



Effective Date: August 13<sup>th</sup>, 2021

REGULATORY INFORMATION PACKET  
**White Colorant**  
MEDICAL WHITE/WHITE NYLON COLOR CONCENTRATE

**Product Manufacturer**

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

**Manufacturing Facility Certifications**

ISO 9001:2008 with Design Certificate

**Chemical Inventories**

Please see SDS for chemical inventory listings.

**Food Contact Status**

US Food and Drug Administration (FDA): According to our information, this material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 178.3297.

**Food Allergens**

No information is available.

**US Pharmacopeia (USP)**

This product is not registered under US Pharmacopeia.

**European Pharmacopoeia (EPHC)**

This product is not registered under European Pharmacopeia.

**Animal Derived Components (BSE/TSE)**

Based on the information available from our raw material supplier; this material does not intentionally contain substances from animal derivatives and do not specifically run any analysis on incoming raw materials or end products to measure for the presence of these substances.

**Plant Derived Components**

This material does not intentionally contain substances from animal derivatives.

**Kosher**

This product does not intentionally contain any animal derivatives and is not Kosher certified.





## **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 ODCs 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 (GMO). This is based on information from our additive suppliers as we believe this product to be GMO free and do not test for it.

## **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)

### **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.