

REGULATORY INFORMATION PACKET

Natural Nylon (NN)

NYLON POLYMER

PRODUCT OVERVIEW

Effective Date

25 March 2026

Product Manufacturer

This material is used by Eldon James Corporation (Fort Collins, Colorado U.S.A.) to manufacture products with the part number designation “NN”.

Manufacturing Facility Certifications

Eldon James’ manufacturing processes are governed by a Quality Management System certified to both ISO 13485:2016 and ISO 9001:2015 standards.

Shelf Life and Expiration Date

The proper storage conditions for “NN” fittings are as follows: low humidity, at room temperatures, and out of direct sunlight or other sources of UV radiation. Improper storage conditions can initiate premature degradation of color, odor, and physical properties.

As these products may be used in many different applications and conditions, Eldon James does not make any assessments or claims regarding product expiration. Each individual condition and application should be tested by the customer to determine the limits of each product, material, and use.

Sterilization Methods

- E-beam / Gamma - 25-35 kGy – May color shift (brown) at higher doses
- EtO - No issues. Can be safely used
- Autoclave - Limited to 121° C with no stress on part.

Use of this Regulatory Information Data Sheet

This content of this document, which is based on supplier declarations and our own material knowledge and testing, is intended to be used for informational purposes only; it is provided free of charge, without prejudice, and should not be viewed as giving technical advice, instruction, or otherwise. Use of this information is intended for persons with the requisite technical expertise and regulatory knowledge, who will make their own determination as to its suitability prior to use and at their own discretion and risk. Eldon James Corporation makes no warranty or representation as to the completeness or accuracy of the information contained herein.

Prior to the specification of a product, evaluation of materials under end-use conditions is essential, as these factors (pressure, temperature, other environmental substances, etc.) may affect the performance of the product. Ultimately, it is the customer’s responsibility to determine that use of this product is safe, lawful, and technically suitable for the intended application.



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REGULATORY SUMMARY

Allergens

The following allergens (including their products thereof) are not used in the manufacture or formulation of this product: celery, cereals containing gluten, corn, crustaceans, eggs, fish, lupin, mollusks, milk (including lactose), mustard, nuts, peanuts, sesame seeds, soybeans.

Animal Derived Components (BSE/TSE)

The stearates used in the manufacture of this 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 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.

Biocompatibility

This product has not been assessed under US Pharmacopeia or European Pharmacopeia requirements.

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. This Act, commonly known as Proposition 65 (Prop.65), establishes a list of chemicals which the state of California's risk assessment process has determined to present a risk of cancer, birth defects or other reproductive harm. The Prop. 65 list can be found on the oehha.ca.gov website.

Chemical Inventories

Please see SDS for chemical inventory listings.

CONEG – Coalition of Northeastern Governors

The raw material manufacturer has certified that this product complies with the relevant requirements of the Coalition of Northeastern Governors' Model Toxics in Packaging Legislation.

Conflict Minerals (Dodd-Frank Wall Street Reform and Consumer Protection Act)

The Dodd-Frank Wall Street Reform and Consumer Protection Act requires all publicly traded manufacturers to report each year to the Securities and Exchange Commission (SEC) whether their products contain metals derived from conflict minerals. These minerals, which originate in the Democratic Republic of Congo or an adjoining country, are defined as columbite-tantalite (coltan, niobium, tantalum), cassiterite (tin), gold, wolframite (tungsten), and their derivatives.

Conflict Minerals are not used in the manufacturing or formulation of this product.



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European Directive (94/62/EC) Packaging and Packaging Waste and EU Directive 2012/19/EU Waste Electrical & Electronic Equipment (WEEE)

Directive 2002/96/EC ("WEEE Directive") including all amendments through 2012/19/EU. Each of the RoHS laws seeks to limit or require disclosure concerning the use of certain hazardous materials in various types of electronic, electrical, medical, packaging and consumer products. These restricted materials are not intentionally added or used in the manufacture of this resin. This 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.

Food Contact Status

This resin may be used worldwide in food contact applications. There are no limitations placed on the use of this material for food contact applications other than what is suitable for the intended purpose.

European Union (EU)

This resin meets all relevant requirements of the following European Regulations and Directives: Regulation (EC) 1935/2004 – The Framework Regulation, Regulation (EC) No 2023/2006 – The Good Manufacturing Practices Regulation, Regulation (EC) No 10/2011 – Plastic Materials and Articles Intended to Come into Contact with Food Regulation.

This resin contains the following substances which are subject to a Specific Migration Limit under Regulation (EC) No 10/2011, Annex I (the Union List): Component SML, Hexamethylene Diamine SML = 2.4 mg/kg, Zinc Oxide SML = 25 mg/kg (expressed as Zinc), Compliance with these SML's, as well as the Overall Migration Limit (OML) is a function of the composition, shape, size and use conditions of the finished article. Compliance with these limits should be determined by the customer.

The following dual use additives in this resin are subject to a specific restriction in food under Regulation (EC) No 1333/2008 on food additives, as amended, and should be further assessed to confirm compliance with any restrictions:

- Adipic acid (Food additive: E 355)

No other dual use additives used in this resin could lead to the food being out of compliance with any restrictions set out in Regulation (EC) No. 1333/2008 on food additives, as amended, or Regulation (EC) No. 1334/2008 on flavorings and certain food ingredients with flavoring properties for use in and on foods, as amended.

FDA

This resin is formulated and manufactured to meet the relevant requirements of the U.S. Food and Drug Administration (FDA) regulations. This resin meets the requirements of 21 CFR 177.1500 (b)(1). This resin contains additives, and each of these proprietary additives meets one or more of various requirements in 21 CFR – Specific citation as a food contact material, GRAS Status, Direct Food Additive status, or Threshold of Regulation (TOR) exemption.

NSF

This resin is certified by the National Sanitation Foundation (NSF) as meeting the requirements of NSF Standard 51 – Food Contact Materials. It is approved for use in contact with all food types without restriction. The listing may be found on the NSF website.



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Medium Chain Chlorinated Paraffins (MCCP)

Medium-chain chlorinated paraffins (i.e., UVCB substances consisting of $\geq 80\%$ linear chloroalkanes with carbon chain lengths within the range from C14 to C17) are not intentionally added or known to be present in this material.

Ozone Depleting Substances

Ozone depleting substances (Class I or Class II) are not intentionally added or used in the manufacture of this material. This assessment is based on data obtained from raw material suppliers, vendor safety data sheets, and the manufacturer's knowledge of the manufacturing process. Therefore, the material is compliant with the requirements of European Regulation EC1005/2009 as no substances (listed in Annex I or II of the regulation) are used in the manufacturing or formulation of this product.

Per- and Polyfluoroalkyl Substances (PFAS)

Per- and polyfluoroalkyl substances (listed below) are not intentionally added or used in the manufacture of this product:

- Perfluorinated Compounds (PFC)
- Perfluorooctanoic Acid (PFOA)
- Per- and Polyfluoroalkyl Substances (PFAS)
- Perfluorooctanesulfonic Acid (PFOS)
- Perfluoroalkyl Carboxylic Acids (PFCA)
- Perfluorohexanoic Acid (PFHxA)
- Perfluorohexane Sulfonic Acid (PFHxS)

This assessment from the raw material manufacturer is based on information obtained from their own raw material suppliers, SDSs, and their knowledge of the manufacturing process.

Persistent Organic Pollutants (POPs)

Persistent Organic Pollutants are not intentionally used in the formulation of this resin, nor are these substances present as impurities in the raw materials in concentrations above the legal limits. This includes substances listed in Annexes I and II of Regulation 2019/1021 (including amended commission delegated regulation (EU) 2023/1021), as well as substances identified by the Stockholm Convention on Persistent Organic Pollutants and the US Environmental Protection Agency.

Plant Derived Components

This product 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.

REACH 253 Substances of Very High Concern (SVHC)

Based on the information provided to Eldon James from our raw material suppliers, and their formulation reviews, this product does not contain SVHC Candidate List materials (in accordance with Article 59 of the European Regulation 1907/2006) above the declaration threshold (0.1%) as updated by the European Chemical Agency as of February 4th, 2026.

RoHS 3 (Restriction of Hazardous Substances) 2015/863/EU

Restriction on use of: lead, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants, at levels of greater than 0.1%; cadmium, at levels greater than 0.01%; and Pentabromodiphenylether, Octabromodiphenylether, and Decabromodiphenyl oxide, in concentrations higher than 0.1%; and HBCDD, Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP) in concentrations greater than 0.1%.

Based on the information provided by our resin suppliers and their formulation reviews, they have found that the product listed above does not contain RoHS substances above listed concentrations



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and would therefore be in compliance with substance restrictions per RoHS 3 Directive 2015/863/EU and amendments in force.

Substances

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

Substance	CAS Number
2,2 dimethoxy-2 phenylacetophenone	24650-42-8
2-benzotriazol-2-yl-4,6-ditert-butyl-phenol	3846-71-7
2-Mercaptobenzothiazole (MBT)	149-30-4
4-hydroxy-benzophenone	1137-42-4
4-methyl-benzophenone	134-84-9
4 tris (2, 3-dibromopropyl) phosphate	126-72-7
8 Tris-(aziridinyl)-phosphin oxide	5455-55-1
Amine, Aniline and Chlorinated Amine and Aniline Compounds, including:	
4 Aminodiphenyl	92-67-1
p-Amino-azobenzene	60-09-3
o-Anisidine	90-04-0
Benzidine	92-87-5
o-Aminoazotoluene	97-56-3
2-Amino-4-nitrotoluene	99-55-8
4-Chloro-o-Toluidine	95-69-2
p-Chloroaniline	106-47-8
p-Cresidine	210-71-8
2,4 Diaminoanisole	615-05-4
4,4-Diaminodiphenylmethane	101-77-9
3,3-Dichlorobenzidine	91-94-1
3,3-Dimethoxybenzidine (o-Dianisidine)	119-90-4
3,3-Dimethyl-4,4'-diaminodiphenylmethane	838-88-0
4,4 Methylene-bis-(2-chloroaniline)	101-14-4
2-Naphthylamine	91-59-8
4,4-Oxydianiline	101-80-4
4,4-Thiodianiline	139-65-1
2,4-Touluediamine	95-80-7
2,4,5-Trimethylaniline	317-17-7
Ammonium nitrate	6484-52-2
Antimony and Antimony	
Arsenic and Arsenic Compounds	
Asbestos, including all mineral types	
Astatine and Astatine compounds	
Azo Dyes and Colorants, all types	
Barium and Barium Compounds	
Benzene	



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Substance	CAS Number
Benzophenone	119-61-9
Benzotriazole	95-14-7
Beryllium and Beryllium Compounds	
Biocides, any type, including:	
Triclosan	3380-34-5
Cadmium and Cadmium Compounds	
Chlorine and Chlorine Compounds	
Chromium and Chromium Compounds	
Cobalt and Cobalt Compounds	
Cyclododecane	294-62-2
Cyclohexane	110-82-7
DBBT	
Diethylene glycol monobutyl ether (DEGBE)	112-34-5
Diethylene glycol monomethyl ether (DEGME)	111-77-3
Diphenyl methane-diisocyanate (MDI)	26447-40-5
Dioxin compounds	
Fluorinated substances	
Formaldehyde	50-00-0
Furan compounds	
Halogenated Organics including:	
Hexachlorobenzene	118-74-1
Organic iodine compounds	
Methyl Bromide	74-83-9
Pentachlorophenol (PCP)	87-86-5
Tetrachlorophenol (TCP)	58-90-2
Bromobenzyl-bromotoluene (DBBT)	99688-47-8
Polychlorinated Biphenyls	
Polychlorinated Naphthalenes	
Poly Trichlorobenzene	
Hypalon® chlorosulfonated polyethylene	68037-39-8
Latex	
Lead and Lead Compounds	
Mercapto Compounds	
Mercury and Mercury Compounds	
Monomethyl Dichloro Diphenyl Methane	
Monomethyl Tetrachloro Diphenyl Methane	76253-60-6
Nickel and Nickel Compounds	
Nitro amines	
Nonyl phenol and nonyl phenol ethoxylates	
Pesticide and herbicide residues	
Regulated Phthalates	
Phenol and Phenol Compounds	



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Substance	CAS Number
Polynuclear aromatic hydrocarbons (PAH's)	
Polyvinyl Chloride	
Potassium Permanganate	7722-64-7
Selenium and Selenium Compounds	
Short-chain Chlorinated Paraffins (SCCPs)	85535-84-8
Silver or Silver Compounds	
Sulphur dioxide and sulphites	
Thio Compounds	
Tin and Organo Tin Compounds, including:	
Tributyl Tin	688-73-3
Tributyl Tin Oxide	56-35-9
Triphenyl Tin	668-34-8
o-Toluene	95-53-4
Tri-(2,2-dibromo-propyl)phosphate	
Triphenyl Phosphate	115-86-6
Tris-(1-aziridinyl)phosphin oxide	
Tris(2-chloroethyl)phosphate (TCEP)	115-96-8
Vinyl substances, including:	
Polyvinylchloride (PVC)	9002-86-2
Volatile organic compounds (VOCs)	

US Toxic Substances Control Act (TSCA) Section 6(h)

The following restricted Persistent, Bioaccumulative, and Toxic (PBT) chemicals (per Section 6(h) of the EPA's Toxic Substances Control Act) are not intentionally added or expected to be present in this material:

- Decabromodiphenyl ether (DecaBDE)
- Phenol, isopropylated phosphate (3:1) (PIP (3:1))
- 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP)
- Hexachlorobutadiene (HCBd)
- Pentachlorothiophenol (PCTP)

Please be aware that, while not included in the manufacturing or formulation of this material, these substances are not tested for.

