

H03W-00 Polypropylene Homopolymer

Regulatory Position Statement

US FDA Compliance

H03W-00, as manufactured, complies with Title 21, CFR Parts 177.1520 (c) (Item 1.1) and 178.2010 as promulgated by the Food and Drug Administration (FDA). They are, 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 A through H of Table 2 in Title 21 CFR, Part 176.170(c).

EU Food Contact Compliance

As dispatched from our plant, H03W-00 meets the requirements of 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. No additives subject to restriction (Specific Migration Limit or Quantitative Maximum) are used. Glycerine is approved as direct food additive. It is present, as an additive, in H03W-00. As the conversion process can affect migration, only the converter can guarantee to the food packager that the limit is not exceeded.

REACH

INEOS Olefins & Polymers USA is well informed of the REACH legislation in the EU and is prepared to take necessary steps to provide business continuity in the EU as appropriate. We have inventoried chemical substances that may be affected by REACH and intend to preregister and register these substances as required through our Only Representative (OR). As progress is made, more information will be provided upon request. Please contact Julie Clifford at julie.clifford@ineos.com if you need further information.

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.

The information contained herein relates only to the specific product and/or material designated and may not be valid for such product and/or material used in combination with any other product and/or material or in any process, unless otherwise specified. This information in no way modifies, amends, enlarges, or creates any specification or warranty, and ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY EXCLUDED. INEOS Olefins & Polymers USA shall not be responsible for any damage or injury resulting from abnormal use, from any failure to follow appropriate practices, or from hazards inherent in the nature of the product and/or material, nor for toxicological effects or Industrial Hygiene associated with particular use of any product described herein. Recipient hereby acknowledges and accepts its responsibility to determine and ensure all conditions, specifications, and regulatory requirements are met and the products fabricated from the specific product and/or material designated are acceptable for use in the intended application.

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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 aid 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 Derived Material/ BSE

One of the additives used in this product is coated with an animal-derived material. We have received from our supplier the guarantee that while this additive is produced from beef tallow, it is BSE-free.

The reasons given are:

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

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.

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.

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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.

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 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, arising from catalyst residues.

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.

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.

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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.

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.

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.

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