



Effective Date: August 16, 2021

REGULATORY INFORMATION PACKET

CrystalVu™

Polyolefin Copolymer

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

US Food and Drug Administration (FDA):

This resin is compliant with the requirements of 21 CFR section 177.1520 in Federal Food, Drug and Cosmetic Act. Additives contained of the grade comply with Federal food, Drug and Cosmetic Act. Substances classified as antioxidants, when migrating from food-packaging material (limit of addition to food, 0.005 percent) shall include Dilauryl thiodipropionate in this resin.

US Pharmacopeia (USP)

This product has been certified as a USP Class VI Plastic (USP<88>).

European Pharmacopoeia (EPHC)

All monomers and additives are listed as authorized substances in the Regulation (EU) No 10/2011, Annex I, as all amended. Monomers with specific migration limits (SML) are 4-Methylpentene-1, and 1-Decene SMLs are 0.5 mg/kg. The additive with SML is Zinc Stearate, SML(T) for Zn is 25 mg/kg. Didodecyl 3,3'-thiodipropionate SML(T) is 5mg/kg.

Hereby we confirm that this product complies with the overall migration limit (60mg/kg) or 10 mg/dm²) of the Regulation (EU) No 10/2011 as following conditions: 10% ethanol, 3% acetic acid, olive oi of 100 °C 2hr at reflux and olive oil of 175 °C at reflux.

Animal Derived Components (BSE/TSE)

This product contains fatty acid salts which are animal derived materials. There is no intentional addition (deliberate use in the formulation of a product or subpart where its continued presence is desired to provide a specific characteristic, appearance or quality), of any chemical substances / animal derived materials into this product. Although one or more ingredients are derived from animal, those are in compliance with EMEA 410/01 6.4 Tallow derivatives.

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REACH 219 Substances (July 8, 2021)

The raw material manufacturer does not believe any of the chemicals as per the EU Candidate List of Substances of Very High Concern (SVHC) are present in their CrystalVu™ products 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).

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)

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.

Phthalates

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

Sterilization Methods

E-beam/Gamma	Some discoloration, odor and deterioration may occur at the higher doses.
EtO	No issues. Can be safely used.
Autoclave	Limited to 121°C with no stress on part.

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.



BPA
BPF
BPS
Latex
Synthetic Latex
Polybrominated Biphenyls (PBB's)
Polybrominated Diphenyl Ethers (PBDE's)

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.