



Effective Date: 02/03/2017

REGULATORY INFORMATION PACKET

Vydyne[®] 21SPF

NATURAL NYLON POLYAMIDE

Product Manufacturer

Manufactured by Ascend Performance Materials Operations, LLC. Houston, TX U.S.A.

Manufacturing Facility Certifications

FDA 21 CFR 177.1500	ASTM D 4066 PA0111	EC 1935/2004
EU 10/2011, EU 2023/2006	ASTM D 6779 PA0111	

Chemical Inventories

Please see SDS for chemical inventory listings.

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.

United States

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.

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.



This resin contains no additives which are authorized as food additives or flavorings by 89/107/EEC or 88/388/EEC. All nylon 6,6 polymers contain Adipic Acid and may contain Acetic Acid as monomers. Adipic Acid and Acetic Acids are authorized by EFSA as food additives and/or flavoring ingredients. This resin meets all relevant requirements of all national European regulations. 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.

USF/ANSI 51 Food Equipment Materials

Meets requirements for all food contact types, maximum temperature of use is 450°F.

Food Allergens

This 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 Pharmacopeia requirements.

Animal Derived Components (BSE/TSE)

Supplier 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 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.

This assessment is based on data obtained from 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

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.

Kosher

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

Halal

This resin is not Halal certified, stearates used in the manufacture are made of animal origin.

REACH 173 Substances (January 12, 2017)

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 dated January 12, 2017 are present in this product at levels greater than 0.1%.

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

RoHS and ELV regulations limit or require disclosure concerning the use of certain hazardous materials in various types of automotive, electronic, electrical, medical, packaging and consumer products. This declaration confirms restricted materials including mercury, lead, cadmium hexavalent chromium, poly-brominated biphenyls (PBB) and poly-brominated diphenyl ethers (PBDE) are not intentionally added to this resin.

Heavy Metals (ELV Directive 2000/53/EC)

Coalition of Northeastern Governors (CONEG)

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. The supplier does not routinely analyze this product for heavy metal content, but based on knowledge of the raw materials and the production process, there is no reason to believe that any heavy metals would be present at levels of regulatory significance. In addition, these 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

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

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 the manufacture of this resin.



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

This product 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. 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.

Conflict Materials (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 materials. 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 materials are not used in the manufacture of or contained as an ingredient in this resin.

Ozone Depleting Chemicals (ODCs)

No ozone depleting substances (ODS's) are ingredients in or used in the manufacture of this resin, and should not be present at detectable levels. This includes all isomers of the ODS's specifically listed below, as well as any other known ODS's. Resin is compliant with the requirements of European Regulation EC1005/2009; no substances listed in Annex I or II of this regulation is used in the manufacture of or contained as ingredients in any Ascend product.

Phthalates

This resin is in compliance with the phthalate restrictions imposed by EU Directive 2005/84/EC and USA Consumer Product Safety Improvement Act of 2008 (SPSIA).

Materials from Genetically Modified Organisms

Genetically Modified Organisms (GMO) and materials are not intentionally added to our nylon resins. This assessment is based on information obtained from raw material supplier, vendor Safety Data Sheets (SDS) and the supplier's knowledge of their manufacturing processes.



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	25-35 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.



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.