

# K50-10-136 Polyethylene Copolymer

## Regulatory Position Statement

### US FDA Compliance

K50-10-136, as manufactured, is in compliance with Title 21, Code of Federal Regulations (CFR) Parts 177.1520 (c)(Item 3.1a) and 178.2010 as promulgated by the US Food and Drug Administration (FDA). It is therefore permitted by 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).

### 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	Y
New Zealand	NZIoC	Y

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

### REACH Appendix 14 Substances of Very High Concern (SVHC)

None of the chemicals listed to date 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.

### 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.

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**INEOS**  
Olefins & Polymers USA



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## Regulatory Position Statement

### **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.

### **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.

### **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).

### **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.

### **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.

### **GMOs – Genetically Modified Organisms**

No GMOs, genetic material from GMOs, materials derived from GMOs, nor any genetically modified ingredients have been used at any time in the manufacture of this product.

### **Ozone Depleting Chemicals (ODCs)**

This product does not contain and is not manufactured with any Class I or Class II ODC and is in compliance with EPA's US Clean Air Act, Title VI.

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## Regulatory Position Statement

### **Phthalates**

Phthalates are not intentionally added or used as additives or raw materials 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**

Organotin compounds are neither contained in, nor 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.

### **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.

### **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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## Regulatory Position Statement

### US Pharmacopoeia

K50-10-136 has not been tested under the criteria specified in the United States Pharmacopoeia for biological testing of materials because it is a raw material and testing must be conducted on the finished product.

### European Pharmacopoeia

K50-10-136, as manufactured, contains an additive that does not appear in the list of additives specified in the European Pharmacopoeia section 3.1.3., “Polyolefins”, therefore this material does not comply with European Pharmacopoeia sections, “Polyethylene with Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations”, or “Plastic Containers and Closures for Pharmaceutical Use”. INEOS has not, at this time, conducted the migration testing specified in the citation because the responsibility for compliance with the Pharmacopoeia rests with the device manufacturer.

### 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 Polyethylene 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	1/30/09	Revision No.	5
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