



# R01A-00 Polypropylene Copolymer

## Regulatory Position Statement

Regulatory Issues

January 2010

### US FDA Compliance

R01A-00, as manufactured, is in compliance with Title 21, Code of Federal Regulations (CFR) Parts 177.1520 (c) (Item 3.2(a)) 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 A through H of Table 2 in Title 21 CFR, Part 176.170(c).

### EU Food Contact Compliance

As dispatched from our plant, R01A-00 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, a Specific Migration Limit (SML) or Quantitative Maximum, are used. Polypropylene Grade R01A-00 contains an additive subject to SML of 12 mg/kg and further specification defined in Annex V of the Directive 2002/72/EC. Modeling results simulated at 40° C for 10 days indicate that the above SML will not be exceeded. The supplier of the above mentioned additive confirms that this additive conforms to the specification listed on Annex V of the Directive 2002/72/EC. As the conversion process can affect migration, only the converter can guarantee to the food packager that the limit is not exceeded.

### DMF Letter of Authorization

This product is filed with the FDA in one of INEOS's Drug Master Files. A letter of authorization for the FDA to access our file on your behalf is available upon request.

### 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.

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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 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	N
Philippines	PICCS	Y
New Zealand	NZIoC	Y

### 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

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submitted prior to the December 1, 2008 deadline. Please contact Julie Clifford at [julie.clifford@ineos.com](mailto:julie.clifford@ineos.com) if you need further information.

### **REACH Substances of Very High Concern (SVHC)**

None of the chemicals listed 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.

### **Substances of Concern to Our Customers**

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#### **Alkyphenols and Ethoxylates**

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

#### **Allergens**

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.

#### **Animal Derived Material/BSE**

One or more 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, and/or
- The source animal is non-bovine, and/or
- 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.

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### **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.

### **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.

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### **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.

### **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 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 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 is contained in, or added to the resin or additives and, therefore, would not be present in this product.

### **Melamine**

No melamine is intentionally added or used as an additive 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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### 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.

### 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.

### PCBs

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

### Short Chain Chlorinated paraffins (SCCPs)

No substances from this category are intentionally used in the manufacture of our products.

### Pharmacopoeias

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#### 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

R01A-00 contains an additive that is not specified in European Pharmacopoeia 3.1.3, "Polyolefins".

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For further information, please see our website [www.ineos-op.com](http://www.ineos-op.com) or contact Product Stewardship.

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