



Effective Date: 01/30/2017

## REGULATORY INFORMATION PACKET

# Flexelene™ 121C

## THERMOPLASTIC ELASTOMER

### Product Manufacturer

This product is manufactured by Eldon James, Denver, CO 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

All components used in manufacture of this product comply with Title 21 CFR 177.2600. Final article compliance may require that extraction testing be performed on the final article. Extraction testing of the final article is the responsibility of its manufacturer and is not part of our quality control. It is the responsibility of the customer to determine the applicability of this regulation in the development of the finished food contact article.

It is up to the customer to determine the applicability of this regulation in the development of the finished food contact article. Based on references to 21 CFR 176.170 Table 1 and Table 2, this product may be used in contact with the following food types, subject to the Conditions of Use Limitations and/or Use Restrictions included below:

Food Type	Description
I	Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0)
II	Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III	Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and include water-in-oil emulsions of low- or high-fat content.
IV	Dairy products and modifications: A: Water-in-oil emulsions, high- or low-fat B: Oil-in water emulsions, high- or low-fat
V	Low-moisture fats and oils
VI	Beverages: A: Containing up to 8% alcohol. B: Nonalcoholic C: Containing more than 8% alcohol.



VII	Bakery products other than those included in Types VIII or IX (below) A: Moist bakery products with surface containing free fat or oil B: Moist bakery products with surface containing no free fat or oil
VIII	Dry solids with the surface containing no free fat or oil ( <i>no end test required</i> )
IX	Dry solids with the surface containing free fat or oil
Limitations <sup>1</sup>	Condition for use A – High temperature heat-sterilized (e.g., over 212°F) <i>through</i> Condition for use H – Frozen or refrigerated storage; Ready - prepared foods intended to be reheated in the container at time of use.
<sup>1</sup> For limitations see CFR 21, 176.170 Tables	

This product can be used in compliance with the above FDA regulations is predicated on the assumption that the chemical composition will not be altered or adulterated by the addition of other unregulated substances, and that the food contact surfaces will be manufactured and employed in accordance with Good Manufacturing Practices outlined in 21 CFR 174.5 and the general provisions applicable to indirect food additives listed there.

The use in medical devices and drug packaging applications is not covered by the above or any other general regulation. It is the responsibility of the device or package manufacturer to establish safety with the FDA through the submission of individual applications on the device or drug.

**Commission Regulation (EU) No. 10/2011**

The composition of this product complies with the formulary provisions (inclusion in Union list in Table I of Annex I) of Regulation (EU) No. 10/2011 involving plastic materials intended to come into contact with food.

Commission Regulation (EU) No. 10/2011 (repealing Commission Directive 2002/72/EC) is a specific measure defining the compositional requirements for plastic materials intended to come into contact with foodstuff according to the general framework Regulation (EC) 1935/2004.

Monomers, additives, and polymer production aids (PPA) used to manufacture this product are included in the Union list within the regulation and comply with any applicable restrictions and limitations. In addition, listed below are substance(s) within this product that have a restriction or limitation:

- 1,3-butadiene (Ref No 13630) SML = ND and 1 mg/kg in final product
- Lithium (Annex II) SML = 0.6 mg/kg
- 9,9-bis(methoxymethyl) fluorene (Ref No 39815) SML = 0.05 mg/kg

**Food Allergens**

Allergen Substances as defined and listed in Annex II of the REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011, on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and



(EC) No 1925/2006 of the European Parliament and of the Council, of the European Parliament and of the Council as regards certain food ingredients. Allergen Substances as defined by Food Allergen Labeling & Consumer Protection Act of 2004 (FALCPA). No major food allergens such as milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat and soybeans, Gluten or Lactose are used in the formulation or manufacture of these parts.

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

This product has been certified as a USP Class VI Plastic (USP<88>, Biological Reactivity Tests, *In Vivo*). USP Class VI and ISO 10993, following conclusions from test laboratory:

- 1) Meets requirements of the guidelines for the Biological Test for Plastics, Class VI - 70°C.
  - a. USP 31, NF 26, 2008. <88> Biological Reactivity Tests, *In Vivo*.
- 2) Considered non-hemolytic
  - a. ISO 10993-4, 2002 guidelines.
- 3) Considered non-cytotoxic and meets the requirements of the L929 MEM Elution Test
  - a. ISO 10993-5, 1999 guidelines.

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

Information is unavailable as this product has not been assessed under European Pharmacopoeia.

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

Based on the information provided by raw material suppliers and by review of their product formula and materials handling and processing procedures, they have been able to determine that the product listed above should not contain animal derived ingredients. Based on this information there would be no known sources of Bovine Spongiform Encephalopathy (BSE) or Transmissible spongiform encephalopathy (TSE).

### **Plant Derived Components**

Based on the information provided to us by our raw material suppliers and their formulation reviews, they have found that this product does contain the following plant derivative(s):

- HEAR Oil (High Erucic Acid Rapeseed Oil); *Brassica napus*
  - Country of Origin = Canada
  - The oil from the seed is used; the seed is genetically modified (GMO)
  - Lot traceability of the plant seed is not available/unknown.
- May also contain an adjuvant from PALM OIL fatty acids.
- Not JATROPHA or PALM OIL derived.

### **Kosher**

This product is not Kosher certified.



## **Halal**

This product is not Halal certified.

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

Based on the information provided to us from our raw material supplier and their formulation reviews, they confirm that this product does not contain SVHC Candidate List Annex XIV materials above the applicable threshold (0.1%) as updated by the European Chemical Agency as of January 12, 2017 (173 substances).

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

Restriction on use of: lead, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants, at levels of greater than 0.1%; cadmium, at levels greater than 0.01%; and Pentabromodiphenylether, Octabromodiphenylether, and Decabromodiphenyl oxide, in concentrations higher than 0.1%; and HBCDD, DEHP, BBP, DBP, DIBP in concentrations greater than 0.1%.

Based on information provided by our raw material suppliers this product does not contain substances above listed concentrations and would therefore be in compliance with EU Directive 2011/65/EU.

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

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

This product has not been checked by tests, thus the fact that these substances are to all intents and purposes absent from this product, does of course, not absolutely exclude that that toxicologically and/or regulatory irrelevant extremely low trace levels of lead, mercury, cadmium and hexavalent chromium may unintentionally be present.

Meets requirements of the Model Toxics in Packaging Legislation developed in 1989 by the CONEG (Coalition of Northeastern Governors, USA).

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

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

Article 11 of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (last amended by Directive 2013/2/EU).

EC Directive on Waste Electrical and Electronic Equipment (WEEE) and EC Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS), Recast 2011/65/EU (HBCDD, DEHP, BBP, DBP, DIBP) as amended through 2015/863/EU on 31 March 2015

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

Therefore, compliance with European Union Commission Regulation 1895/2005/EC of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (repeals Directive 2002/16/EC & 2004/13/EC).



## **California Proposition 65**

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

This product does not contain any chemical known to the State of California to cause cancer, birth defects, other reproductive harm, to require warning under California's Proposition 65.

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

According to the recipe and manufacturing processes of the above-mentioned product, we have no reason to believe any of the following metals or their derivatives originating from the Democratic Republic of the Congo or adjoining countries, which include Angola, Burundi, Central African Republic, the Republic of the Congo, Rwanda, South Sudan, Tanzania, Uganda, and Zambia, and which are so-called "Conflict Minerals" under US laws and regulations.

The absence has not been checked by tests. The investigation on those substances does not belong to our quality and production controls, thus the fact that the above listings of substances are to all intents and purposes absent from these product(s), does of course, not absolutely exclude that that toxicologically and/or regulatory irrelevant extremely low trace levels of these substances may be unintentionally present.

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

Complies with Class I/Class II ozone depleting substances as listed in the Clean Air Act of 1990.

## **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**

Based on the information provided to us by our raw material suppliers and their formulation reviews, they have found that this product does contain the following plant derivative(s):

- HEAR Oil (High Erucic Acid Rapeseed Oil); *Brassica napus*
  - Country of Origin = Canada
  - The oil from the seed is used; the seed is genetically modified (GMO)
  - Lot traceability of the plant seed is not available/unknown.
- May also contain an adjuvant from PALM OIL fatty acids.
- Not JATROPHA or PALM OIL derived.

## **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 to 35 kGy, no deficiencies, may color shift at higher doses.
EtO	No issues. Can safely be used.
Autoclave	Limited to 121 °C.

### **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.