



Effective Date: 04/19/2017

REGULATORY INFORMATION PACKET

Sintered 316L SS Fittings

STAINLESS STEEL FITTINGS

Product Manufacturer

This product is manufactured by Eldon James Corporation in Denver, Colorado U.S.A.

Manufacturing Facility Certifications

ISO 9001:2008 and ISO 13485:2003 Quality Standards, ISO Class 7 Cleanroom.

Metal Powder Industry Federation Standard 35

Supplier complies with the Metal Powder Industry Federation Standard 35 for this alloy.

Chemical Inventories

Please see SDS for chemical inventory listings.

Food Contact Status

No information available.

Food Allergens

No information available.

US Pharmacopeia (USP)

No information available.

European Pharmacopoeia (EPHc)

No information available.

Animal Derived Components (BSE/TSE)

To the best of our knowledge, this product is not manufactured or formulated with ingredients of animal origin or animal product.

Plant Derived Components

Product is not manufactured or formulated with ingredients of plant origin.

Kosher

Product does not contain any animal product and is not Kosher certified.



Halal

Product does not contain any animal product and is not Halal certified.

REACH 173 Substances (January 12, 2017)

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 stainless steel products at levels greater than 0.1%.

EU Directive 2011/65/EU Restriction of Hazardous Substances (RoHS)

This product conforms to the RoHS Directive (2011/65/EU) and/or amendments restricting the use of Heavy Metals, PBB's, PBDE's, and phthalates; does not intentionally add any heavy metals (Lead, Mercury, Cadmium, Hexavalent Chromium), Polybrominated Biphenyls (PBB's), or Polybrominated Diphenyl Ethers (PBDE's).

Heavy Metals (ELV Directive 2000/53/EC)

Coalition of Northeastern Governors (CONEG)

No information available.

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

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

No information available.

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

No information available.

California Proposition 65

(Safe Drinking Water and Toxic Enforcement Act of 1986)

No information available.

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 product is in compliance with and does not intentionally contain Ozone Depleting Substances that deplete the Ozone Layer based on the information available from our raw material suppliers.

Phthalates

This product is not intentionally manufactured or formulated with phthalate esters.

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, 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
- 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 (PCBs)
- Polycyclic aromatic hydrocarbon (PAH)
- Polyurethane



Polyvinyl Chloride (PVC)
Polyvinylidene Chloride (PVDC)
Tris-nonylphenol Phosphite (TNPP)

Sterilization Methods

E-beam/Gamma	Up to 125 kGy.
EtO	Acceptable, no issues.
Autoclave	Sterilization with steam up to 134°C.

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.