

NK Fittings

Effective Date: August 23rd, 2021

POLYVINYLIDENE FLUORIDE (PVDF)

Product Manufacturer

This product is manufactured by Eldon James Corporation.

Manufacturing Facility Certifications

Eldon James Corporation is certified to the ISO 9001 & ISO 13485 Quality standards.

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. It is the responsibility of our customer to determine and evaluate if product used as a food packaging material is suitable for each application food type and condition of use.

MERCOSUR

Food Packaging and Equipment (Common Market of the South)

Resolution GMC 03/92 applies to packages, packaging equipment, and articles intended for direct contact with foodstuffs during the manufacture, production, portioning, handling, storage, distribution, commercialization and consumption of foods. This product contains one or more substances which are not currently included on the positive lists. As such, this product is not authorized for use in food contact articles.

Global Food Allergens

Allergens associated with eight major food groups include: milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soy 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

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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>, Systemic Toxicity; ISO 10993-11, Plastic Materials of Construction USP<661.1>, and Plastic Packaging Systems for Pharmaceutical Use USP <661.2>.

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). Based on a review of the raw 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 219 Substances (July 8, 2021)

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. Based upon a review of the final product composition, CMR substances categories 1A and 1B listed on appendices 1-6 of REACH Annex XVII are not known to be present in the above-mentioned product 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: 03/31/2015 Based on a review of the final product composition, there are no ROHS substances known to be present above the reporting threshold.

EU Directive 2015/863/EU

Restriction of Hazardous Substances (RoHS)

Based on a review of the final product composition, there are no RoHS substance known to be present above the reporting threshold. This includes Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls (PBB's) or Polybrominated Diphenyl Ethers (PBDE's) or any of the phthalates (DEHP, BBP, DBP, and DIPB).

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

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

HEAVY METALS

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 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.

AUTOMOTIVE

The Global automotive Declarable Substances List covers substances that are expected to be present in a material or part that remains in the vehicle or part at point of sale. The list is available on the GADSL website 02/01/2019. Substances list in the Global automotive Declarable Substances List are not known to be present in this product above the reporting threshold. The review was based on the known final composition of our raw material supplier.

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: 06/28/2019. Please refer to the SDS for the most current information regarding the presence of any Proposition 65 listed chemicals. Based on review of the final product composition, there are no listed substances known to be present above the reporting threshold.

NSF/ANSI 61

This product is NSF 61 certified – Drinking Water System Components.

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.

Pollution Prevention - Waste Management-Ecolabeling Hazardous Air Pollutants - US Clean Air Act Section 112

Under the Clean air Act, US EPA is required to regulate emissions of hazardous air pollutants (HAPs). This assessment is based on the 187 substances identified by the EPA as hazardous air pollutants including the general class of glycol ether substances as defined by the Toxic Release Inventory (TRI - EPA 745-R-00-004). Based on the final product composition and information from our raw material supplier, this product is not known or expected to contain any US HAPs as defined by the regulation.

Phthalates

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Viral Contamination

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.