

# R05C-00 Polypropylene Random Copolymer

## Regulatory Position Statement

### US FDA Compliance

R05C-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, II, IV-B, VI, VII-B, VIII in Table 1, under conditions of use A through H of Table 2 in Title 21, CFR Part 176.170 (c).

### 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](mailto: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.

### 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.

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### **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.

### **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.

### **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.

### **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.

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### **Bisphenol A**

No bisphenol A (BPA) is intentionally added or used as an additive or raw material in the manufacture of this product.

### **Alkyphenols and Ethoxylates**

No alkyphenols, 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.

### **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.

### **US Pharmacopoeia**

This product 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**

R05C-00 contains an additive that is not specified in European Pharmacopoeia 3.1.3, "Polyolefins".

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### 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	7/30/08	Revision No.	6
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