



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).

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 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.

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.

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. 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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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.

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.

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.

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Organotin Compounds

Organotin compounds are neither contained in, nor added to, the resin or additives and, therefore, would not be present in 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.

Alkylphenols and Ethoxylates

No alkylphenols, 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.

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.

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

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

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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.

Issue Date	8/5/08	Revision No.	3
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