of 21 CFR 177.1210. The use of this substance is subject to the restrictions stated in the regulations as well as the general provisions for indirect food additives in 21 CFR

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	174.5.
FCN Number	770
FALCPA	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.

MEDICAL DEVICE / PACKAGING INFORMATION	
Other medical device or packaging information	Refer to information below.

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. The ranges of tests under FDA-Modified ISO-10993, Part 1 'Biological Evaluation of Medical Devices' include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (sub-acute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information 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.

PHARMACEUTICAL / PHARMACEUTICAL PACKAGING INFORMATION	
U.S. FDA Drug Master File Number	15671

OTHER APPLICABLE REGULATIONS	
EMEA Region	
European Union	
Regulation (EC) No. 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (REACH)	With reference to the Substance of Very High Concern (SVHC) Candidate List published on 28 October 2008 and updated 13 January 2010, bis(2-ethyl(hexyl)phthalate (EINECS No. 204-211-0) is listed as a SVHC. Our analysis demonstrates that the concentration of this substance is well below the 0.1% (w/w) threshold concentration.
Directive 2006/122/EC (Relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations (perfluorooctane Sulfonates), as	We do not analyse this product for the perfluorooctane sulfonates (PFOS) and related compounds. 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

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amended	materials and manufacturing processes, we have no reason to expect that these substances would be present.
Directive 94/62/EC (Packaging and Packaging Waste), 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.
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	Our product is a terephthalate plasticizer and is not an ortho-phthalate plasticizer. There are trace levels of ortho-phthalate compounds in our product derived from the raw materials used in its manufacture. The level has been determined to be well below 0.05% total ortho-phthalates.
Regulation (EC) No. 2037/2000 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 (including chlorofluorocarbons, other fully halogenated chlorofluorocarbons, halons, carbon tetrachloride, 1,1,1-trichloroethane, methyl bromide, hydrobromofluorocarbons, and hydrochlorofluorocarbons). Based on our knowledge of the raw materials and our manufacturing process, we do not expect the listed substances to be present in our products.
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. These substances are not used as a raw material, nor are they added to the manufacturing process or the end product. Further, these substances would not be formed during manufacturing or under normal handling, storage and use conditions.
Directive 2002/95/EC (Restrictions of Hazardous Substances - RoHS), as amended	RoHS states that "Member States shall ensure that from 1 July 2006, new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE), including decabromodiphenyl ether." To our knowledge, these 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

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	these substances, we have no reason to expect that lead, mercury, cadmium, hexavalent chromium, PBB or PBDE are present in this product, except as a possible trace impurity.
Directive 2002/96/EC (Waste Electrical and Electronic Equipment (WEEE)), as amended	The purpose of this directive, as a first priority, is the prevention of waste electrical and electronic equipment. In addition, it addresses the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste. It also seeks to improve the environmental performance of all operators involved in the life cycle of electrical and electronic equipment, e.g. producers, distributors and consumers, and in particular those operators directly involved in the treatment of waste electrical and electronic equipment. We have no reason to expect that this product as marketed by Eastman would contain substances that will obstruct the reuse, recycling or other forms of recovery of the waste of electrical and electronic waste.
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.
Directive 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 BFDGEH2O, BFDGEHCl; BFDGE2HCl; BFDGEH2O.HCl]; 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (BADGE) [i.e. Bisphenol-A DiGlycidyl Ether, 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 EU Directive 2002/16/EC.
Directive 67/548/EEC and Directive 76/769/EEC (Carcinogens, Mutagens, Reproductive Toxins), as amended	Eastman Chemical Company does not analyze this product for all of the carcinogens, mutagens, reproductive toxins (CMRs) identified under this directive, as amended. Based on our understanding of the raw materials and manufacturing process, we have no reason to expect that this product contains impurities at levels that need to be taken into account under the requirements of these Directives.
Directive 76/769/EEC (Marketing and Use of Certain Dangerous Chemicals), as amended	This statement covers the following heavy metals (or their compounds): Arsenic (As), Cadmium (Cd), Cobalt (Co), Hexavalent chromium (Cr (6+)), Lead (Pb), Mercury (Hg), Nickel (Ni), Zinc (Zn). These substances are not used as a raw material, nor are they added to the manufacturing process or the end product. Further, these substances would not be formed during manufacturing or under normal handling, storage and use conditions. This product complies with the heavy metal content limits of this legislation.
Directive 98/8/EC (Biocides), as amended; Commission Decision 2009/251/EC (Dimethylfumarate)	Eastman Chemical Company does not analyse this product for the listed biocides. However, the listed biocides 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

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	substances would be present.
EN71-3 (Safety of Toys - Specification for Migration of Certain Elements)	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.
EN71-9 (Safety of Toys-Organic chemical compounds)	Standard EN71-9 specifies requirements for the migration or content of certain hazardous organic chemical compounds from or in certain toys and toy materials by mouthing, ingestion, skin contact, eye contact and inhalation. The following groups of organic chemicals are addressed in EN71-9: flame retardants, colorants, primary aromatic amines, monomers (acrylamide, Bisphenol A, formaldehyde, phenol, styrene), solvents, plasticizers (phosphates only), preservatives, and wood preservatives. None of the chemicals listed in these categories in EN-71-9: 2005 are used in the manufacture of this Eastman product. We have not analyzed our product for the presence of these chemicals as specified in EN71 Part 10 and Part 11.
Directive 88/378/EEC (Toy Safety), as amended by 2009/48/EC	This statement covers the following elements: Aluminum (Al); Antimony (Sb), Arsenic (As), Barium (Ba), Boron (Bo), 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). This product complies with the heavy metal content limits of this legislation.
WGK Identification Number:	1 - weak hazard for water
Regulation 850/2004 on persistent organic pollutants	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 Convention of Persistent Organic Pollutants: aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, polychlorinated biphenyls, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, toxaphene
EU Regulation 208/2005 (Polycyclic Aromatic Hydrocarbons), as amended	Eastman Chemical Company does not analyse this product for the following polycyclic aromatic hydrocarbons (PAH): Acenaphthene; Acenaphthylene; Anthracene; 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; Fluoroanthene; Fluorene; Indeno[1,2,3-cd]pyrene; Naphthalene; Phenanthrene; Pyrene; 5-methylchrysene. 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.
Regulation (EC) No. 1881/2006/EC (Maximum levels for certain contaminants in	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

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foodstuffs), as amended	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.
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". Vapor Pressure: 1.33 mbar @ 217 °C Boiling Point: 400 °C
North America Region	
United States	
9 CFR 94.18 (BSE/TSE)	The U.S. Food and Drug Administration and the U.S. Department of Agriculture have recommended that products intended for use in foods, drug, cosmetics, or medical devices not be manufactured using bovine-derived materials from countries where bovine spongiform encephalopathy (BSE) has been diagnosed. BSE is one type of Transmissible Spongiform Encephalitis (TSE). The BSE-identified countries are listed in the U.S. Code of Federal Regulations at 9 CFR 94.18. 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). 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	A Proposition 65-listed chemical may be present in this product as supplied by Eastman. Based on our knowledge of the manufacture of this product, di-(2-ethylhexyl) phthalate (CAS No. 117-81-7) can be present at less than 0.1% (< 0.1%). The State of California has established a No Significant Risk Level (NSRL) for di-(2-ethylhexyl) phthalate of 310 µg per day and Maximum Allowable Dose Levels (MADL) that vary depending on exposure conditions (Updated September 12, 2008). In considering whether a cancer or reproductive hazard warning label is required under

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	the Proposition 65 regulation, product manufacturers whose products contain di-(2-ethylhexyl) phthalate must make their own determination of whether the possible daily intake of this chemical by consumers is less than the reported NSRL or MADLs. This determination can be made on a product-by-product basis, not on a per capita basis. That is, the calculated values are not additive or cumulative. Additional information on the NSRL, MADLs, and how to perform appropriate exposure assessments is available from the California's Office of Environmental Health Hazard Assessment (OEHHA) at www.oehha.org/prop65.html.
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.
40 CFR 63 Subpart 112(b)(1), HAP	Eastman has not determined whether each of the HAPs identified in this list are found in this product. However, based on Eastman's current knowledge of the raw materials, the manufacturing processes and analyses of representative product samples, Eastman does not expect that HAPs are present at or greater than 1.0 percent. Eastman does not expect that any carcinogenic HAPs are present at or greater than 0.1 percent. The only HAP currently identified in this product is di(2-ethylhexyl) phthalate (CAS Registry Number 000117-81-7) (DEHP). Eastman's analysis of the concentration of DEHP is well below 0.05 percent.
40 CFR Part 60, VOC	This product has 1.14% volatile content when tested by EPA Method 24. Vapor Pressure: 1.33 mbar @ 217 °C Boiling Point: 400 °C
CERCLA List of Hazardous Substances and Reportable Quantities (40 CFR 302, Table 302.4)	This product or its components are not listed.
SARA Title III, Section 313 List of Toxic Substances (40 CFR 372.65)	Substances subject to restrictions under this regulation will be provided in Section 15 of our MSDS for this product.
Consumer Product Safety Improvement Act of 2008	We have not analyzed this product for lead. However, lead is not used as a raw material, nor added to the manufacturing process or the end product. We have no reason to expect that lead would be present above the threshold levels in this legislation (>300 ppm for lead) and will comply with the limit in this legislation. This legislation limits the concentration of the following ortho-phthalates: Di-iso-nonyl phthalate (DINP); Di(2-ethylhexyl) phthalate (DEHP); Dibutyl phthalate (DBP); Di-iso-decyl phthalate

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	(DIDP); Di-n-octyl phthalate (DNOP); Butylbenzyl phthalate (BBP). Products subject to this legislation cannot contain more than 0.1% of these plasticizers. Our product is a terephthalate plasticizer and is not an ortho-phthalate plasticizer. There are trace levels of ortho-phthalate compounds in our product derived from the raw materials used in its manufacture. The level has been determined to be well below 0.05% total ortho-phthalates.

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.

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