June 29, 2026

The Regulatory Status of Pinnacle Polymers Products

Pinnacle's 1000 series homopolymer polypropylene products as marketed by Pinnacle Polymers Company in natural, uncolored pellet form conform to the following:

FDA regulations

Pinnacle's 1000 series comply with all of the appropriate requirements of CFR Title 21, Part 177, Subpart B, Section 177.1520 (c) 1.1a, entitles "Olefin Polymers" of the Food Additives Amendment of 1958 to the United States Food, Drug and Cosmetic Act of 1938. Consult current individual product datasheets for any limitations of food type or conditions of use.
It is, however, the responsibility of the customer to determine that the products fabricated from these materials are acceptable to the FDA for use in their intended applications.

Country of Origin

United States of America

Food Allergens

Products are not formulated to contain, or known to contain, any of the following materials: celery, eggs, fish, milk, mustard, peanuts, sesame seeds, crustacean shellfish, soybeans, sulfites, sulfur dioxide, tree nuts, or wheat. Not known to contain foods listed in EU No 1169/2011.

CONEG – Coalition of Northeastern Governors (Heavy Metals)

In these products the sum of concentration of lead, mercury, cadmium and hexavalent chromium is less than 100 ppm by weight. Pinnacle products are also in compliance with Minnesota's regulations on lead and cadmium.

ASTM F963 Standard Consumer Safety for Toy Safety

These products are not formulated, or known to contain antimony, arsenic, chromium, selenium, or barium.

California Proposition 65

Please refer to the Safety Data Sheet (SDS) for 1000 series products.

Chemicals of High Concern to Children (CHCC)

Products are not formulated with, or known to contain, the chemicals of high concern to children as listed by the states of Washington, Oregon, Vermont and Maine; however, our products are not tested for these materials.

Animal Derivatives

Most products are not formulated, or known to contain animal or tallow based materials. However, to obtain information for a specific product grade, please contact Pinnacle.

Kosher

Products are not certified Kosher.

US FDA Drug Master File (DMF)

Information concerning these products is listed in DMF 17038. Contact Pinnacle for a DMF letter of authorization to be sent to the FDA.

Pinnacle Polymers makes no warranty of merchantability and there is no warranty that materials shall be fit for any particular application. Users should make their own independent evaluation whether a Pinnacle product is suitable for a specific end-use. No one is authorized to assume any warranties on behalf of Pinnacle without written agreement from an authorized Pinnacle employee. Pinnacle limits it liability to either replacement of non-performing material, or payment not to exceed the cost of the polypropylene supplied plus transportation charges.

Substances of Interest

Products are not formulated with, or known to contain, these substances; however, our products are not tested for these materials:

- 2,4-di-tert-butylphenol or 4-hydroxybenzene
- Acrylamide
- Alkyl Phenol Ethoxylates – Nonyl and Octyl
- Aromatic Amines
- Asbestos
- ATP (Adenosine Triphosphate)
- Azodicarbonamide (ADA)
- Benzophenone
- Bisphenol A (CAS number: 80-05-7)
- Bisphenol F (CAS number 87139-40-0)
- Bisphenol S (CAS number: 80-09-1)
- Butylated Hydroxyanisole (BHA)
- Butylated Hydroxytoluene (BHT)
- Chlorofluorocarbons (CFC's) ozone depleting substances
- Cyanuric Acid
- Decabromodiphenyl ether (Deca-BDE)
- Dimethyl Fumarate (DMF)
- Dioxins
- Elemental Boron or Phosphorus
- Epichlorohydrin
- Flame Retardants in general, which includes:
  - Decabromodiphenyl ethane (DBDPE)
  - Decabromodiphenyl ether (Deca-BDE)
  - Dechlorane Plus (DP)
  - Hexabromocyclododecane (HBCD)
- Formaldehyde
- Gluten
- GMO – Genetically Modified Organisms
- Latex, or natural rubber latex
- Latex related polymers
- Long-Chain Perfluorinated Carboxylic Acid (LC-PFCA)
- Melamine
- Nitrosamines
- Nonylphenol
- Organo-tin Compounds
- Ozone Depleting Chemicals (ODCs)
- Perfluorooctanoic Acid (PFOA)
- Perfluorooctane Sulfonate (PFOS)
- Perfluorononanoic acid (PFNA)
- Phthalates in general, which includes:
  - Butyl benzyl phthalate (BBP) - (CAS# 85-68-7)
  - Di-isodecyl phthalate (DIDP) - (CAS# 26761-40-0 & 68515-49-1)
  - Di-isononyl phthalate (DINP) - (CAS# 28553-12-0 & 68515-48-0)

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  - Di-n-butyl phthalate (DBP) - (CAS# 84-74-2)
  - Di-n-hexyl phthalate (DNHP) - (CAS# 84-75-3)
  - Di-n-octyl phthalate (DNOP) - (CAS# 117-84-0)
  - Di-(2-ethylhexyl) phthalate (DEHP) - (CAS# 117-81-7)
  - Diisobutyl phthalate (DIBP) - (CAS# 84-69-5)
- Polybrominated Biphenyls (PBBs)
- Polybrominated Diphenyl Ethers (PBDEs)
- Polybrominated Terphenyls (PBTs)
- Polychlorinated Biphenyls (PCBs)
- Polychlorinated Terphenyls (PCTs)
- Polyvinyl Chloride (PVC)
- Silicone
- Solvents: benzene, carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethene, or 1,1,1- trichloroethane
- Styrene
- Vinyl Chloride
- BADGE, NOGE and BFDGE are not used in the manufacture of or the formulation of this product according to requirement of Regulation N.1895/2005
- Arsenic
- Perchlorate
- Bisphenol B
- Bisphenol A diglycidyl ether
- 2-Ethoxyethanol
- 2-Methoxyethanol
- N-methyl-2-pyrrolidone
- ToluenePhenol, isopropylatedphosphate (3:1)
- Decabromodiphenyl ether
- 2,4,6-tris(tert-butyl)phenol
- Hexachlorobutadiene
- Pentachlorothiophenol
- Polycarbonates
- Polyhydroxyalkanoates
- Polylactic Acid as a rigid structure

Health Canada

Most products have "no objection" letters issued from HPFB. Contact Pinnacle if you need to obtain this information.

RoHS

Products comply with the requirements of Directives 2002/95/EC, 2011/65/EU, and 2015/863. Pinnacle products are not known to contain cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers, bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), or diisobutyl phthalate (DIBP).

European Legislation 1935/2004 Framework Directive EC as amended by 89/109/EEC

Products comply with relevant requirements.

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REACH Registration

Pinnacle 1000 series products are registered for EU importation, or use in production of articles to be imported, under registration no 01-2119447103-50-0301, based on Article 20(2) of Regulation (EC) No 1907/2006 ('REACH').

UK REACH Registration

Pinnacle 1000 series products are registered for UK importation, or use in production of articles to be imported, under registration no. UK-01-3689956022-5-0039 for propene.

94/62/EC Packaging and Waste compliant to heavy metals not to exceed 100ppm

Products comply.

2008/282/EC Use of recycled plastic material

No recycled materials are used in our products.

10/2011/EC Monomers and Additives

Products comply with relevant requirements. Contact Pinnacle concerning the identification of any additives having SML requirements for the testing of finished articles.

2006/2023/EC Good Manufacturing Practices

Products comply with relevant requirements.

DSL (Domestic Substances List) and Chemical Batches

The above Pinnacle products are compliant with Canadian DSL and are not known to contain any of the substances listed in the CCMP 12 Batches of Chemicals.

REACH

We also confirm that the intentional composition of the above mentioned products do not contain any of the 253 SVHC substances appearing in the REACH candidate list most recently updated by ECHA on February 4, 2026.

Medical Policy

Usage Restrictions: Pinnacle products shall not be used in connection with the following applications:

- The manufacture of any US FDA Class III Medical Device, Health Canada Class IV Medical Device or European Union Class III Medical Device.
- The manufacture of implanted medical or surgical devices.
- Life-sustaining medical applications.

Conflict Minerals

"Conflict Minerals" are a source of Tin, Tungsten, Tantalum and Gold (known as 3TGs). Polypropylene products marketed by Pinnacle Polymers contain no known sources of the 3TGs or their derivatives.

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PFAS

Pinnacle's 1000 series homopolymer polypropylene products (produced after September 1, 2024) , as marketed by Pinnacle Polymers Company, in natural, uncolored pellet form, is not known to contain any per and polyfluoroalkyl substances – known as PFAS (as defined by OECD, EU, ECHA, and the US EPA).

Animal Derived Substances

Pinnacle's polypropylene as marketed by Pinnacle Polymers Company, in natural, uncolored pellet form, are not formulated, or known to contain, any animal derived substances.

Paul Benenati

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