

# R12C-01 Polypropylene Copolymer

## Regulatory Position Statement

Regulatory Issues

January 2012

### US FDA Compliance

R12C-01, as manufactured, is in compliance with Title 21 (Edition 2011), Code of Federal Regulations (CFR) Parts 177.1520 (c) (Item 3.1 (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-type categories and the conditions of use defined in Table 2 in Title 21 CFR, Part 176.170(c) as follows:

- Food Contact Categories I through IX
- Conditions of Use B-H

### EU Food Contact Compliance – (EU) No. 10/2011

As dispatched from our plant, the monomers and additives of this INEOS product may not meet the requirements of Commission Regulation (EU) No 10/2011 of January 2011 on plastic materials and articles intended to come into contact with food. Modeling results simulated for 10 days at 40° C with the partition coefficient of 1 indicate that one of these additives may migrate at the level of its corresponding SML or greater. As the conversion process can affect migration, only the converter can guarantee to the food packager that the limit is not exceeded.

### 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, R12C-01 may not meet the requirements of GB 9685-2008 and its subsequent amendments. Modeling results simulated for 10 days at 40° C with the partition coefficient of 1 indicate that one of these additives may migrate at the level of its corresponding SML or greater. 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 these additives may be disclosed to you on a confidential basis upon request.

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### Drug Master File(s)

This product is filed with the FDA in INEOS Drug Master File 12-042. 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.

### 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 polymers are 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	ELINCS	Y
China	IECSC	Y
Canada	DSL	Y

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

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### REACH

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#### REACH EC 1907/2006

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](mailto:julie.clifford@ineos.com) if you need further information.

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

##### Current Candidate List Total: 73

None of the chemicals listed on the REACH SVHC list are intentionally added in the manufacturing process as components of this material. 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.

#### Substances of Concern to Our Customers

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##### 3-MCPD (3-monochloropropane)

No 3-MCPD is intentionally added to the resin or used as additives or raw material in the manufacture of this product.

##### Alkylphenols and Ethoxylates

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

##### Allergens

No known allergens or allergen derivatives from such things as almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts; peanuts, lupine, soy/soybeans, carmine/cochineal, milk, eggs, fish, shellfish/crustacea, tree nuts, celery, sesame seeds, mustard or mustard seeds, glutamites, glutamic acid, MSG or hydrolyzed vegetable proteins, nitrites or sulfites, or gluten from the grains of the following cereals: barley; oats; rye; triticale; or wheat; have been intentionally

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

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

One or more of the additives used in this product may be produced from animal-derived material. We have received from our suppliers a statement that their additives are BSE/TSE-free. The reason(s) given are:

1. The source material is from the US, or
2. The source material complies with the Animal by Products Directive 1774/2002 and its amendments, or
3. The raw materials:
  - a. originate from GBR-C1 and C2 countries (e.g. countries with very small risk of BSE), or
  - b. originate from GBR-C3 and C4 countries (e.g. countries with very small BSE risk) and the base products have food or feed quality and the specific risk material was removed and
4. The material has been processed at a minimum of 200° C at the appropriate pressure for at least 20 minutes following EU (99/534/EC) guidelines.

### **Antimicrobial agents/Fungicides/Pesticides**

No antimicrobial agents, fungicides or pesticides are intentionally added or used as an additive or raw material in the manufacture of this product.

### **Asbestos**

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

### **Azo Colorants/Pigments**

No azo colorants or other pigments are intentionally added or used as additives or raw materials in the manufacture of this product.

### **Benzophenones**

No benzophenones are intentionally added to the resin or used as additives or raw material in the manufacture of this product.

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### **Bisphenol A, BADGE, BFDGE, NOGE/ (EC) No. 1895/2005**

No bisphenol A (BPA), 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether ('BADGE' i.e. Bisphenol-A DiGlycidyl Ether), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers ('BFDGE' i.e. Bisphenol-F DiGlycidyl Ether) and novolac glycidyl ethers (NOGE) is intentionally added or used as an additive 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 intentionally added 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 or 0.0015%, 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.

### **Dioxins**

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

### **Flame Retardants**

No brominated flame retardants either PBBs or PBDEs, TBA or TBP, or hexabromo cyclododecane (HBCDD), or tris-aziridinyl-phosphin oxide, is intentionally added to the resin or used as additives or raw material in the manufacture of this product.

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### 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, or any genetically modified ingredients have been intentionally used at any time in the manufacture of this product.

### HAPs (Hazardous Air Pollutants)

None of the HAPs listed by US EPA in 40 CFR 63.3360 (c)(3.) are intentionally added to the product in the manufacturing process.

### 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 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.

### Nanoparticles

Nanoparticles are not intentionally added or used as additives or raw materials in the manufacture of this product.

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### **N-Ethyl-toluenesulfonamide (Ortho/Para)**

No N-Ethyl-toluenesulfonamide is intentionally added or used as an additive or raw material in the manufacture of this product.

### **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.

### **PAHs (Polycyclic Aromatic Hydrocarbons)**

None of the PAHs listed by US EPA are intentionally introduced in the process or is known to be produced in the process.

### **PCBs**

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

### **Pesticides**

None of the pesticides banned or severely restricted by the US EPA are intentionally used in the manufacturing, storage or transport process of this product.

### **FAAs: 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.

### **Phthalates**

No phthalates (e.g., DEHP, DIDP, DINP, DMP, DIDP, BBP, DNOP, DBP, DEP) are intentionally added nor used as additives or raw materials in the manufacture of this product. However, as with all

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### **PVC**

No polyvinyl chloride (PVC) is intentionally added to the resin or used as additives or raw material in the manufacture of this product.

### **Short Chain Chlorinated paraffins (SCCPs)**

No short chain chlorinated paraffins are intentionally added to the resin or used as additives or raw material in the manufacture of this product.

### **Silicone**

No silicone is intentionally added to the resin or used as additives or raw material in the manufacture of this product.

### **TNPP**

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

### **Triclosan (2,4,4' –trichloro-2'-hydroxydiphenyl ether)**

No 2,4,4' –trichloro-2'-hydroxydiphenyl ether (Triclosan) is intentionally added or used as additive or raw material in the manufacture of this product.

### **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.

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### European Pharmacopoeia

This product 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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