

Series Lock

Effective Date: August 24th, 2021

Quick Disconnect Coupler

Product Manufacturer

This product is manufactured by WilMarc.

Manufacturing Facility Certifications

- ISO 13485:2016
- Food & Drug Administration (FDA) 21CFR820
- CE Marks for Breathing Circuits and Gas Sample Line
- Woman Owned Company

Food Contact Status

Main Body Components (PVDF Option)

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.

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Food Contact Status

Main Body Components (Polypropylene Option)

US Food and Drug Administration (FDA): This material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(3)(i) and (c)3.1a. According to our information, all other ingredients used in the formulation meet their respective FDA regulations and 21 CFR 177.1520(b). Specifically, this product meets the FDA criteria for food contact, except for cooking, under conditions of use C through H as listed in 21 CFR 176.170(c), Table 2.

Food Allergens (PVDF and Polypropylene Options)

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>, Biological Reactivity Test, *In Vivo*), USP<661>, USP<661.1>, USP<661.2> (PVDF Option Only for the USP<661.2>).

European Pharmacopoeia (EP)

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

Animal Derived Components (BSE/TSE)

Based on a review of the product composition, this product is not manufactured or formulated with ingredients of animal origin or associated with BSE/TSE infectivity.

Plant Derived Components

Product is not known or expected to contain vegetable or plant origin substances in (PVDF Option). Polypropylene product may contain one or more additive(s)/substance(s) synthesized from plant extracts, i.e. hydrolysis, etc. of plant oils into fatty acids and/or their derivatives, as per information from the raw material supplier.

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Kosher

Supplier does certify this resin to be Kosher and in compliance with Kosher requirements (PVDF Option).

The raw materials used in the manufacture of this product are derived from non-animal sources. There is no animal fat, no animal derived materials, grain derived, or fermentation products used in this product. The product is not certified as kosher but will comply with kosher dietary laws. Therefore, this product can be used with kosher products without compromising the status of the products (Polypropylene Option).

Halal

Supplier does certify this resin to comply with dietary laws of Halal and is not Halal certified.

REACH 219 Substances (July 8, 2021))

In accordance with Article 59 of the European Regulation 1907/2006. Based on the information from our raw material supplier and 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 at levels greater than 0.1%.

EU Directive 2011/65/EU

Restriction of Hazardous Substances (RoHS2)

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 our raw material supplier, there are no ROHS substances known to be present above the reporting threshold.

EU Directive 2015/863/EU

Restriction of Hazardous Substances (RoHS3)

Based on the information received from our raw material supplier, there are no RoHS substances 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 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

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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)

Based on available information this product does not contain any components or chemicals currently known to the State of California to cause cancer, birth defects or reproductive harm at levels which would be subject to Proposition 65.

NSF/ANSI 61

This product is NSF 61 certified – Drinking Water System Components (PVDF option).

Conflict Minerals

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

This product is not intentionally manufactured or formulated with the listed conflict Materials as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; tin, tantalum, tungsten, or gold.

- Columbite-Tantalite – refined into Tantalum (Ta) (CAS# 7440-25-7)
- Cassiterite – refined into Tin (Sn) (CAS# 7440-31-5)
- Wolframite refined into Tungsten (W) (CAS# 7440-33-7)
- Gold (Au) (CAS# 7440-57-5)

We are disclosing the above information, to the best of our knowledge based upon data from our raw material supplier. We believe this information to be accurate and reliable as of the effective date of this Regulatory Data Sheet.

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 (PVDF Option). Although phthalates are not intentionally added in the formulation of this product, there are phthalates in the final resin as a result of catalyst residues. Analytical testing has been performed on several grades with specific phthalates determined to be in concentrations less than 5 ppm. Dibutyl phthalate, Diisobutyl phthalate, and Bis (2-ethylhexyl) phthalate. Benzyl butyl phthalate was below the detection limit of the instrument used to test (Polypropylene Option).

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 (PVDF Option).

13R9A utilizes a component produced from material of unknown genetic origin in its formulation (Polypropylene Option).

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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
Benzyl butyl phthalate (BBP)
Bis(2-ethylhexyl) adipate (DEHA)
Bis(2-Ethylhexyl) phthalate (DEHP)
Bisphenol compounds: BPA, BPF
Bisphenol compounds: BPB, BPC, BPE, BPS, and BPZ
Butylated Hydroxyanisole (BHA)
Butylated Hydroxytoluene (BHT)
Dibutyl phthalate (DBP)
Diisobutyl phthalate (DIBP)
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 Limited to 121°C - Multiple cycles

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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.