

Effective Date: August 26, 2021

THERMOPLASTIC ELASTOMER (Inner Flow-Path)

Product Manufacturer

This product is manufactured by Eldon James, 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 product may be used for the manufacture of food contact materials according to the following regulations listed below.

This product is manufactured only with raw materials (Monomer, Polymer Production Aids and Aids to polymerization) that are authorized to prepare plastic materials and articles intended to come into contact with foodstuffs. This product may come into contact with drinking water.

It is the responsibility of the company to request approval for compliance with the requirements in force relating to drinking water materials. NSF certification for Water Contact Material is available on the NSF website.

USA FDA Food Packaging

Compliance with the US Federal Food, Drug and Cosmetic Act and all applicable food additive regulations requires that the regulatory status of products intended for use as food packaging materials be evaluated based on the regulatory status of each individual substance that comprises the product. This evaluation encompasses those listings in Title 21 Code of Federal Regulations, GRAS approvals, prior sanction letters, Threshold of Regulation (TOR) exemptions, or effective Food Contact Substance Notifications (FCN).

The following applications of the subject product can be said to fully comply with the US Federal Food, Drug and Cosmetic Act and all applicable food additive regulations subject to the limitations provided herein. It is the responsibility of our customer to determine if the following clearances or cross-references to the clearances are appropriate for the final intended use.

- **21 CFR Sec. 177.1520.** Olefin polymers. (b), optional adjuvant substances: For use only as a processing aid in the production of olefin polymers complying with 177.1520 paragraph (c) at levels not to exceed 1.0 percent by weight of the polymer. Finished polymers may be used only under conditions B through H described in 21 CFR 176.170(c), table 2. FCN 1448 expands the use of this product at up to 2000 ppm as a processing aid in the production of olefin polymers complying with 177.1520 paragraph (c) for all food type excluding infant formula and breast milk under condition of use A described in 21 CFR 176.170(c), table 2.
- **21 CFR Sec. 177.2600.** Rubber articles intended for repeated use. (c)(4)(i) For use as an elastomer in the preparation of rubber articles intended for repeated use.

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- **FCN 1448.** Processing aid for use in all food contact polymers subject to the limitations provided herein. For use at levels not to exceed 2000 ppm in all polymers with a maximum thickness of 10 mils in contact with all Food Types (I-IX) under Conditions of Use A through H, as defined in Tables 1 and 2, respectively. The FCS is not for use in contact with infant formula and breast milk.
- **NSF/ANSI Standard 51: Food Equipment Materials.** The NSF certification for this product's Water Contact Material is available on the NSF website.
- **NSF/ANSI Standard 61: Drinking Water System Components - Health Effects.** The NSF certification for this product's Water Contact Material is available on the NSF website.

Food Allergens

Global Food Allergens associated with eight major food groups including milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans account for over 90% of the global food allergy concerns. Other potential allergens have also been identified in certain regions or populations. The commonly understood 'global' food allergens list provided herein is based upon the food allergenic substance listings in regulations in the U.S., Canada, European Union, Asia, and Codex Alimentarius.

US Pharmacopeia (USP)

This product is not registered with the US Pharmacopeia.

European Pharmacopeia (EPHC)

There is no European Pharmacopoeia Monograph relative to this product.

Animal Derived Components (BSE/TSE)

Bovine Spongiform or Transmissible Spongiform Encephalopathy BSE/TSE

No chemical substance coming from animal resources are intentionally added in the manufacturing process; therefore, this product is not known or expected to contain substances which are animal derived or associated with BSE/TSE infectivity.

Plant Derived Components

Determination of the presence of GMOs in our products is limited to chemical substances which may have been derived from genetically modified agricultural plants.

Kosher

This material complies with Kosher requirements: no products or raw materials of animal origin, no grain or pulse origin, no grape derivatives, no animal, grain or pulse source present during manufacturing and equipment used to process was not for grain or animal based product. This product is not known or expected to contain animal derived substances associated with BSE/TSE infectivity.

Halal

This product is a synthetic material is manufactured by chemical process in a dedicated unit and no raw materials of animal origin are intentionally introduced. Equipment is not used for animal based products and ethyl-alcohol is not used in the manufacturing process. This material is not known or expected to contain animal derived substances associated with BSE/TSE infectivity.

REACH 219 Substances (July 8, 2021)

We or our resin supplier do not intentionally add any of the SVHC substances in the manufacture or formulation of this product and do not believe that any of the chemicals listed on the EU Candidate List of Substances of Very High Concern (SVHC) are present in this product at levels greater than 0.1%.

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

RoHS is defined in Directive 2011/65/EU which concerns restrictions on the use of certain hazardous substances in electric and electronic equipment (EEE). RoHS specifically restricts the concentration of the following materials in electric and electronic equipment: lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), other polybrominated compounds present in the product to a level equal to or less than 0.1% by weight. It further restricts the concentration of cadmium present in the product to a level equal to or less than 0.01% by weight. Based on the final product composition and the specifications of the raw materials, no RoHS substances are known or expected to be present.

Restriction of Hazardous Substances - EU. 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 the final product composition, there are no ROHS substances known to be present above the reporting threshold.

Restricted Substances in Electronic Information Products - 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)**

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)

Novolac glycidyl ethers (NOGE), Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE), 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (BADGE), and some of its derivatives: BADGE.H₂O, BADGE.2H₂O, BADGE.HCl, BADGE.2HCl and BADGE.H₂O.HCl as listed in Annex I of Regulation (EC) No. 1895/2005 are not known to be present in the above mentioned product, based on the final product composition and chemical nature of the raw ingredients.

**California Proposition 65
(Safe Drinking Water and Toxic Enforcement Act of 1986)**

Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted as a ballot initiative in November 1986. The Proposition was intended by its authors to protect California citizens

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and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals.

Substances as defined in Proposition 65 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 and its amendments. Effective: 05/11/2015. Please refer to the SDS for the most current information regarding the presence of any Proposition 65 listed chemicals.

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)

Ozone Depleting Substances - US Clean Air Act. Ozone depleting substances (ODS) as defined in accordance with section 602 of the United States Clean Air Act (40 CFR Part 82). Based on the product composition this product is not known or expected to contain Ozone Depleting Substances as defined by the regulation.

Volatile Organic Compounds (VOCs)

In the Clean Air Act, 40 Code of Federal Regulations Section 51.100, the Environmental Protection Agency (EPA) defines a VOC as any compound of carbon excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reaction. EPA has excluded many compounds, which have been determined to have negligible photochemical reactivity such as: ethane, methane, methylene chloride, methyl chloroform, perchloroethylene, acetone, and numerous fluorochemicals. Water is not considered a VOC. We recommend review of State and Federal regulations to determine if a more restrictive requirement exists regarding analytical methods or chemical exclusions during the consideration of VOC content.

Based on the final product composition and the specifications of the raw materials, this product is not known or expected to contain substances identified as VOCs.

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: Bis(2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), Diisononyl Phthalate (DINP), Diisodecyl phthalate (DIDP), Di-n-octyl phthalate (DnOP) or Di-n-hexyl phthalate (DnHP).

Materials from Genetically Modified Organisms

A Genetically Modified Organism (GMO), for purposes of this review, is considered to be an organism that contains recombinant DNA elements. The genome of these organisms has been altered by insertion of foreign DNA sequences by means of genetic engineering. They are referred to as transgenic or bioengineered organisms.

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Determination of the presence of GMOs in our products is limited to chemical substances which may have been derived from genetically modified agricultural plants.

Based on a review of the final product composition, none of the substances in this product are expected to be sourced or derived from GMOs.

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	No issues at levels 25-100kGy.
EtO	No issues. Can be safely used.
Autoclave	Primarily 15 psi steam, 121 °C or 250 °F.

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.