REGULATORY INFORMATION PACKET

PP FITTINGS

POLYPROPYLENE COPOLYMER

Product Manufacturer
This product is manufactured by Eldon James Corporation.

Manufacturing Facility Certifications
Eldon James Corporation is certified to the ISO 9001:2015 & ISO 13485:2016 Quality standards.

Chemical Inventories
Please see SDS for chemical inventory listings.

Food Contact Status
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.

European Union (EU) Food Contact: PP fittings do not meet the requirements of EU Regulation 10/2011 for food contact as the material resin contains an additive not included in Annex 1.

Food Allergens
This material does not contain allergens - as defined by FDA as Milk, Eggs, Fish, Crustaceans, Wheat, Soy, Peanuts, Tree Nuts - in the manufacture or formulation of this product.

US Pharmacopeia (USP)
This product has been certified as a USP Class VI Plastic (USP<88>, Biological Reactivity Tests, *In Vivo*). Endotoxin (USP<85>) testing have also been performed.

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
This product may contain one or more additives(s)/substances(s) synthesized from plant extracts, i.e. hydrolysis, etc. of plant oils into fatty acids and/or their derivatives, as per information from our raw material suppliers.

Kosher
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.

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Therefore, this product can be used with kosher products without compromising the status of the products.

Halal

This product has no animal fats or ingredients derived from animal or fermentation products; therefore, it will comply with the dietary laws of Halal; however, it is not Halal certified.

REACH 233 Substances of Very High Concern (SVHC) January 17th, 2023

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 our polypropylene products at levels greater than 0.1%.

Testing has indicated that some of our polypropylene products may contain trace residues (<8 ppm) of Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP), and Bis (2-ethylhexyl) phthalate (DEHP). Benzyl butyl phthalate (BBP) was below the detection limit of the instrument used to test.

EU Directive 2015/863/EU Restriction of Hazardous Substances (RoHS)

The resin manufacturer does not intentionally use (suggest to add: or add heavy metals) Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls (PBB's), or Polybrominated Diphenyl Ethers (PBDE's) or phthalates (DEHP, BBP, DBP, or DIBP)to any of the polypropylene products.

Testing has indicated that some of our polypropylene products may contain trace catalyst residues (<8 ppm) of Dibutyl phthalate, Diisobutyl phthalate, and/or Bis (2-ethylhexyl) phthalate. Benzyl butyl phthalate was below the detection limit of the instrument used to test.

This product conforms to the RoHS 3 Directive (2015/863/EU) and/or amendments restricting the use of Heavy Metals, PBB's, PBDE's, and phthalates.

Heavy Metals (ELV Directive 2000/53/EC)
Coalition of Northeastern Governors (CONEG)

The raw material supplier does not use cadmium, chromium, lead, or mercury in the manufacture or formulation of this product. In addition, this product meets the CONEG limitation of 100 ppm for the total incidental content of cadmium, chromium, lead, and mercury.

European Directive (94/62/EC) Packaging and Packaging Waste
EU Directive 2012/19/EU Waste Electrical & Electronic Equipment (WEEE)

EU Directive 202/19/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. This product is a hydrocarbon; however, liquid hydrocarbons are not present in this product.

This product conforms to the European Commission Directive 94/62/EC (Article 11) and its amendments on packaging and packaging waste. This product is recyclable according to the recycle code 5.

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

The resin manufacturer does not use 2,2-bis(4-hydroxyphenyl) propane bis (2,3- epoxypropyl) ether (BADGE), bus(hydroxyphenyl)methane bus(2,3-epoxypropyl) ethers (BFDGE) or novolac glycidyl ethers (NOGE) in the manufacture or formulation of this product.

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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.

Medical Device Regulation (EU) 2017/745

Polypropylene does not intentionally use any substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR 1A/1B/2) or endocrine disrupting substances (EDS) in amounts over 0.1%w/w (weight-by-weight)

Conflict Materials
(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)

This material does not use Class I or Class II ODCs listed in the Resolution 1005/2009/EC in the manufacture or formulation of this product.

Phthalates

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.

Materials from Genetically Modified Organisms

Resin manufacturer utilizes a component produced from material of unknown genetic origin in its formulation.

Additional Substance Information

As with almost all polypropylenes, anti-oxidants (preservatives) are used to some degree to protect the polymer during conversion/processing. A phenolic anti-oxidant (phenyl group containing) is used in the formulation.

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)

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Aflatoxin-like compounds
Aldehydes
Azoxy compounds
Biocides
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
Fluoropolymers or Fluorinated materials
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
Perfluorooctanoic Acid (PFOA)
Perfluorooctane Sulfonate (PFOS)
Persistent Organic Pollutants
Perfluorohexane sulfonic acid (PFHxS)
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)
Materials considered Pyretic (Pyrogens)
Tris-nonylphenol Phosphite (TNPP)

Sterilization Methods

Gamma	25-50 kGY – Some discoloration may occur at the higher doses. No significant effect on physical properties.
EtO	No issues. Can be safely used.
Autoclave	Limited to 121° C with no stress on part.

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 Polypropylene fittings have a minimum shelf life of 10

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years; provided the fittings are stored in dry conditions at temperatures below 50°C (122°F) and protected from UV and nitrous oxide exposure. Improper storage conditions can initiate premature degradation of color, odor, and physical properties. Each individual condition and application should 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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