



# B54-25H-127 Polyethylene Copolymer

## Regulatory Position Statement

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### US FDA Compliance

B54-25H-127, as manufactured, is in compliance with Title 21, Code of Federal Regulations (CFR) Parts 177.1520 (c)(Item 3.2a) 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 A through H of Table 2 in Title 21, CFR Part 176.170 (c).

### EU Food Contact Compliance

As dispatched from our plant, B54-25H-127 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 subsequent amendments. A monomer subject to a Specific Migration Limit (SML) of 3 mg/kg is used in manufacturing Polyethylene Copolymer Grade B54-25H-127. No additives subject to an SML or QM are contained in this product. Modeling results simulated at 40° C for 10 days indicate that the monomer does not migrate at a level greater than its SML. As the conversion process can affect migration, only the converter can guarantee to the food packager that the limit is not exceeded.

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### 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

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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 – 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.

### 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.

### 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.

### Latex Content

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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.

### **Organotin Compounds**

Organotin compounds are neither 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.

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**INEOS**  
**Olefins & Polymers USA**



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### 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 B54-25H-127, as manufactured, contains only additives that appear in the list of additives specified in the European Pharmacopoeia 3.1.3., "Polyolefins".

### 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	7/25/08	Revision No.	8
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