



Effective Date: August 19, 2021

## REGULATORY INFORMATION PACKET

# Flexelene™ CFXAG

POLYOLEFIN ELASTOMER

### Product Manufacturer

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

### Manufacturing Facility Certifications

ISO 9001 and ISO 13485 Quality Standards, ISO Class 7 Cleanroom.

### Chemical Inventories

Please see SDS for chemical inventory listings.

### Food Contact Status

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.

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.

### 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, sunflowers, 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, sulfites, or sulfur dioxide are used in the synthesis of this material. This evaluation is based on information provided by our raw material and additive suppliers for the presence of the allergen-stimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances, we cannot guarantee this.

### US Pharmacopeia (USP)

This product has been assessed under U.S. Pharmacopoeia (Class VI).

Eldon James Corp · 10325 East 47<sup>th</sup> Avenue · Denver, CO 80238

Phone 970.667.2728 · Fax 970.667.3204

Document # RI-CFXAG, Flexelene™ CFXAG Regulatory Information [ Rev: 2 ] Eff. Date 07/31/2021



### **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.

### **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)**

Animal Derived Components (BSE/TSE) Based on a review of the product composition, this product is not manufactured or formulated with ingredients of animal origin or associated with BSE/TSE infectivity.

### **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.

### **REACH 219 Substances (July 8, 2021)**

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 (SVHC) are present in this product at levels greater than 0.1%.

### **EU Directive 2011/65/EU Restriction of Hazardous Substances (RoHS 3)**

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)**

This product is not intentionally manufactured or formulated with 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).

### **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.

### **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.



## **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 or derivatives
- 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
- Perfluorooctanoic Acid (PFOA)
- 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.