



Effective Date: 02/14/2017

## REGULATORY INFORMATION PACKET

# Beverage Ultra Barrier™ BFX

### **Product Manufacturer**

This product is manufactured by Eldon James Corporation in Denver, Colorado U.S.A.

### **Manufacturing Facility Certifications**

ISO 9001:2008 and ISO 13485:2003 Quality Standards, ISO Class 7 Cleanroom.

### **Chemical Inventories**

Please see SDS for chemical inventory listings.

### **Food Contact Status**

This product is formulated with ingredients that when used, unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications, complies with the U.S. Food and Drug Administration's food additive regulation at 21 CFR 177.1520(c) 3.2c, 21 CFR Food and Drugs, 178.2010 Stabilizer for Polymers, 181.28 Release Agents and 177.1520 Olefin Polymers Paragraphs (c) 3.1a.

This product may be used to produce articles or components of articles used in contact with food to all food types described in Table 1 and Conditions of Use C-H described in Table 2 of U.S. FDA's regulation at 21 CFR § 176.170(c). The preceding statement refers to regulatory requirements only, not to the product's physical utility. It is the responsibility of the article producer or food packager to determine that the article is suitable for its intended use.

### **US FDA Drug Master File (DMF)**

One of the ingredients of this product is listed under FDA Drug Master File 4251.

### **Food Allergens**

To the best of our knowledge, there are no raw materials, including additives, that have their origin in peanuts, soybeans, milk, eggs, fish, crustaceans/shellfish (mollusks, shrimp, prawn, crab, lobster or crayfish), crustaceans, tree nuts (not including coconuts), mustard, celery, sesame, lupine, animal or vegetable proteins, caffeine, monosodium glutamate (MSG), colorants (including carmine and cochineal), corn, wheat, barley, rye, triticale, gluten, mushrooms, yams, and/or phenylalanine and its derivatives. No sulfates or sulfites are used in the synthesis of this material, Nickel or Nickel compounds or latex. These components are not introduced during our manufacturing of this product and the raw materials used are not expected to contain any of these substances. We do not test for these substances but believe they should not be present based on the chemical composition and/or literature from our suppliers.



### **US Pharmacopeia (USP)**

This product meets the requirements of USP Class VI (USP <88> Biological Test for Plastics, Class VI-50°C) and is considered non-hemolytic ISO 10993-12.

### **Canadian Food Contact (HPFB or CFIA)**

The composition of this product has not been assessed for use in contact with food per the Canadian Health Products and Food Branch (HPFB).

### **European Pharmacopoeia (EPHc)**

#### **European Commission Regulation (EU) No 10/2011 (Food Contact)**

The composition of this product complies with the requirements for use in contact with non-fatty foodstuffs under European Commission Regulation (EU) No 10/2011, including any subsequent amendments that are in force prior to the effective date of this Regulatory Data Sheet. Contact supplier to obtain a detailed food contact compliance letter for the individual European Countries and information about the imposed migration requirement.

### **Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA)**

This product is registered under the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) for use in food contact packaging applications.

### **Latin America MERCOSUR Food Contact Status**

The composition of this product has not been assessed for use in contact with food per MERCOSUR GMC Resolution No. 32/07 and/or Resolution No. 02/12.

### **Animal Derived Components (BSE/TSE)**

One or more ingredients used to manufacture this product may have been synthesized from animal extracts, i.e. hydrolysis, etc. of animal fats (tallow) into fatty acids. If used, the manufacturing process of the fatty acids includes a multi-step chemical treatment involving high temperatures, high pressures, and long residence times. Thus, the tallow derivatives used in the manufacturing of this product are therefore considered compliant. These processing conditions greatly exceed the requirements as specified in Section 6.4 of the “Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products” (EMA/410/01 Rev. 3 – July 1, 2011), adopted by the European Commission and published in the Official Journal of the European Union March 5, 2011 (2011/C 73/01).

### **Plant Derived Components**

This product may contain one or more additive(s)/substance(s) synthesized from plant extracts, i.e. hydrolysis, etc. of plant oils into fatty acids and/or their derivatives, as per information from our raw material suppliers; one or more of the substances used does contain plant derived materials, is vegetable derived and does not comply with Kosher or Halal requirements.



### **REACH 173 Substances (January 12, 2017)**

We or our resin supplier do not intentionally add any of the SVHC substances in the manufacture or formulation of this product and do not believe that any of the chemicals listed on the EU Candidate List of Substances of Very High Concern dated January 12, 2017 are present in this product at levels greater than 0.1%.

### **EU Directive 2011/65/EU Restriction of Hazardous Substances (RoHS)**

This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS 2), as amended (Directive (EU) 2015/863 inclusive). It is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), or Diisobutyl phthalate (DIBP).

### **China ROHS**

The above listed product complies with Administrative Measure on the Control of Pollution Caused by Electronic Information Products (China RoHS banned substances). Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls, and Polybrominated Diphenyl Ethers are not intentionally added to the above listed product and the raw materials used do not contain these substances.

### **Heavy Metals (ELV Directive 2000/53/EC)**

#### **Coalition of Northeastern Governors (CONEG)**

This product conforms to the Coalition of Northeastern Governors (CONEG) and the European Directive 94/62/EC, as amended, on Packaging and Packaging Waste, Article 11. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

### **European Directive (94/62/EC) Packaging and Packaging Waste**

#### **EU Directive 2012/19/EU Waste Electrical & Electronic Equipment (WEEE)**

EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) EU Directive 2012/19/EU on WEEE: Selective treatment of the waste (Annex VII). None of the substances listed in Annex VII are intentionally added or used in the formulation of this product with the following exception. This product is a hydrocarbon; however, liquid hydrocarbons are not present in this product.

### **European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)**



The resin manufacturer does not use 2,2-bis(4-hydroxyphenyl) propane bis (2,3- epoxypropyl) ether (BADGE), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE) or novolac glycidyl ethers (NOGE) in the manufacture or formulation of this product.

### **California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)**

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute as of the effective date of this regulatory datasheet.

### **Conflict Materials (Dodd-Frank Wall Street Reform and Consumer Protection Act)**

This product is not intentionally manufactured or formulated with the listed conflict minerals as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; however, we do not analyze for these specific substances or compounds.

- Columbite – Tantalite – refined into Tantalum (Ta) (CAS # 7440-25-7)
- Cassiterite – refined into Tin (Sn) (CAS # 7440-31-5)
- Wolframite – refined into Tungsten (W) (CAS # 7440-33-7)
- Gold (Au) (CAS # 7440-57-5)

We are disclosing the above information, to the best of our knowledge based upon data from our raw material suppliers. We believe this information to be accurate and reliable as of the effective date of this Regulatory Data Sheet.

### **Ozone Depleting Chemicals (ODCs)**

This product is not manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1990, as amended (58 FR 8136).

### **Phthalates**

This product is not intentionally manufactured or formulated with phthalate esters; however, we do not analyze for these specific substances or compounds.

### **Materials from Genetically Modified Organisms**

To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO). This is based on information from our



additive suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee it at this time.

### **Additional Substance Information**

This product is not intentionally manufactured or formulated with the following substances or compounds; however, we do not analyze for these substances or compounds.

- 2-Mercaptobenzothiazole (MBT)
- Aflatoxin-like compounds
- Aldehydes
- Azoxy compounds
- Bis(2-ethylhexyl) Adipate (DEHA)
- Bisphenol compounds, incl. but not limited to: BPA, BPB, BPC, BPE, BPF, BPS, and BPZ
- Butylated Hydroxyanisole (BHA)
- Butylated Hydroxytoluene (BHT)
- Dioxins and similar compounds
- Endocrine Disruptors (proven by the industry)
- Epoxy Resin
- Formaldehyde
- Halogenated (Brominated or chlorinated) or phosphorous based flame retardants
- Isocyanate
- Melamine
- Natural rubber latex, dry natural rubber, or synthetic latex
- Nitroso compounds
- Nitrosamines
- Novolac Glycidyl Ethers (NOGE)
- Organic phosphates
- Parabens
- Perfluorooctane Sulfonate (PFOS)
- Phthalates / Phthalate esters
- Plasticizers
- Polybrominated Biphenyls (PBB's)
- Polybrominated Diphenyl Ethers (PBDEs)
- Polybrominated Terphenyls (PBTs)
- Polychlorinated Biphenyls (PCBs)
- Polycyclic aromatic hydrocarbon (PAH)
- Polyurethane
- Polyvinyl Chloride (PVC)
- Polyvinylidene Chloride (PVDC)
- Tris-nonylphenol Phosphite (TNPP)

### **Sterilization Methods**



E-beam/Gamma	25-35 kGY – may be used if application is not too sensitive.
EtO	No issues. Can be safely used.
Autoclave	Limited to 121° C with no stress on part.

### **Shelf Life and Expiration Date**

Eldon James has tight controls on inventory, so finished products are manufactured and sold quickly. Consequently, raw materials are stored for a relatively short time before use in the manufacturing process. Eldon James cannot commit to a shelf life on products, but we stand by the quality and use of new raw materials. Resin manufacturers usually make no commitment on shelf life. Eldon James does not make any claims regarding Expiration Date because our customers use our products in many different applications and conditions. Eldon James cannot make any assessment or claims regarding expiration. Each individual condition and application must be tested by the customer to determine the limits of each product, material, and use.

### **Use of this Regulatory Information Data Sheet**

The information provided as requested is intended to be used for informational purposes only. The information is provided on a without prejudice basis and should not be viewed as giving technical advice, instruction, or otherwise. The information is furnished free of charge and is based on supplier knowledge and understanding. Eldon James Corporation makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of any compound under end-use conditions prior to specification is essential. Ultimately, customers must make their own determination that use of this product is safe, lawful, and technically suitable for their intended applications.