



Effective Date: May 1, 2017

REGULATORY INFORMATION PACKET
Kynar® 1000 HD
POLYVINYLIDENE FLUORIDE (PVDF)

Product Manufacturer

This product is manufactured by Arkema.

Manufacturing Facility Certifications

- National Sanitation Foundation (NSF), NSF-61 (Potable Water)
- Food & Drug Administration (FDA) for Repeated Contact with Food [177.2510]
- 3A Sanitary Standards for Multiple Use Plastic Materials used as Product Contact Surfaces for Dairy Equipment
- United States Pharmacopeia Classification VI (USP Class VI)
- FDA Single Use Adjuvant for use in Polyolefins to 1% Concentration [177.1520]
- NSF-14 Plastics Piping Systems Components
- ISO 9001-2008
- ISO 14001:2004
- OHSAS 18001-2007

Chemical Inventories

Please see SDS for chemical inventory listings.

Food Contact Status

This product may be used for the manufacture of food contact materials according to the following regulations:

USA

By FDA Regulation, 21 CFR, product complies with the US Federal Food, Drug and Cosmetic Act. 177.2510(a) "POLYVINYLIDENE FLUORIDE" resins articles intended for repeated use.

CHINA

National Standard of People's Republic of China "Hygienic Standard for Uses of Additive in Food Containers and Packaging Materials": Ethene, 1,1-difluoro-, homopolymer [CAS: 24937-79-9] can be used in Coating with the following restrictions: Maximum level of use 1%.



EU

By the Regulation (EU) No. 10/2011 Compositional requirements. Restriction for vinylidene fluoride [PM/Ref: 26140]: Specific Migration Limit (SML): 5 mg/kg.

One chemical used as Polymer Production Aids (PPA) in the manufacture of this product is not listed in the annex I of the Regulation (EU) No 10/2011. However according to the article 19 of this regulation, the compliance with Article 3 of Regulation (EC) No 1935/2004 for substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of the Regulation (EU) No 10/2011 which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognized scientific principles on risk assessment.

Based on our resin supplier's own risk assessment, and the tests they made with an independent laboratory, they consider the above-mentioned product is adapted for repeated used food contact applications and for contact with fatty food. The migration of the wax is below 20 ppb at a maximum temperature of 60°C in repeated use conditions (according to the annex V chapter 2 paragraph 2.1.6 of the regulation (Eu) n° 10/2011).

This product cannot be used for preparing packaging materials and articles intended to come into contact with foodstuff.

Food Allergens

Allergens associated with eight major food groups include: milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans and account for over 90% of the global food allergy concerns. Other potential allergens have also been identified in certain regions or populations and are commonly understood as 'global' food allergens based upon the food allergenic substance listings in regulations.

Based on review of the product composition, substances are not included or derived from:

- Bee and bee products
- Certain Foods: Celery, Tomato, Yam, Apple, Orange, Peach, Kiwi, Banana, Mushroom, Chicken, Beef, Pork
- Coconut and coconut derivatives
- Crustacean, shellfish, mollusks, fish and fish products
- Egg and egg products
- Gelatin
- Milk and Milk Products
- Other Gluten Containing Cereals
- Peanut and unrefined peanut derivatives
- Soy and unrefined soy derivatives
- Sulfites > 10 ppm
- Tree nuts, and unrefined tree nut derivatives



US Pharmacopeia (USP)

This product has been assessed and certified under USP Class VI Plastic (USP<88> and Systemic Toxicity; ISO 10993-11.

European Pharmacopoeia (EP)

Product has not been assessed or registered under the EPhC. Pharmacopeia.

Animal Derived Components (BSE/TSE)

Bovine Spongiform or Transmissible Spongiform Encephalopathy BSE/TSE transmission risk is associated with substances derived from certain animal tissues sourced from at risk regions as determined by The World Organization for Animal Health (OIE). Disease transmission risk may be eliminated based on the substance position in the manufacturing chain. Chemical substances that are determined to meet the definition of highly refined or transformed have an insignificant risk of BSE/TSE infectivity. Based on a review of the product composition, this product is not known or expected to contain substances which are animal derived or associated with BSE/TSE infectivity.

Plant Derived Components

Product is not known or expected to contain vegetable or plant origin substances.

Kosher

Supplier does certify this resin to be Kosher and in compliance with Kosher requirements.

Halal

Supplier does certify this resin to comply with dietary laws of Halal and is Halal certified.

REACH 173 Substances (January 12, 2017)

This paragraph concerns substances listed in the Candidate List of Substances of Very High Concern, in accordance with Article 59 of the European Regulation 1907/2006 effective: 1/12/2017. Based on the final product composition this product is not a Substance of Very High Concern and does not contain any SVHC substance(s) above the declaration threshold.

EU Directive 2011/65/EU

Restriction of Hazardous Substances (RoHS)

Restrictions on the use of certain hazardous substances in electric and electronic equipment (EEE) as defined in Commission Delegated Directive (EU) 2015/863 effective: 01/30/2015 Based on a review of the final product composition, there are no ROHS substances known to be present above the reporting threshold.

China RoHS

As defined by the 2006 Chinese Ministry released Administrative Measures on the Control of Pollution Caused by Electronic Information Products (EIP) # 39. Based on a review of the final



product composition, there are no listed substances known to be present above the reporting threshold.

Heavy Metals (ELV Directive 2000/53/EC)

Coalition of Northeastern Governors (CONEG)

Model Toxics in Packaging Legislation (also referred to as CONEG) concerns restrictions on the use of certain hazardous substances in packaging or packaging components (including printing inks used in packaging), and restricts the sum of the incidental concentration levels of lead, mercury, cadmium and hexavalent chromium present in the product to a level equal to or less than 100 parts per million by weight. Based on a review of the final product composition, this product is not known to contain CONEG substances at or above the 100 ppm reporting threshold.

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

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

Supplier complies to prevent and reduce the adverse impacts of the generation and management of waste to reduce the overall impacts and improve efficiency in accordance with 2008/98/EC; waste includes all components, sub-assemblies and consumables which are part of the product at the time of discarding, not to the material used to prepare the equipment. Reference Additional Substance Information section below for substances not known or expected to be present.

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

See Additional Substance Information section below for substances as listed in Regulation (EC) No. 1895/2005 are not known to be present in this product, based on the final product composition and the chemical nature of the raw materials.

California Proposition 65

(Safe Drinking Water and Toxic Enforcement Act of 1986)

Substances as defined in Proposition 65 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 and its amendments. Effective: 05/11/2015. Please refer to the SDS for the most current information regarding the presence of any Proposition 65 listed chemicals.

Conflict Minerals

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

Product does not contain any “conflict minerals” that are necessary to the functionality or production of the product.

Ozone Depleting Chemicals (ODCs)

Substances related to ozone layer depleting substances Regulation (EC) No. 1005/2009, not known or expected to be present based on the final product composition and raw ingredients.

Phthalates

Based on the final product composition and the specifications of the raw materials, this product is not known or expected to contain substances that are identified as Phthalates.



Materials from Genetically Modified Organisms (GMOs)

Based on a review of the final product composition, none of the substances in this product are known or expected contain substances identified as GMOs.

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: BPA, BPF
Bisphenol compounds: BPB, BPC, BPE, 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 (PCB)
Polycyclic Aromatic Hydrocarbon (PAH)
Polyurethane
Polyvinylidene Chloride (PVDC)
Polyvinyl Chloride (PVC)
Tris-nonylphenol Phosphite (TNPP)



Sterilization Methods

Gamma	Stable to 50 kGY – May discolor slightly at higher doses.
EtO	Excellent - No issues.
Autoclave	Excellent - Multiple cycles

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.