



H12Z-00

CAS # 9003-07-0

Regulatory Position Statement

Food Contact Clearances

March 2015

US FDA Compliance (21 CFR 2014)

Under 21 CFR 177.1520(c) 1.1a, this resin may be safely used in articles or components of articles intended for use in contact with food. All adjuvants used in the manufacture of this resin are cleared for use in 21 CFR 170-189 by specific citation, generally recognized as safe (GRAS), prior sanctioned or under a specific Food Contact Notification (FCN). The finished polymers may be safely used in contact with food types I, II, IV-B, VIA, VIB, VII-B and VIII described in Table 1 of 21 CFR 176.170(c), under conditions of use A through H described in Table 2 of 176.170(c) and with food types III, IV-A, V, VI-C, VII-A, and IX under conditions of use B through H.

EU Food Contact Compliance – Commission Regulation (EU) No 10/2011

As dispatched from our plant, the monomers and additives of this INEOS product meet the relevant requirements of Commission Regulation (EU) No 10/2011 as amended under the Framework Regulation EU 1935/2004. Please send an email to Product Stewardship* if you need an EU Declaration of Compliance.

Health Canada, Health Products and Food Branch “No Objection” Letter

A Letter of No Objection (LONO) is not available for this product.

China’s Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials (GB 9685-2008)

As dispatched from our plant, this product meets relevant requirements laid down in GB 9685-2008 and its subsequent amendments. As the conversion process can affect migration, only the converter can guarantee to the food packager that any limit is not exceeded.

MERCOSUR

Please be advised that the monomers and additive(s) used in this product conform to the requirements and listings of MERCOSUR/ GMC/RES N° 02/12 and RES N° 32/07.

Regulations/Directives Applicable to End Use Articles

This product conforms to the substance limits and prohibition requirements of the following:

- **EU Cosmetic Regulation (EC) No 1223/2009**
- **Consumer Product Safety Improvement Act (CPSIA) of 2008/Lead and Phthalates in Toys**
- **EU Safety of Toys EN 71-3:2013**
- **RoHS 2, Directive 2011/65/EU**
- **WEEE EU 2012/19/EU**

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2600 South Shore Boulevard
Suite 500
League City, TX 77573
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U.S. Pharmacopeial Convention (USP)

This resin has not been tested under the criteria specified in the United States Pharmacopoeia, nor that specified by ISO 10993 for biological testing of materials.

European Pharmacopoeia

This product contains an additive that is not specified in European Pharmacopoeia 3.1.3, “Polyolefins”.

CONEG/EU Directive 94/62/EC/Heavy Metals

The regulated metals – lead, mercury, cadmium, and hexavalent chromium – are not intentionally added during the manufacturing process. Testing for heavy metals – cadmium, chromium, lead and mercury - resulted in a total for all metals detected of < 2 ppm, compared to the CONEG requirement of < 100 ppm. The result for incidental lead concentration was less than the detection limit of 0.1 ppm.

Other Regulations/Directives

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 intentionally added in the manufacture of this product.

Canada’s Challenge and Chemical Management Plan

None of the chemicals on either Canada’s *Prohibition of Certain Toxic Substances* list or the Canadian Chemical Management Plan are intentionally added as raw materials to this product.

EU Commission Regulation (EC) No 1895/2005

This Regulation does not apply to our product because it is not manufactured with any of the following substances:

- (a) 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether, hereinafter referred to as ‘BADGE’ (CAS No 001675-54-3), and some of its derivatives;
- (b) bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers, hereinafter referred to as ‘BFDGE’ (CAS No 039817-09-9);
- (c) other novolac glycidyl ethers, hereinafter referred to as ‘NOGE’.

GMP and EU Commission Regulation (EC) No 2023/2006

INEOS O&P USA maintains an ISO 9001 system that corresponds to the requirements of EC No 2023/2006 and addresses good manufacturing practice for materials and articles intended to come into contact with food. US FDA regulations do not specifically address good manufacturing practices (GMP) for food contact materials. A copy of the current certificate is available online at [ISO Certificate.pdf](#).

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REACH

Please refer to our REACH statement online at [REACH SVHCs](#) covering REACH registration issues, CoRAP and SVHCs.

GLOBAL INVENTORY STATUS

Country	Inventory	Y/N	Country	Inventory	Y/N
United States	TSCA	Y	Japan	ENCS (METT) ISHL	N
European Union	ELINCS	Y	New Zealand	NZIoC	Y
China	IECSC	Y	Korea	KECI	Y
Canada	DSL	Y	Philippines	PICCS	N
Australia	AICS	Y	Taiwan	NECI	Y

Drug Master File

Drug Master File(s)

This product is filed with the FDA in INEOS Drug Master File 12-042. A letter of authorization for the FDA to access our file on your behalf is available upon request.

Substances of Concern to Our Customers

Based on knowledge of our raw materials and information from our suppliers, we can state that none of the substances of concern to our customers listed below are intentionally added to this product. We do not conduct routine analytical testing for these substances.

• 3-MCPD (3-monochloropropane)	• Materials banned by Lacey Act of 1900
• Alkyphenols and Ethoxylates	• Latex
• Allergens or allergen derivatives ¹	• Melamine
• Animal Derived Material/TSE/BSE ²	• Nanoparticles
• Antimicrobial agents/Biocides/Fungicides/ Pesticides (<i>Substances identified as such and used for such purpose</i>)	• N-Ethyl-toluenesulfonamide (Ortho/Para)
	• Organotin Compounds

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• Asbestos	• Ozone Depleting Chemicals (ODCs)
• Azo dyes/ Colorants/Pigments	• PAHs (Polycyclic Aromatic Hydrocarbons)
• Azodicarbonamide	• Parabens
• Benzophenones	• PCBs
• Bisphenols A (BPA) or S (BPS)	• Perfluorooctanoic acid, salts and precursors: PFCs, PFAs, PFNs, PFOs and PFOA and PFCAs
• Carboxymethylcellulose	• Phthalates (e.g., BBP, BDP, DBP, DCP, DEHP, DEP, DiDP, DiNP, DMP, DnHP, DnOP, DiHP)
• Conflict Minerals (columbite-tantalite (coltan, niobium, tantalum), cassiterite (tin), gold, and wolframite (tungsten) ³	• Polysorbate 80
• Cocamide diethanolamide	• PVC
• Decabromodiphenyl ether (Deca)	• Radioactive Substances
• Dimethyl Fumarate (DMF)	• Short Chain Chlorinated paraffins (SCCPs)
• Dioxins	• Silicone
• Flame Retardants (Brominated, Phosphorous- or Nitrogen-based, or Chlorinated)	• Solvents, residual solvents
• Formaldehyde	• State Lists
• Genetically Modified Organisms - GMOs	o Washington <i>CHCC</i>
• Halogens (fluorine, chlorine, bromine, iodine, astatine)	o Minnesota <i>Chemicals of High Concern</i>
• HAPs (Hazardous Air Pollutants) Section 112(b) of the US Clean Air Act	• SVHCs (<i>Please refer to our REACH statement online at www.ineos-op.com covering REACH registration issues, CoRAP and SVHCs.</i>)
• Heavy Metals (As, Ba, Cd, Cr, Hg, Pb, Sb, Se)	• Tris (Nonylphenyl) phosphite (TNPP)
• “Intelligent packaging” materials	• Triclosan (2,4,4' -trichloro-2'-hydroxy-diphenyl ether)
• Jatropha Oil	

¹ from such things as pigments, artificial sweeteners (e.g. aspartame), almonds, Brazil nuts, cashews, corn, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts; peanuts, lupine, soy/soybeans, peas, carmine/cochineal, milk, lecithin, eggs, fish, shellfish/crustacea or mollusks, tree nuts, celery, sesame seeds, mustard or mustard seeds, glutamites, glutamic acid, MSG or hydrolyzed vegetable proteins, nitrites or sulfites, or gluten from the grains of the following cereals: barley; oats; rye; triticale; or wheat

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- ² One or more of the additives used in this product may be produced from animal-derived material. We have received from our suppliers a statement that their additives are BSE/TSE-free. The reason(s) given are:
1. The source material is from the US, or
 2. The source material complies with the Animal by Products Directive 1774/2002 and its amendments, or
 3. The raw materials:
 - a. originate from GBR-C1 and C2 countries (e.g. countries with very small risk of BSE), or
 - b. originate from GBR-C3 and C4 countries (e.g. countries with very small BSE risk) and the base products have food or feed quality and the specific risk material was removed and
 4. The material has been processed at a minimum of 200° C at the appropriate pressure for at least 20 minutes following EU (99/534/EC) guidelines.
- ³ INEOS O&P USA (INEOS O&P) is not a publicly traded company so is not subject to the SEC reporting requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

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

As agent for INEOS O&P USA,



*Email: julie.clifford@ineos.com
Phone: 281-535-6729

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. The representations herein expressed are neither intended nor shall be construed as a definitive or comprehensive statement of all constituents sought. 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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