



January 3, 2018

## **The Regulatory Status of Pinnacle Polymers Products**

Pinnacle's 5000, 6000, and 7000 series random copolymer polypropylene products as marketed by Pinnacle Polymers Company, in natural, uncolored pellet form conform to the following:

### **FDA regulations**

Pinnacle's random copolymer products are cleared by way of FCN 1538 for use in single- and repeated-use articles intended to contact food. Consult current individual product datasheets for limitations of food type, or conditions of use. FDA has not evaluated use of these copolymers in contact with infant formula or breast milk.

It is, however, the responsibility of the customer to determine that the articles fabricated from these products are acceptable 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.

### **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**

These products conform to Prop 65.

### **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 its 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, or known to contain these substances. However our products are not tested for these materials:

- Latex, or natural rubber latex
- Bisphenol A (CAS number: 80-05-7)
- Bisphenol F (CAS number 87139-40-0)
- Bisphenol S (CAS number: 80-09-1)
- Asbestos
- ATP (Adenosine Triphosphate)
- Phthalates:
  - 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)
  - 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)
- Polyvinyl Chloride (PVC)
- Chlorofluorocarbons (CFC's) ozone depleting substances
- Elemental Boron or Phosphorus
- 2,4-di-tert-butylphenol or 4-hydroxybenzene
- Cyanuric Acid, Benzophenone, Melamine, Perfluorooctanoic Acid, Silicone
- Solvents: benzene, carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethene, or 1,1,1-trichloroethane
- Gluten
- GMO – Genetically Modified Organisms
- Perfluoro Substances
- Ozone Depleting Chemicals (ODCs)
- Phthalates
- Acrylamide
- Aromatic Amines
- Asbestos
- Bisphenol A
- Nitrosamines
- Dioxins
- Epichlorohydrin
- Nonylphenol
- Organo-tin Compounds
- Fluorocarbons
- Polychlorinated Biphenyls (PCBs)
- Polybrominated Biphenyls (PBBs)
- Polychlorinated
- Terphenyls (PCTs)

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- Polybrominated Diphenyl Ethers (PBDEs)
- Polybrominated Terphenyls (PBTs)
- Polybrominated diphenyl ethers (PBDEs)
- 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.
- Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
- Latex related polymers

### **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 and 2011/65/EU. Pinnacle products are not known to contain cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers.

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

Products comply with relevant requirements.

### **2002/72/EC Plastic Materials and Articles intended to come into contact with food - stuff amended by Commission Directive and all subsequent amendments including 2008/39/EC**

Products comply with relevant requirements. Some additives may not be on the list of authorized substances.

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

Products comply.

### **2005/1895/EC BADGE**

Products comply with relevant requirements.

### **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. Some additives may not be on the list of authorized substances. 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.

### **RoHS & WEEE- EU Directive 2002/95/EC**

This is to certify that all Pinnacle Polypropylene products are RoHS compliant with the EU Directive 2002/95/EC and 2011/65/EU concerning the prohibited hazardous substances.

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**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 SVHC substances appearing in the REACH candidate list most recently updated by ECHA.

**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.

Sincerely,



Chang Hoon Song, Ph.D

Technical Manager

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