

R12C-01

CAS # 9010-79-1

Regulatory Position Statement

Food Contact Clearances

January 2019

US FDA Compliance (21 CFR 2019)

Under 21 CFR 177.1520(c) 3.1a, this resin may be safely used in articles that contact food except for articles used for packing or holding food during cooking. 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 polymer is limited to Conditions of Use B-H as defined in 21 CFR 176.170(c) Table 2.

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) under File Number KS09073144 is available for this product. Further restrictions may apply. Please contact Product Stewardship for details.

China’s Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials (GB 4806-2016 and GB 9685-2016)

As dispatched from our plant, this product meets relevant requirements laid down in GB 4806-2016 and GB 9685-2016. 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, as amended by 2015/863/EU
- WEEE EU 2012/19/EU

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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. This resin is not intentionally formulated with aluminum, arsenic, cadmium, lead, mercury, cobalt, nickel, chromium, titanium, vanadium, zinc, and/or zirconium. We do not test for ingredients not intentionally added. Please contact us for additive information if needed for USP 661.2 testing.

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 (WHMIS, Toxic Substances and Chemical Management Plan)

None of the chemicals on WHMIS, 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 our products are 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'.

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RECYCLING

The recycling code shown to the right applies to the resin only. It may not apply to products manufactured from this resin. Recycling codes for finished articles must be determined by the manufacturer on a case by case basis.



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

INEOS O&P USA maintains an ISO 9001 system that corresponds to the requirements of FSMA and EC No 2023/2006 and addresses good manufacturing practice for materials 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](#).

REACH

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

GLOBAL INVENTORY STATUS

<i>Country</i>	<i>Inventory</i>	<i>Y/N</i>
United States	TSCA This product has been verified with a status of "active" on the TSCA inventory prior to Feb 7, 2018.	Y
European Union	ELINCS	Y
China	IECSC	Y
Canada	DSL	Y
Australia	AICS	Y

<i>Country</i>	<i>Inventory</i>	<i>Y/N</i>
Japan	ENCS (METI) ISHL	Y
New Zealand	NZIoC	Y
Korea	KECI	Y
Philippines	PICCS	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.

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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 the presence of these substances in our products.

Genetically Modified Organisms (GMO) Because of the multitude of crop sources used, our suppliers of plant-based additives are unable to certify that their products are 100% GMO-free.

• 3-MCPD (3-monochloropropane)	• Melamine
• Alkylphenols and Ethoxylates	• Methylisothiazolinone (MI / MIT) & Methylchloroisothiazolinone (MCI / CMIT)
• Allergens or allergen derivatives ¹	• Microbeads
• 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)
• Asbestos	• Nonylphenol ethoxylates (NPEs)
• Azo dyes/ Colorants/Pigments	• Organotin Compounds
• Azodicarbonamide	• Ozone Depleting Chemicals (ODCs)
• Benzophenones	• PAHs (Polycyclic Aromatic Hydrocarbons)
• Benzoate Preservatives (BHA, TBHQ)	• Parabens and PABA
• Bisphenols (e.g., A, F, S)	• Pentanoic acid
• Carboxymethylcellulose	• Perfluoroalkyl substituted phosphate ester acids
• CITES Appendix (I, II, III)	• Perfluorinated and polyfluorinated compounds, including their acid, salts and precursors such as PFCs, PFAs and PFASs, PFNs, PFOs and PFOA and PFCAs
• Conflict Minerals (columbite-tantalite (coltan, niobium, tantalum), cassiterite (tin), gold, and wolframite (tungsten) ³	• Persistent Organic pollutants (POPs) EU No 757/2010 Annex I amending EC No 850/2004
• Cocamide diethanolamide	• Phthalates ⁴ (e.g., BBP, BDP, DBP, DCP, DCHP, DEHP, DEP, DiBP, DiDP, DiNP, DMP, DnHP, DnOP, DiHP)
	• Photoinitiators (e.g., ITX)

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<ul style="list-style-type: none">Decabromodiphenyl ether (Deca)	<ul style="list-style-type: none">Polysorbate 80
<ul style="list-style-type: none">Diethanolamine salts of mono- and bis-	
<ul style="list-style-type: none">Dimethyl/Methyl Fumarate (DMF)	<ul style="list-style-type: none">Polyhalogenated Organo Compounds (PCBs, PCTs and Ugilec)
<ul style="list-style-type: none">Dioxins	<ul style="list-style-type: none">PVC
<ul style="list-style-type: none">Flame Retardants (e.g. Brominated, Halogenated, Phosphorous- or Nitrogen-based, Chlorinated, etc.)	<ul style="list-style-type: none">Radioactive Substances
	<ul style="list-style-type: none">REACH Annexes XIV and XVII
<ul style="list-style-type: none">Formaldehyde	<ul style="list-style-type: none">Red List (Living Future bldg. materials list)
<ul style="list-style-type: none">Fragrances	<ul style="list-style-type: none">Short Chain Chlorinated paraffins (SCCPs)
<ul style="list-style-type: none">GADSL	<ul style="list-style-type: none">Silica
<ul style="list-style-type: none">Halogens (fluorine, chlorine, bromine, iodine, astatine)	<ul style="list-style-type: none">Silicone
<ul style="list-style-type: none">HAPs (Hazardous Air Pollutants) Section 112(b) of the US Clean Air Act	<ul style="list-style-type: none">Solvents, residual solvents
<ul style="list-style-type: none">Heavy Metals (As, Ba, Cd, Cr, Hg, Pb, Sb, Se)	<ul style="list-style-type: none">State Lists – including Maine, Massachusetts, Minnesota, Vermont, Washington
<ul style="list-style-type: none">International Council for Harmonisation (ICH) Q3D <i>Elemental Impurities</i>	
<ul style="list-style-type: none">“Intelligent packaging” materials	<ul style="list-style-type: none">SVHCs (<i>Please refer to our REACH statement online at www.ineos-op.com covering REACH registration issues, CoRAP and SVHCs.</i>)
<ul style="list-style-type: none">IUCN Red List of Threatened Species	<ul style="list-style-type: none">Triclosan (2,4,4'-trichloro-2'-hydroxy-diphenyl ether)
<ul style="list-style-type: none">Jatropha Oil	
<ul style="list-style-type: none">Latex	
<ul style="list-style-type: none">Materials banned by Lacey Act of 1900	

¹ from such things as pigments, fragrances, 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, diacetyl, 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 No animal-derived products are intentionally used as components of, or in the manufacture of, this product.
- 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.
- ⁴ As with most polypropylene grades, including grades from other producers, this resin may contain trace levels of phthalates. If needed, please contact Product Stewardship for further information.

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: carolyn.ramsden@ineos.com

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