

# Medical Nylon

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Effective Date: August 23<sup>rd</sup>, 2021

## MEDICAL WHITE NYLON POLYAMIDE

### Product Manufacturer

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

### Manufacturing Facility Certifications

ISO 9001:2008  
ISO 13485:2016(E)

### 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

The base resin does not contain Biological Allergens, including: Celery, Cereals containing gluten, Corn, Crustaceans, Eggs, Fish, Lupin, Mollusks, Milk (including lactose), Mustard, Nuts, Peanuts Sesame seeds and Soybeans.

### US Pharmacopeia (USP)

This product has not been assessed under US Pharmacopeia requirements.

### European Pharmacopoeia (EPHC)

This product has not been assessed under European Pharmacopoeia requirements.

### Animal Derived Components (BSE/TSE)

Supplier of the base resin uses various stearic acid-based lubricants in the production of lubricated grades of this resin. This material is not revealed on MSDS, as the exact identity and use levels are considered trade secrets. For risk assessment purposes, these materials are esters or amides of stearic acid, and levels used in any of these products is less than 3000 parts per million.

The stearates used in the manufacture of the base resin are of both vegetable and animal origin. The animal derived stearates are obtained from bovine material that originates in the United States, Canada, and Mexico. The tallow used does not contain and is not derived from specified risk material or mechanically recovered meat of animals.

Furthermore, severe processing conditions are used in the manufacture of the base resin stearates used in our product including hydrogenation of tallow at 200 °C, hydrolysis at 260 °C and 48 bar for 1.5 to 2 hours and vacuum distillation at 232 °C. These exceed the European Union recommendation laid down in the 22nd Commission Directive 98/16/EC of 5 March 1998, as annexed to council Directive 76/768/EEC, and as agreed to by the Scientific Committee on Cosmetology's (SCC) opinion concerning tallow derivatives for processing conditions of 200 °C and 40 bar for 20 minutes. Therefore, this material is considered BSE/TSE compliant.

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This assessment is based on data obtained from the base resin raw material supplier, vendor Material Safety Data Sheets, and knowledge of the supplier's manufacturing processes. The product information presented above is true, complete, and correct to the best of our knowledge.

### **Plant Derived Components**

The base resin is considered compliant although various stearic acid-based lubricants are used in the product, it is considered compliant exceeding recommendations concerning derivatives for under severe processing conditions.

### **Kosher**

The base resin is not Kosher certified, stearates used in the manufacture are made of animal origin.

### **Halal**

The base resin is not Halal certified; stearates used in the manufacture are made of animal origin.

### **REACH 219 Substances (July 8<sup>th</sup>, 2021)**

Based on a review of the final product composition, there are no RoHS substance known to be present above the reporting threshold. This includes Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls (PBB's) or Polybrominated Diphenyl Ethers (PBDE's) or any of the phthalates (DEHP, BBP, DBP, and DIBP) EU Directive 2015/863/EU "RoHS 3 Directive" in addition to the six RoHS 2 substances (Lead, Chromium VI, Mercury, Cadmium, PBB, PBDE).

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

Based on a review of the final product composition, there are no RoHS substance known to be present above the reporting threshold. This includes Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls (PBB's) or Polybrominated Diphenyl Ethers (PBDE's) or any of the phthalates (DEHP, BBP, DBP, and DIBP) for the **EU Directive 2015/863/EU "RoHS 3 Directive"** in addition to the RoHS 2 substances (Lead, Chromium VI, Mercury, Cadmium, PBB, PBDE).

### **EU Directive 2015/863/EU Restriction of Hazardous Substances (RoHS3)**

Based on a review of the final product composition, there are no RoHS substance known to be present above the reporting threshold. This includes Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls (PBB's) or Polybrominated Diphenyl Ethers (PBDE's) or any of the phthalates (DEHP, BBP, DBP, and DIBP) EU Directive 2015/863/EU "RoHS 3 Directive" in addition to the six RoHS 2 substances (Lead, Chromium VI, Mercury, Cadmium, PBB, PBDE).

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

This material supplier does not intentionally add or 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. In addition, the base resin or similar products have been tested and none of these metals were found (detection limit 5 ppm).

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

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

These restricted materials are not intentionally added or used in the manufacture of the base resin. The base resin is not formulated and manufactured with the use or addition of heavy metals (cadmium, lead, mercury, chromium or brominated fire retardants) regulated and in conformity with the EU Directive 2002/95/EC.

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

The base resin is compliant with Regulation EC No 1895/2005, which places restrictions on the use of certain epoxy derivatives in food contact materials and are not intentionally added or used in the manufacture of this product.

### **California Proposition 65**

#### **(Safe Drinking Water and Toxic Enforcement Act of 1986)**

California Proposition 65 (as amended effective July 1, 2016).

Chemicals listed on California's Safe Drinking Water and Toxic Enforcement Act of 1986 are not intentionally added or used in the manufacture of this resin. The Prop. 65 list can be found on the oehha.ca.gov website.

### **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. This letter is to inform all of our customers that products received by our raw materials supplier are "DRC Conflict Free" as defined by the SEC Conflict Minerals Final Rule (Release No. 34- 67716; File No. S7- 40-10; Date: 2012-08-22). 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 resin meets compliance with the phthalate restrictions imposed by EU Directive 2005/84/EC including all amendments and USA Consumer Product Safety Improvement Act of 2008 (SPSIA).

### **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.

### **Persistent Organic Pollutants (POP)**

The product is not intentionally manufactured or formulated with any persistent organic pollutants in reference to EU Regulation No. 850/2004 including all amendments.

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### Nano Substances

This product is not intentionally manufactured or formulated with any nanomaterials as defined in EU 2011/696 and French Decree No. 2012-232 of February 17, 2012.

### 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  
Benzyl butyl phthalate (BBP)  
Biocides, any type, including: Triclosan  
Bis(2-ethylhexyl) Adipate (DEHA)  
Bis(2-Ethylhexyl) phthalate (DEHP)  
Bisphenol compounds, incl. but not limited to: BPA, BPB, BPC, BPE, BPF, BPS, and BPZ  
Butylated Hydroxyanisole (BHA)  
Butylated Hydroxytoluene (BHT)  
Dibutyl phthalate (DBP)  
Diisobutyl phthalate (DIBP)  
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 | 25-35 kGY – May color shift (brown) at higher doses |
| EtO          | No issues. Can be safely used or Not applicable?    |
| Autoclave    | Limited to 121° C with no stress on part.           |

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### **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.