

H02C-00 Polypropylene Homopolymer

Regulatory Position Statement

Regulatory Issues

June 20, 2010

US FDA Compliance

H02C-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). 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, H02C-00 may not meet 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. H02C-00 contains one additive which is subject to a Specific Migration Limit (SML) of 0.6 mg/kg. The modeling result shows that greater than 0.6 mg/kg of this additive migrates to the food stuff. As the conversion process can affect migration, only the converter can guarantee to the food packager that the limit is not exceeded. The identity of this additive may be disclosed to you on a confidential basis upon request.

Health Canada “No Objection” Letter

INEOS has received a “No Objection” letter for this product from Health Canada. The file number may be provided upon request.

China’s Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials (GB 9685-2008)

As dispatched from our plant, this product may not China’s hygienic standards for uses of additives in food containers and packaging materials. H02C-00 contains one additive which is subject to a Specific Migration Limit (SML) of 0.6 mg/kg. The modeling result shows that greater than 0.6 mg/kg of this additive migrates to the food stuff. As the conversion process can affect migration, only the converter can guarantee to the food packager that the limit is not exceeded. The identity of this additive may be disclosed to you on a confidential basis upon request.

Drug Master File

Composition information on this product is contained in our drug master file at the FDA. A Letter of Authorization is available upon request.

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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.

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 is not manufactured intentionally with any substances classified as hazardous.

Dangerous Substances - EU Directive 67/548/EC

None of the substances classified as dangerous for the environment are intentionally added or used as an additive or raw material in the manufacture of this product.

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.

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	N
New Zealand	NZIoC	N

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REACH

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.

REACH Substances of Very High Concern (SVHC)

None of the chemicals listed on REACH 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.

Substances of Concern to Our Customers

Alkylphenols and Ethoxylates

No alkylphenols, ethoxylates or estrogen-mimicking compounds are intentionally used in the manufacture of this product.

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 intentionally added during the formulation, or used as a processing aid in the manufacture of this product.

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.

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- The raw materials used, and the finished products they sell, comply with the existing legislations.

Asbestos

No asbestos is intentionally added or used as an additive or raw material in the manufacture of this product.

Azo Colorants

No azo colorants 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.

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.

Canadian Chemical Management Plan

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

Decabromodiphenyl ether (Deca)

No decabromodiphenyl ether (Deca) is intentionally added or used as an additive or raw material in the manufacture of this product.

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. The representations herein expressed are neither intended nor shall be construed as a definitive or comprehensive statement of all constituents sought. 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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Dimethyl Fumarate (DMF)

No dimethyl fumarate, CAS #624-49-7, is intentionally added or used as an additive or raw material in the manufacture of this product.

Dioxins

No dioxin or dioxin isomers are intentionally added or used as an additive or raw material in the manufacture of this product.

Formaldehyde

No formaldehyde is intentionally added or used as an additive or raw material 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 intentionally used at any time in the manufacture of this product.

Heavy Metals/CONEG/EU Directive 94/62/EC

No antimony, arsenic, barium, beryllium, cadmium, chromium, lead, mercury or selenium is intentionally used in the formulation of this product. Previous testing for these metals resulted in a total incidental amount for all metals detected of < 5 ppm, compared to the CONEG requirement of < 100 ppm. The result for incidental lead concentrations was less than the detection limit of 10 ppb (0.01 ppm).

Latex Content

No latex, latex compounds or natural rubber are intentionally added or used as an additive or raw material in the manufacture of this product.

Melamine

No melamine is intentionally added or used as an additive or raw material in the manufacture of this product.

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Organotin Compounds

No organotin compounds are intentionally added or used as an additive or raw material in the manufacture of 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 intentionally added or used as an additive or raw material in the manufacture of this product.

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

No perfluorooctanoic acid (PFOA), perfluoro-alkyl sulphonates (PFAS), or perfluorooctane sulfonates (PFOs) are intentionally 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.

PCBs

No polychlorinated biphenyl compounds (PCBs) are intentionally added or used as an additive or raw material in the manufacture of this product.

Phthalates

No phthalates are intentionally added or 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 0.001%, arising from catalyst residues.

TNPP

No Tris(nonylphenyl) phosphite (TNPP) is intentionally added or used as additives or raw materials in the manufacture of this product.

Pharmacopoeias

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.

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European 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.

For further information, please see our website www.ineos-op.com or contact Product Stewardship.

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