



Effective Date: December 14, 2016

## REGULATORY INFORMATION PACKET

# Flexelene™ CFX / FX

POLYOLEFIN ELASTOMER

### Product Manufacturer

This product is manufactured by Eldon James 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

US Food and Drug Administration (FDA): When used unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications, this resin will comply with the U.S. Food and Drug Administration's food additive regulation at 21 CFR 177.1520(c) 3.2c. 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 the 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 products physical utility. It is the responsibility of the article producer or food packager to determine that the article is suitable for intended use.

Canadian Food Contact (HPFB or CFIA): The composition of this product has been assessed for use in contact with food according to the Canadian Health Products and Food Branch (HPFB).

European Union (EU) 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 Sheet.

Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA): This product is not currently registered under the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) for use in food contact packaging applications.

India Standard for Contact with Food, Pharmaceuticals, or Drinking Water: The composition of this product has not been assessed for use in contact with foodstuff, pharmaceutical, or drinking water applications under the Indian Standards.



Latin America MERCOSUR Food Contact Status: The composition of this product has not been assessed for use in contact with food according to MERCOSUR GMC Resolution No. 32/07 and/or Resolution No. 02/12.

### **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, shellfish (mollusks), crustaceans, tree nuts, 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.

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

This product has been assessed and certified under U.S. Pharmacopoeia Class VI Plastic (USP<88>, Biological Reactivity Tests, In Vivo).

### **European Pharmacopoeia (EPHC)**

Information is unavailable and has not been assessed under European Pharmacopoeia.

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

To the best of our knowledge, this product is not manufactured or formulated with ingredients of animal origin.

### **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 suppliers.

### **Kosher**

The raw materials used in the manufacture of this product are derived from non-animal sources. There is no animal fat, no animal derived materials, grain derived, or fermentation products used in this product. The product is not certified as kosher but will comply with the kosher dietary laws. Therefore, this product can be used with kosher products without compromising the status of the products.

### **Halal**

This product has no animal fats or ingredients derived from animal or fermentation products; therefore, it will comply with the dietary laws of Halal; however, it is not Halal certified.

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

This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this regulatory datasheet that would require reporting under this regulation.



### **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).

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

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

This product conforms to the European Directive 94/62/EC. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

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

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

This product conforms to 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.

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	Up to 25 kGY.
EtO	No issues. Can be safely used.
Autoclave	Not recommended.

### **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.