



Effective Date: August 16, 2021

REGULATORY INFORMATION PACKET

EJPreneTM

THERMOPLASTIC ELASTOMER

Product Manufacturer

This product is manufactured by Eldon James, Denver, CO 80238 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 Allergens/Plant Derived Components

This letter is information for this product, based on the information provided to us by our raw material supplier and their formulation reviews are not utilized in this product: Celery, cottonseed, crustacean shellfish, eggs, fish, legumes, lupin, milk, mollusks, monosodium glutamate (MSG), mustard, peanuts, seeds (e.g. poppy, sesame, sunflower), sulfites, tree nuts (eg., almonds, pecans, walnuts), and wheat (gluten). Note: This product utilizes raw material(s) which contain additives with material derived from palm or soybeans.

US Pharmacopeia (USP)

This product has been certified by our supplier to meet the following for USP Class VI and ISO 10993 guidelines:

- 1) Meets requirements of the guidelines for the Biological Test for Plastics, Class VI - 70°C.
 - a. USP 35, NF 30, 2012. <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, 2009 guidelines.

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Although the information above is provided, only actual testing of the final medical device product will positively establish this status for your final product. Please note that meeting Class VI criteria is only the base starting point. The ultimate suitability for use in a medical device application would depend on the specifics of the final product, its specific end use application and meeting the USP or ISO testing criteria required for that specific end use application. We do not control the conditions under which this product is used and are therefore not in a position to warrant that these product meets FDA or other regulatory requirements.

Animal Derived Components (BSE/TSE)

To the best of our knowledge and based on information from our raw material suppliers, this product does not intentionally contain any ingredients of animal origin (including additives used in raw materials).

Kosher/Halal

Does not meet Halal or Kosher status.

REACH 219 Substances (July 8, 2021)

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 July 8, 2021 (219 substances).

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

Based on the information provided by our resin suppliers and their formulation reviews, this material does not contain any of the listed concentrations and is in compliance with the EC Directive on the Restriction of Use of Certain Hazardous Substances (RoHS), RECAST 2011/65/EU (RoHS2) & Directive (EU) 2015/863 (RoHS 3).

Restriction on the 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, Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP) in concentrations greater than 0.1%.

Heavy Metals (ELV Directive 2000/53/EC)

Coalition of Northeastern Governors (CONEG)

Meets requirements of the Model Toxics in Packaging Legislation developed in 1989 by the CONEG (Coalition of Northeastern Governors, USA). 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 toxicologically and/or regulatory irrelevant extremely low trace levels of lead, mercury, cadmium and hexavalent chromium may unintentionally be present.



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

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). No intentional addition or use of lead, mercury, cadmium, or hexavalent chromium.

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

This product complies with and does not contain any of the 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, or birth defects or other reproductive harm, in concentrations that require a warning notice under California's Proposition 65.

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

We have no reason to believe from our raw material manufacturer that any of the following metals or their derivatives originate 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

May be present in this product as a result of specific characteristics of the raw materials utilized by PolyOne's raw material supplier(s) and/or of their manufacturing process(es).

Reviews, previously had found that this product does contain the following plant derivative(s):

- May contain adjuvants from PALM OIL fatty acids.
 - These adjuvants may be from genetically modified organisms (GMO).
- Not JATROPHA 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
Perfluorinated compounds or derivatives incl. PFOS, PFOA



Persistent Organic Pollutants (POP)
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 up to 45 kGy, no deficiencies, may color shift at higher doses.
EtO	No issues. Can safely be used.
Autoclave	Up to 135°C.

Note: extractable testing is 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.

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