

H00G-00 Polypropylene Homopolymer

Regulatory Position Statement

US FDA Compliance

H00G-00, as manufactured, complies with Title 21, CFR Parts 177.1520 (c) (Item 1.1) and 178.2010 as promulgated by the US Food and Drug Administration (FDA). It is, therefore, permitted by the FDA for use in food-contact applications for food types identified in Categories I through IX of Table 1, under conditions of use B through H of Table 2 in Title 21 CFR, Part 176.170(c).

EU Food Contact Compliance

As dispatched from our plant, H00G-00 may not meet 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 monomer subject to a restriction such as a Specific Migration Limit (SML) or a Quantitative Maximum (QM) is used in manufacturing this product. H00G-00 contains an additive subject to an SML of 0.6 mg/kg. Modeling results simulated at 40° C for 10 days with the partitioning coefficient of 1 indicate that this additive migrates to the foodstuff at a level 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.

GLOBAL INVENTORY STATUS

<i>Country</i>	<i>Inventory</i>	<i>Y/N</i>
United States	TSCA	Y
European Union	EINECS	Y
China	IECS	Y
Canada	DSL	Y

<i>Country</i>	<i>Inventory</i>	<i>Y/N</i>
Japan	ENCS	Y
Korea	KECI	Y
Australia	AICS	Y
Philippines	PICCS	Y
New Zealand	NZIoC	Y

REACH

INEOS Olefins & Polymers USA has completed the REACH pre-registration of all required chemicals. This was accomplished through agreements with our INEOS colleagues in the EU to act as our Only Representatives (OR). One OR pre-registered our monomers, the other OR pre-registered the necessary additives used in our polypropylene and/or polyethylene products. All required pre-registrations were submitted prior to the December 1, 2008 deadline. Please contact Julie Clifford at julie.clifford@ineos.com if you need further information.

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REACH Appendix 14 Substances of Very High Concern (SVHC)

None of the chemicals listed to date on REACH Appendix 14 SVHC list are intentionally added as components of, or in the manufacture of, this product. We will continue to review the list as it is updated and will amend this statement if necessary.

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.

GMP and EU 2023/2006/EC

INEOS O&P USA's product safety program ensures that our products are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition or organoleptic characteristics of the food.

Allergen Content

No known allergens or allergen derivatives such as peanuts, soy/soybeans, milk, eggs, fish, shellfish/crustacea, tree nuts, celery, mustard, 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/EU Directive 94/62/EC

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. This product complies with the Council of Northeaster Governors (CONEG) model requirements and can meet the requirements of the EU packaging and packaging waste directive.

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 used in the manufacture of this product. However, as with all polypropylene grades, including grades from other producers, these resins may contain trace levels of phthalates, typically less than 15 ppm, arising from catalyst residues.

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Animal Derived Material/BSE

One of the additives used in this product is produced from animal-derived material. We have received from our supplier the guarantee that this additive is BSE-free. The reasons given are:

- The processing includes very high temperatures and pressure which eliminates the risk of BSE contamination.
- Our suppliers also confirm that the raw materials used, and the finished products they sell, comply with the existing legislations.

Melamine

No melamine is intentionally added or used as an additive or raw material 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.

Alkylphenols and Ethoxylates

No alkylphenols, ethoxylates or estrogen-mimicking compounds are used 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.

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.

PCBs

No polychlorinated biphenyl compounds (PCBs) are contained in, nor added to, the resin or additives in this product.

Dioxins

No dioxin or dioxin isomers are contained in, nor added to, the resin or additives and, therefore, should not be present in this product.

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Ozone Depleting Chemicals (ODCs)

In compliance with EPA's US Clean Air Act, Title VI, no Class I nor Class II ODC is contained in, nor used in the manufacture of 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.

Phthalates

No phthalates are intentionally added nor used as additives or raw materials in the manufacture of this product. However, as with all polypropylene grades, including grades from other producers, this resin may contain trace levels of phthalates, typically less than 15 ppm or 0.0015%, arising from catalyst residues.

Organotin Compounds

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

Canadian Chemical Management Plan

None of the chemicals listed on the Canadian Chemical Management Plan are intentionally added as components of, or in the manufacture of, this product.

US Pharmacopoeia

This product has not been tested under the criteria specified in the United States Pharmacopoeia for biological testing of materials because this product is a raw material and testing must be conducted on the finished product.

EU Pharmacopoeia

An additive in this product is not on the list of approved additives in the European Pharmacopoeia section 3.1.3., "Polyolefins." It is possible to use components that are not listed in the Pharmacopoeia, as long as the components do not migrate into the content of the medical device at concentrations that are harmful to humans or interact with the content biologically or chemically. 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.

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WEEE

European Directive 2002/96/EC covers waste from electrical and electronic equipment (WEEE). INEOS products are raw materials used in the manufacture of articles and components; therefore, this Directive is not directly applicable to our products. This product does not contain any substances classified as hazardous.

Dangerous Substances - EU Directive 67/548/EC

None of the substances used in the manufacture of this product are intentionally added above the level classified by this Directive as dangerous for the environment.

RoHS

INEOS Polypropylene 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.

Issue Date	4/02/09	Revision No.	11
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