



G50-100 Polyethylene Copolymer

Regulatory Position Statement

Regulatory Issues

June 20, 2010

US FDA Compliance

G50-100, 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 the 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).

EU Food Contact Compliance

As dispatched from our plant, G50-100 may not meet 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 this product. G50-100 also contains an additive subject to an SML of 0.6 mg/kg. Modeling results simulated at 40° C for 10 days indicate that this additive migrates to food stuff at a level greater than the SML, while 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.

Drug Master File

Composition information on this product is contained in our US FDA drug master file. A Letter of Authorization is available upon request.

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.

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

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2600 South Shore Boulevard
Suite 500
League City, TX 77573
Tel: 281-535-6600
www.ineos-op.com

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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.

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

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 if you need further information.

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REACH Substances of Very High Concern (SVHC)

None of the chemicals listed to date on REACH 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.

Substances of Concern to Our Customers

Alkylphenols and Ethoxylates

No alkylphenols, ethoxylates or estrogen-mimicking compounds are used in the manufacture of this product.

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.

Animal Derived Material

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.

Asbestos

No asbestos is intentionally added or used as an additive or raw material in the manufacture of this product.

Azo Colorants/Pigments

No azo colorants, or other pigments, are intentionally added or used as additives or raw materials 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.

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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.

California Proposition 65

No substance listed on California's Proposition 65 chemicals listing, known to the State of California to cause cancer or reproductive toxicology, is intentionally added 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.

Decabromodiphenyl ether (Deca)

No decabromodiphenyl ether (Deca) is intentionally added or used as an additive or raw material in the manufacture of this product.

Dimethyl Fumarate (DMF)

No dimethyl fumarate, CAS #624-49-7, is intentionally added or used as an additive or raw material in the manufacture of 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.

Formaldehyde

No formaldehyde is intentionally added or used as an additive or raw material 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.

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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).

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.

Melamine

No melamine is intentionally added or used as an additive or raw material 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.

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.

PFAAs: PFOs (Perfluorooctane sulfonates) and PFOA (Perfluorooctanic acid) EU Directive 2006/122/EC

No perfluorooctanic acid (PFOA) 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.

PCBs

No polychlorinated biphenyl compounds (PCBs) are added to the resin or used as additives or raw material in the manufacture of this product.

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Phthalates are not intentionally added or used as additives or raw materials in the manufacture of this product.

Pharmacopoeias

US Pharmacopoeia

This resin 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

An additive in this product is not on the list of approved additives in the European Pharmacopoeia section 3.1.3., "Polyolefins." It is possible to use components that are not listed in the Pharmacopoeia, as long as the components do not migrate into the content of the medical device at concentrations that are harmful to humans or interact with the content biologically or chemically.

For further information, please see our website www.ineos-op.com or contact Product Stewardship.

Email: julie.clifford@ineos.com

Phone: 281-535-6729

Fax: 281-535-6760

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