



# K38-20-188

CAS# 25213-02-9

## Regulatory Position Statement

Regulatory Issues

July 2019

### International Standards

For information relating to compliance with NSF International or CSA International standards, please visit the corresponding website(s) at [www.nsf.org](http://www.nsf.org) or [www.csagroup.org](http://www.csagroup.org), or contact INEOS Technical Services at 1-800-338-0489.

### US FDA Food Contact Clearance

This product is not suitable for use in food contact products.

### 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**
- **RoHS 2, Directive 2011/65/EU, as amended by 2015/863/EU**
- **WEEE EU 2012/19/EU**

### 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, 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.

#### Canada's Challenge and Chemical Management Plan, as amended

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.

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

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 ISO certificate is available online at [ISO Certificate](#) under Technical Information.

## 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	EINECS	Y
China	IECSC	Y
Canada	DSL	Y
Australia	AICS	Y

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

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### Substances of Concern to Our Customers

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None of the raw materials used in the manufacturing of our product are identified as any of the substances of concern to our customers as listed below. Our raw material suppliers are asked to indicate whether any of these substances are components of their supplied materials, but we do not conduct routine analytical testing on our product for any of these substances.

- 3-MCPD (3-monochloropropane)
- Alkylphenols and Ethoxylates
- Allergens or allergen derivatives<sup>1</sup>
- Animal Derived Material/TSE/BSE<sup>2</sup>
- Antimicrobial agents/Biocides/Fungicides/Pesticides (*Substances identified as such and used for such purpose*)
- Asbestos
- Azo dyes/ Colorants/Pigments
- Azodicarbonamide
- Benzophenones
- Benzoate Preservatives (BHA, TBHQ)
- Bisphenols (e.g., A, F, S)
- Carboxymethylcellulose
- CITES Appendix (I, II, III)
- Conflict Minerals (columbite-tantalite (coltan, niobium, tantalum), cassiterite (tin), gold, and wolframite (tungsten)<sup>3</sup>)
- Cocamide diethanolamide
- Decabromodiphenyl ether (Deca)
- Diethanolamine salts of mono- and bis-
- Dimethyl Fumarate (DMF)
- Dioxins
- Flame Retardants (e.g. Brominated, Halogenated, Phosphorous- or Nitrogen-based, Chlorinated, etc.)
- Formaldehyde
- Fragrances
- GADSL, “Global Automotive Declarable Substance List,” as amended
- Halogens (fluorine, chlorine, bromine, iodine, astatine)
- HAPs (Hazardous Air Pollutants) Section 112(b) of the US Clean Air Act
- Heavy Metals (As, Ba, Cd, Cr, Hg, Pb, Sb, Se)
- International Council for Harmonisation (ICH) Q3D *Elemental Impurities*
- “Intelligent packaging” materials
- IUCN Red List of Threatened Species
- Jatropha Oil
- Latex
- Materials banned by Lacey Act of 1900
- Melamine and cyanuric acid

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- Methylisothiazolinone (MI / MIT) & Methylchloroisothiazolinone (MCI / CMIT)
- Microbeads
- Nanoparticles
- N-Ethyl-toluenesulfonamide (Ortho/Para)
- Nonylphenol ethoxylates (NPEs)
- Organotin Compounds
- Ozone Depleting Chemicals (ODCs)
- PAHs (Polycyclic Aromatic Hydrocarbons)
- Parabens
- Pentanoic acid
- Perfluoroalkyl substituted phosphate ester acids
- Perfluorinated and polyfluorinated compounds, including their acid, salts and pre-cursors such as PFCs, PFAs and PFASs, PFNs, PFOs and PFOA and PFCAs
- Persistent Organic pollutants (POPs)  
EU No 757/2010 Annex I amending EC No 850/2004
- Phthalates (e.g., BBP, BDP, DBP, DCP, DEHP, DEP, DiBP, DiDP, DiNP, DMP, DnHP, DnOP, DiHP)
- Photoinitiators (e.g., ITX)
- Polysorbate 80
- Polybrominated compounds (PBBs, PBDEs, and PBTs)
- Polyhalogenated Organo Compounds (PCBs, PCTs, PCNs, and Ugilec)
- PVC
- Radioactive Substances
- REACH Annexes XIV and XVII
- Recycled or reused material
- Red List (Living Future Bldg. Materials List)
- Short Chain Chlorinated paraffins (SCCPs)
- Silica
- Silicone
- Solvents, residual solvents
- State Lists – including Maine, Massachusetts, Minnesota, Vermont, Washington
- SVHCs (*Please refer to our REACH statement online at [www.ineos-op.com](http://www.ineos-op.com) covering REACH registration issues, CoRAP and SVHCs.*)
- Triclosan (2,4,4' –trichloro-2'-hydroxy-diphenyl ether)
- Tris (Nonylphenyl) phosphite (TNPP)

<sup>1</sup> 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, 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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<sup>2</sup> No animal fats, oils, milk products or other animal- or tallow-derived products are intentionally used as components of, or in the manufacture of, this product.

<sup>3</sup> 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.

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For further information, please see our website [www.ineos.com](http://www.ineos.com) or contact me in Product Stewardship:

As agent for INEOS O&P USA,



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