



K44-11-128 Polyethylene Copolymer

Regulatory Position Statement

US FDA Compliance

K44-11-128, 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 permitted by FDA for use in food-contact applications for food types I, II, IV-B, VI-B, VII-B, and VIII, under Conditions of Use B through H, as described in Tables 1 and 2, and with food of types III, IV-A, V, VI-A, VI-C, VII-A, and IX, under Conditions of Use C through G, as described in Tables 1 and 2 in Title 21, CFR Part 176.170 (c).

EU Food Contact Compliance

As dispatched from our plant, INEOS Polyethylene Copolymer Grade K44-11-128 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 amendments 2004/1/EC (06/01/04), 2004/19/EC (01/03/2004), 2005/79/EC (18/11/05), 2007/19/EC (02/04/2007). A monomer subject to restriction (Specific Migration Limit or Quantitative Maximum) is used in manufacturing K44-11-128, however, it is not expected to migrate out the polymer matrix. K44-11-128 contains an additive subject to a Specific Migration Limit (SML) of 5 mg/kg. Modeling simulated for 10 days at 40° C with the partition coefficient of 1 indicates that this additive does not migrate at the level of its 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.

Allergen Content

No known allergens or allergen derivatives such as peanuts, soy/soybeans, milk, eggs, fish, shellfish/crustacea, tree nuts, sulfites or wheat/gluten substances have been added during the formulation, or used as a processing aide in the manufacture of this product.

Animal Derivatives

No animal fats, oils, milk products or other animal- or tallow-derived products are used as components of, or in the manufacture of, this product.

Kosher Certified

This product is Kosher certified.

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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.

Organotin Compounds

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

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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.

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.

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.

Canadian Chemical Management Plan

No 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 for biological testing of materials because it is a raw material and testing must be conducted on the finished product.

European Pharmacopoeia

INEOS Polyethylene Grade K44-11-128, as manufactured, contains an additive that does not appear in the list of additives specified in the European Pharmacopoeia section 3.1.3., "Polyolefins."

Issue Date	4/17/08	Revision No.	6
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