



# J60-1700-173 Polyethylene Homopolymer

## Regulatory Position Statement

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### US FDA Compliance

J60-1700-173, as manufactured, is in compliance with Title 21, Code of Federal Regulations (CFR) Parts 177.1520 (c) (Item 2.2) and 178.2010 as promulgated by the US Food and Drug Administration (FDA). It is therefore permitted by FDA for use in food-contact applications for food-types identified in Categories I through IX of Table 1, under conditions of use A through H of Table 2 in Title 21, CFR Part 176.170 (c).

### EU Food Contact Compliance

As dispatched from our plant, J60-1700-173 meets the requirements of the Directive 2002/72/EC (06/08/2002) relating to plastic materials and articles intended to come into contact with foodstuffs and its subsequent amendments. No monomers subject to restriction (Specific Migration Limit or Quantitative Maximum) are used in the manufacture of J60-1700-173. J60-1700-173 contains an additive which is subject to a Specific Migration Limit of 3 mg/kg. The modeling results, simulated at 40° C for 10 days with partition factor of 1, shows that this additive does not migrate to the food stuff at greater than its SML. As the conversion process can affect migration, only the converter can guarantee to the food packager that the limit is not exceeded.

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### Allergen Content

No known allergens or allergen derivatives such as peanuts, soy/soybeans, milk, eggs, fish, shellfish/crustacea, tree nuts, sulfites or wheat/gluten substances have been added during the formulation, or used as a processing aide in the manufacture of this product.

### Heavy Metals/CONEG – Coalition of Northeastern Governors

No cadmium, chromium, lead or mercury is used in the formulation of this product. Please be advised that the total incidental amount of cadmium, lead, mercury and hexavalent chromium does not exceed 100 ppm and complies with CONEG model requirements.

### Animal Derivatives

No animal fats, oils, milk products or other animal- or tallow-derived products are used as components of, or in the manufacture of, this product.

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### California Proposition 65

No substance listed on California's Proposition 65 chemicals listing, known to the State of California to cause cancer or reproductive toxicity, is intentionally added as an additive or raw material in the manufacture of this product.

### Latex Content

No latex, latex compounds or natural rubber are contained in, or added to the resin or additives and, therefore, would not be present in this product.

### GMOs – Genetically Modified Organisms

No GMOs, genetic material from GMOs, materials derived from GMOs, nor any genetically modified ingredients have been used at any time in the manufacture of this product.

### Ozone Depleting Chemicals (ODCs)

This product does not contain and is not manufactured with any Class I or Class II ODC and is in compliance with EPA's US Clean Air Act, Title VI.

### Phthalates

No phthalates are intentionally added or used as additives or raw materials in the manufacture of this product.

### Bisphenol A

No bisphenol A (BPA) is intentionally added or used as an additive or raw material in the manufacture of this product.

### Brominated Flame Retardants

No brominated flame retardants, either PBBs or PBDEs, are intentionally added to the resin or used as additives or raw material in the manufacture of this product.

### Organotin Compounds

No organotin compounds are contained in, nor added to, the resin or additives and, therefore, would not be present in this product.

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**INEOS**  
**Olefins & Polymers USA**



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### Canadian Chemical Management Plan

No chemicals listed on the Canadian Chemical Management Plan are intentionally added as components of, or in the manufacture of, this product.

### US Pharmacopoeia

This resin has not been tested under the criteria specified in the United States Pharmacopoeia, nor ISO 10993 for biological testing of materials, because testing must be conducted on the finished product.

### European Pharmacopoeia

This grade contains only additives that appear in the list of additives specified in the European Pharmacopoeia section 3.1.3., "Polyolefins". INEOS has not, at this time, conducted the migration testing specified in the citation, because the responsibility for compliance with the Pharmacopoeia, and demonstrating that the contents do not react chemically or biologically with its container, rests with the device manufacturer.

### PFAAs: PFOs, PFAs and PFOA and EU Directive 2006/122/EC

No perfluorooctanic acid (PFOA), perfluoro-alkyl sulphonates (PFAS), or perfluorooctane sulfonates (PFOs) are added to the resin or used as additives or raw material in the manufacture of this product. Therefore, this product is compliant with EU directive 2006/122/EC.

### RoHS

INEOS Polyethylene is in compliance with European Directive 2002/95/EC (RoHS) as it relates to the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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