



Effective Date: August 17, 2021

REGULATORY INFORMATION PACKET

Antimicrobial Agent

(Agent for NN Fittings)

Product Manufacturer

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

Manufacturing Facility Certifications

ISO 9001 and ISO 13485 Quality Standards, ISO Class 7 Cleanroom.

Chemical Inventories

Please see SDS for chemical inventory listings.

Food Contact Status

This antimicrobial material complies under Food Contact Substance Notification FDN000535, is NSF/ANSI Standard 51 certified, meets the requirements of EU Regulation 10/2011 for food contact and compliant with Canadian Food Contact (HPFB or CFIA).

European Union (EU)

This product complies with CONEG-EU 94/62/EC Heavy Metals, EU 10/2011/EC Plastic Regulations – food contact regulations, EU 2023/2006/EC Good Manufacturing Practices Regulations, and EU 1935/2004/EC Framework Regulation.

Food Allergens

To the best of our knowledge, there are no allergen-stimulating substances used in the manufacture of or formulation of this product and has not been tested for these.

US Pharmacopeia (USP)

Complies with USP Class VI, ISO 10993-4 and ISO 10993-5.

European Pharmacopoeia (EPHC)

This product does not have any supporting documentation stating that it complies with the compositional requirements of the European Pharmacopoeia.

Animal Derived Components (BSE/TSE)

The resin manufacturer states they do not intentionally add any animal derivatives in the manufacturing or formulation of this resin. To the best of our knowledge, this product does not contain ingredients of animal origin or animal product.

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Plant Derived Components

To the best of our knowledge, this product is not manufactured or formulated with ingredients of vegetable or plant origin and is compliant.

Kosher

To the best of our knowledge and based on information from our material supplier, this product does not intentionally contain any ingredients of animal origin. We do not certify this product to be Kosher or in compliance with Kosher requirements, is compliant.

Halal

To the best of our knowledge and based on information from our material supplier, this product does not intentionally contain any ingredients of any animal origin. We do not certify this product to be Halal or in compliance with Halal requirements is compliant.

REACH 219 Substances (July 8th, 2021)

Based on our supplier's review have declared that the material provided does not contain any of the banned chemical substances listed in EU REACH Article 57 Substance of Very High Concern (SVHCs). This statement refers to the total of 201 substances of very high concern on the candidate EU REACH SVHC list as it was disseminated by ECHA. Therefore, our product complies with EU REACH SVH 1907/2006/EC Article 57 Substance of Very High Concern (SVHCs) RSL Inventory/regulatory requirement.

EU Directive 2011/65/EU Restriction of Hazardous Substances (RoHS3)

This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS 2), as amended (Directive (EU) 2015/863 inclusive) (RoHS 3). It is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), or Diisobutyl phthalate (DIBP).

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

This product conforms to the European Commission Directive 94/62/EC (Article 11) and its amendments on 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.



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), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE) or novolac glycidyl ethers (NOGE) in the manufacture or formulation of this product.

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.

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.

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

This product is not intentionally manufactured or formulated with phthalate esters; however, we do not analyze for these specific substances or compounds.

Materials from Genetically Modified Organisms

To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms based on information from our material supplier.

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	25-40 kGY
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

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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.