

July 2023

Food Contact Clearances

US FDA Compliance (Title 21 CFR)

Under 21 CFR 177.1520(c) 3.2a, this resin may be safely used in 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.

The Food Types & Conditions of Use for Food Contact Substances as described in 21 CFR 176.170(c) Tables 1 and 2 can be found on FDA's website: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.

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 (GMP) for materials intended to come into contact with food. US FDA regulations do not specifically require food contact material manufacturers to be GMP certified. A copy of the current certificate is available online under Technical Information or by following the link provided here: [ISO Certificate](#).

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

As dispatched from our plant, the monomer(s) and additive(s) of this INEOS intermediate polymer product meet the relevant requirements of Commission Regulation (EU) No 10/2011 as amended under the Framework Regulation EU 1935/2004 on materials and articles intended to come into contact with food. Aids to Polymerization (APs) and Polymer Production Aids (PPAs) are not necessarily listed under the Union List, Annex I of Regulation (EU) 10/2011 and are considered as authorized to be used in plastic packaging for food contact when they are listed in National Regulations or Listings, such as the German BfR or Netherlands Warenwet.

As the conversion process can affect migration, only the converter can guarantee to the food packager that any specific migration limit (SML) or overall migration limit (OML) (less than 10 mg/dm²) is not exceeded. It is the responsibility of the final food contact article manufacturer to determine the technical suitability of this product and the intended use.

Please send an email to your INEOS Sales or Technical Service Representative to request an EU Declaration of Compliance.

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

A Letter of No Objection (LONO) under File Number KS02020703 is available for this product. Based on the information submitted and on the understanding that the temperature conditions for use of the final product does not exceed 48.9 °C (120°F), there is no reason to object, in principle, to the use of the resin in food contact applications, provided it is technically suitable for the intended use.

Additional restrictions may apply. Please contact INEOS for additional information.

Contact us:

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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, the monomer(s) and additive(s) used in manufacture of this INEOS product meet the relevant requirements:

Standard	Subject
GB 31603-2015	National Food Safety Standard - General Hygiene Norm
GB 4806.1-2016	General Safety Requirements on Food Contact Materials and Articles.
GB 4806.6-2016	Plastic Resin used in food-contact.
GB 9685-2016	Standard for Uses of Additives in Food Contact Materials and Their Products.

As the conversion process can affect migration, only the converter can guarantee to the food packager that any limit is not exceeded. Additional restrictions may apply. Please contact INEOS for additional information.

Japan Food Contact Compliance - Positive List of substances

Japanese Ministry of Health, Labor and Welfare (MHLW) published a formal Positive List (PL) System for food-contact materials (FCM) used in the manufacture of food-contact utensils, containers, and packaging (UCP). As dispatched from our plant, the base polymer used in manufacture of this INEOS product is listed in Table 1(1) – Base Polymers (Plastics) and can be used to pack all types of food at temperatures exceeding 100°C (condition III).

The additive(s) used in the manufacture of this INEOS product are listed in the Positive List Table 2 – Additives, Coating Agents, Etc. Additional restrictions may apply. Please contact INEOS for additional information.

MERCOSUR - Argentina, Brazil, Paraguay, Uruguay, and Venezuela

This product complies with the relevant requirements of the Resolution GMC N° 03/92 - General provisions for food contact materials published by MERCOSUR.

As dispatched from our plant, the monomer(s) and additive(s) used in manufacture of this INEOS product meet the relevant requirements:

Standard	Subject
GMC Res. N° 19/2021	Positive List of monomers, other starting substances, and polymers authorized for the manufacture of plastic packaging in contact with food.
GMC Res. N° 39/2019	Positive List of additives for plastic materials intended for packaging in contact with food.

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In order to complete the food contact compliance according to the Resolutions mentioned above, the final article must be tested by the manufacturer to determine the total migration limit (must be less than 50 mg/kg or 8 mg/dm²). Additional restrictions may apply.

As the conversion process can affect migration, only the converter can guarantee to the food packager that any specific migration limit is not exceeded. It is the sole responsibility of the Purchaser of this Product to verify whether the MERCOSUR legislation was incorporated by each member country into their domestic laws.

Halal, Kosher Status

This grade has not received Halal or Kosher certification. However, we can hereby confirm that 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.

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.



Global Inventory Status

Country	Inventory	Status
Australia	Australia Inventory of Industrial Chemicals: AIIC	Y
Canada	Domestic Substances List: DSL	Y
China	Chinese List on New Chemical Substances: IECSC	Y
European Union	European Inventory of Existing Commercial Chemical Substances: EINECS	Y
Japan	Japan Inventory of Existing & New Chemical Substances: METI/ENCS Japan Industrial Safety & Health Law: ISHL	Y Y
Korea	Korea Existing Chemicals Inventory: KECI	Y
New Zealand	New Zealand Inventory of Chemicals: NZIoC	Y
Philippines	Philippines Inventory of Chemicals and Chemical Substances: PICCS	Y
Taiwan	Taiwan Chemical Substance Inventory: TCSI	Y
United States	EPA Toxic Substance Control Act: TSCA – Active Substance List	Y

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Regulations/Directives Applicable to End Use Articles

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

- EU Cosmetic Regulation (EC) No 1223/2009, Annexes II and III
- Consumer Product Safety Improvement Act (CPSIA) of 2008/Lead and Phthalates in Toys
- EU Safety of Toys EN 71-3: 2019
- RoHS 3, Directive 2011/65/EU, as amended by 2015/863/EU
- WEEE EU 2012/19/EU
- End-of-Life (EoL) Vehicles Directive 2000/53/EC

CONEG - “Toxics in Packaging”/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.

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”.

Other Regulations/Directives

California Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1986, as amended

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. It remains the responsibility of the final article’s producer to ensure compliance with California Proposition 65 requirements.

Canada (WHMIS, Toxic Substances and Chemical Management Plan, as amended)

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.

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Other Regulations/Directives

EU Commission Regulation (EC) No 1895/2005, as amended

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'.

Japan

None of the chemicals on CSCL: Class I or II Specified Chemical Substances, ISHA Chemical Substances Prohibited or Requiring Permission for Manufacturing, or Japan Poisonous and Deleterious Substances Control Act are intentionally added as raw materials to this product.

EU REACH

Please refer to our REACH Statement online covering applicable registration, CoRAP, and SVHC under Technical Information or by following the link provided here: [REACH SVHC](#).

Drug Master Files

This product is filed with the FDA in INEOS Drug Master File 12042. A letter of authorization for the FDA to access our file on your behalf is available upon request.

This product is not filed with Health Canada in one of INEOS's Drug Master Files.

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.

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Substance List	
3-MCPD (3-monochloropropane)	Decabromodiphenyl ether (Deca)
Acrylamide	Diethanolamine salts of mono- and bis
Alkyphenols and Ethoxylates: Octylphenol and Nonylphenol ethoxylates	Dimethyl Fumarate (DMF)
Allergens or allergen derivatives ¹	Dioxins and furans
Animal or Human Derived Material/TSE/BSE ²	Endocrine Disruptors ⁴
Antimicrobial agents/ Biocides/ Fungicides/ Pesticides (Substances identified as such and used for such purpose)	Epoxidized Soy Bean Oil (ESBO)
Aromatic amines	Flame Retardants (e.g. Brominated, Halogenated, Phosphorous- or Nitrogen-based, Chlorinated, etc.)
Asbestos	Formaldehyde
Azo dyes/ Colorants/Pigments	Fragrances
Azodicarbonamide or semi-carbazide compounds	GADSL, "Global Automotive Declarable Substance List," as amended, listed as Declarable or Prohibited above 0.1% wt.
Benzophenones, hydroxybenzophenone and 4-methyl benzophenone	Halogens (fluorine, chlorine, bromine, iodine, astatine) or Halogenated Compounds containing these elements
Benzoate Preservatives (BHA, BHT, TBHQ)	HAPs (Hazardous Air Pollutants) Section 112(b) of the US Clean Air Act
Bisphenols (e.g. A, AF, AP, B, BP, C, E, F, FL, G, M, P, PH, S, TMC, Z)	Heavy Metals (As, Ba, Cd, Cr, Hg, Ni, Pb, Sb, Se)
Carboxymethylcellulose	International Council for Harmonisation (ICH) Q3D <i>Elemental Impurities</i>
Chlorinated paraffins (Short Chain (SCCPs), Medium Chain (MCCPs), and Long Chain (LCCPs))	"Intelligent packaging" materials
Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)	IUCN Red List of Threatened Species
CITES Appendix (I, II, III)	Jatropha Oil
Cocamide diethanolamide	Latex
Conflict Minerals: columbite-tantalite, coltan, niobium, tantalum, cassiterite (tin), gold, and wolframite (tungsten) ³	Melamine and cyanuric acid

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Substance List	
Methylisothiazolinone (MI / MIT) & Methylchloroisothiazolinone (MCI / CMIT)	Polysorbate 80
Microbeads	Polybrominated compounds (PBBs, PBDEs, and PBTs)
Mineral Oils - MOAH or MOSH ⁵	Polyhalogenated Organo Compounds (PCBs, PCTs, PCNs, and Ugilec)
Nanoparticles	Primary aromatic amines
N-Ethyl-toluenesulfonamide (Ortho/Para)	Radioactive Substances
Nitrates	REACH Annexes XIV and XVII
Nitrocellulose	Recycled or reused material
Nitrosamines	Red List (Living Future Bldg. Materials List)
Organotin Compounds, such as tributyl tin, trimethyl tin oxide, triphenyl tin, and trialkyl tin	Silica
Ozone Depleting Chemicals (ODCs)	Silicone
PAHs (Polycyclic Aromatic Hydrocarbons)	Styrene
Parabens	Solvents, residual solvents
Pentanoic acid	State Lists – including Maine, Massachusetts, Minnesota, Oregon, Vermont, Washington
Perchlorates	Substances Very High Concern (<i>Please refer to our REACH statement online at www.ineos-op.com</i>)
Perfluoroalkyl substituted phosphate ester acids	Thiuram mix
Per- and Polyfluorinated compounds (PFAS), including their acid, salts and pre-cursors such as PFCs, PFAs and PFASs, PFNs, PFOs and PFOA and PFCAs ⁶	Triclosan (2,4,4' –trichloro-2'-hydroxy-diphenyl ether)
Persistent Organic Pollutants (POPs) as listed in Regulation (EU) 2019/1021 Annex I-IV, including all amendments up to (EU) 2021/277, amending EC No 850/2004 & Annexes A, B, & C of Stockholm Convention	Tris (Nonylphenyl) phosphite (TNPP)
Phthalates (e.g., BBP, BDP, DBP, DCP, DEHP, DEP, DiBP, DiDP, DiNP, DMP, DnHP, DnOP, DiiHP) ⁷	Vinyl chloride monomer (VCM) and its polymers or copolymers (PVC, PVDC)
Photoinitiators (e.g., ITX)	

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1. from such things as pigments, fragrances, artificial sweeteners (e.g. aspartame), corn, tree nuts (e.g. almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts); peanuts, lupins, soy/soybeans, peas, carmine/cochineal, milk, lecithin, eggs, fish (e.g. bass, flounder, cod), crustacea shellfish (e.g. crab, lobster, or shrimp), mollusks, celery, sesame or sesame seeds, mustard or mustard seeds, diacetyl, glutamites, glutamic acid, sulphur dioxide, MSG or hydrolyzed vegetable proteins, nitrites or sulfites, or gluten from the grains of the following cereals: barley; oats; rye; triticale; or wheat.
2. 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.
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. None of the substances intentionally used in the manufacture of this grade are listed as having Endocrine Disrupting properties under Lists I, II and III of Endocrine Disruptors List on <https://edlists.org/the-ed-lists> and under the Candidate List of substances of very high concern for Authorisation as published under REACH Regulation (EC) 1907/2006.
5. Mineral Oils are not intentionally used as raw materials or additives in the manufacture of this grade. MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons) are not intentionally added as raw materials or additives. MOAH are not expected to be present. However, we cannot confirm the absence of MOSH as they represent a chromatographic fraction of hydrocarbons which could come from other sources, including but not exclusively oligomers, also known as POSH (Polyolefin Oligomeric Saturated Hydrocarbons). POSH are an intrinsic part of polyolefins and the result of the polymerization process. They can present hydrocarbon fractions similar to MOSH depending on the analytical technique used. It has been demonstrated that consumer exposure to oligomers from polyolefins food packaging under typical conditions of use is not a safety concern to human health.
6. PFAS as defined by OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris.
7. As with most polypropylene grades, including grades from other producers, this resin may contain trace levels of phthalates. If needed, please contact INEOS for further information.

For further information, please visit our website www.ineos-op.com.

As agent for INEOS O&P USA,



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