

Regulatory Position Statement

INEOS O&P USA RESPONDS TO PRODUCT STEWARDSHIPS REQUESTS WITH A STANDARDIZED REGULATORY POSITION STATEMENT (RPS) WHICH SUMMARIZES THE GLOBAL REGULATORY STATUS OF THE ABOVE-MENTIONED PRODUCT. PLEASE NOTE THAT COMPLIANCE WITH THESE REGULATIONS SHOULD NOT BE INTERPRETED TO GUARANTEE THAT THE PRODUCT, WILL, IN FACT, PERFORM IN A PARTICULAR APPLICATION. YOUR TECHNICAL SERVICE REPRESENTATIVE CAN HELP YOU DETERMINE THAT THE CHARACTERISTICS OF THE PRODUCT ARE COMPATIBLE WITH THE DESIRED CONDITIONS OF USE.

Global Food Contact Regulations

Regarding the compliance status of the product referenced above with the regulation(s) identified below the following can be declared, as applicable to plastic intermediate materials:

United States FDA Compliance -Title 21 Code of Federal Regulations (CFR)

The base resin in this product meets the FDA specifications under 21 CFR 177.1520(c) (olefin polymers), item 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). No further restrictions apply to the finished polymer.

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.

GMP, FSMA, and EU Commission Reg. (EU) No 2023/2006

INEOS O&P USA maintains an ISO 9001:2015 quality management 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.

This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP) and as amended, applicable to intermediate materials (e.g., plastic powders, plastic granules, or plastic flakes).

A copy of the current certificate is available online by following the link provided here: ISO CERTIFICATE

European Union - Commission Reg. (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 plastic 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.

Contact us:

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Regulatory Position Statement

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 KS21100101 is available for this product. Based on the information submitted for general food packaging applications intended for direct contact with all types of food under conditions of use which range from boiling water sterilized 100°C (212°F) to frozen or refrigerated storage: ready prepared foods intended to be reheated in container at time of use, there is no reason to object, in principle, provided it is technically suitable for the intended use.

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

China's Hygienic Standards for Uses of Additives in Food Containers and Packaging

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 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.

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Regulatory Position Statement

South America - MERCOSUR Resolutions

This product complies with the relevant requirements of the Resolution GMC No 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. Nº 19/2021	Positive List of monomers, other starting substances, and polymers authorized for the manufacture of plastic packaging in contact with food.
GMC Res. Nº 39/2019	Positive List of additives for plastic materials intended for packaging in contact with food.

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.

Please contact INEOS O&P USA if you require any additional information.

It remains the responsibility of the food producer to determine the suitability of the product for the end use and to ensure the legal and regulatory compliance of the product as incorporated into foods. It remains the responsibility of the manufacturer of the material/article which in its finished state is intended for food contact applications to determine the suitability of the product for the end use and to ensure the legal and regulatory compliance of the product as incorporated in the material/article intended for food contact applications, including SMLs, QM and other restrictions/limits under the applicable law/regulations.

Halal, Kosher Status

This grade has not received Halal or Kosher certification. However, we can hereby confirm that no ethanol, 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.

Allergens

None of the substances listed as causing allergies or intolerances in the following legislations or standards are intentionally added to this grade or expected to be present:

Annex II of Regulation (EU) 1169/2011

China food safety standard GB 7718-2011

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www.ineos-op.com



Regulatory Position Statement

- Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA)
- Brazil Anvisa RDC 727/2022

Allergens and/or their derivatives 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), molluscs, celery, sesame or sesame seeds, mustard or mustard seeds, diacetyl, glutamites, glutamic acid, sulphur dioxide, MSG or hydrolysed vegetable proteins, nitrites or sulphites, or gluten from the grains of the following cereals: barley; oats; rye; triticale; or wheat.

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.

Global Inventory Status

The base polymer of this product is a Polyethylene Copolymer with CAS number 25213-02-9. For information on the components of our product and their concentration, please refer to the Safety Data Sheet (SDS) and the Technical Data Sheet (TDS). Any hazardous constituents above regulatory disclosure cut-off limits determined according to their regional and/or specific GHS classification(s) will appear in the ingredients section of the SDS.

Country	Inventory	Status
United States of America	EPA Toxic Substance Control Act: TSCA – Active Substance List	Υ
Canada	Domestic Substances List: DSL or Non-Domestic Substance List: NDSL	Υ
Australia	Australian Inventory of Industrial Chemicals: AIIC	Υ
European Union	European Inventory of Existing Commercial Chemical Substances: EINECS	Υ
Japan	Japan Inventory of Existing & New Chemical Substances: METI/ENCS	Υ
South Korea	Korea Existing Chemicals Inventory: KECI	Υ
China	Chinese List on New Chemical Substances: IECSC	Υ
Philippines	Philippines Inventory of Chemicals and Chemical Substances: PICCS	Υ
New Zealand	New Zealand Inventory of Chemicals: NZIoC	Υ
Taiwan	Taiwan Chemical Substance Inventory: TCSI	Υ

EU REACH

Please refer to our INEOS REACH Statement online covering applicable REACH registration under Technical Information or by following the link provided here: <u>INEOS REACH Statement</u>.

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www.ineos-op.com

Page 4 of 11 Revision date: January 2024



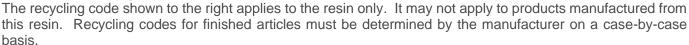
Regulatory Position Statement

This grade is compliant with CLP Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, as amended. A Safety Data Sheet can be downloaded here: Product SDS.

On January 23, 2024, the European Chemicals Agency (ECHA) added five new substances to the Candidate List of Substances for eventual inclusion on the Annex XIV List of Substances subject to Authorisation; bringing the total number of Substances of Very High Concern (SVHC) on the List to 240. The full Candidate List of SVHC for Authorisation can be found here: SVHC List.

This product is not manufactured or formulated with any of the Annex XIV substances on the Authorisation list that would require reporting, if present above the 0.1% threshold, as stated in REACH (Article 57, Reg. No. 1907/2006).

Recycling





Drug Master Files

This product is filed with the FDA in INEOS Drug Master File 1362. A letter of authorization for the FDA to access our file on your behalf is available upon request.

This product is filed with Health Canada in INEOS Drug Master File 2007-157. A letter of authorization for Health Canada to access our file on your behalf is available upon request.

Regulations Applicable to End-Use Articles

Medical

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 aluminium, 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

All additives in this product are listed as approved in European Pharmacopoeia 3.1.3, "Polyolefins".

International Chemical for Harmonization (ICH) Q3D Guideline (Elemental Impurities)

The elemental impurities of Class 1, 2, 3 listed in the ICH Harmonized Guideline Q3D of 24 September 2022 are not intentionally used in the manufacture or formulation of this product. However, this product has not been tested for the presence of these substances.

Contact us:

Customer Service: 1-800-527-5419 Technical Service: 1-800-338-0489

www.ineos-op.com

Page 5 of 11 Revision date: January 2024



Regulatory Position Statement

Medical Device Regulation (MDR) (EU) 2017/745

This product has not been tested under the criteria specified in the EU MDR 2017/745 Regulation, because testing must be conducted on the finished product. This polymer does not intentionally add substances listed on EU MDR 2017/745 Annex I, Chapter II, paragraphs 10.4.1 in concentrations above 0.1% weight.

Cosmetics

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, applies to cosmetics products and their ingredients as defined by the Article 1 of this regulation.

This polymer does not intentionally add substances listed in in Annex II or III of the Cosmetics Regulation 1223/2009, as amended up to Regulation 2019/1966, which may be present at levels above 10 ppm.

Safety of Toys

Directive 2009/48/EC on the safety of toys, as amended to Commission directive (EU) 2019/1922, includes safety requirements the toys need to comply with to be placed on the market and not specifically to intermediate plastic materials.

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

- Consumer Product Safety Improvement Act (CPSIA) of 2008/Lead and Phthalates in Toys
- EU Safety of Toys EN 71-3: 2019+A1:2021

Other Regulations

This product is in compliance with the relevant requirements of the following regulations:

BADGE/NOGE - 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:

- 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;
- bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers, hereinafter referred to as 'BFDGE' (CAS No 039817-09-9);
- other novolac glycidyl ethers, hereinafter referred to as 'NOGE'.

CA Prop 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 and reporting according to California Proposition 65 requirements.

Contact us:

Customer Service: 1-800-527-5419 Technical Service: 1-800-338-0489

www.ineos-op.com

Page 6 of 11 Revision date: January 2024



Regulatory Position Statement

Canadian Environmental Protection Act (CEPA, 1999)

The List of Toxic Substances in Schedule 1 of the Canadian Environmental Protection Act, 1999 (CEPA) includes substances that are considered to be toxic as defined in Section 64 of the Act. 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.

Japan Chemical Substance Control Law (CSCL)

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.

Microplastics - Commission Regulation (EU) 2023/2055

INEOS intermediate plastic raw materials are supplied in the form of pellets or powder and fall under the definition of synthetic polymer microparticles. However, according to point 4. (a) of this Restriction, this shall not apply to the placing on the market of synthetic polymer microparticles, as substances on their own or in mixtures, for use at industrial sites. In this respect, we consider that synthetic polymer microparticles are no more present in this grade as dispatched from our plant.

Metals

US CONEG – "Toxics in Packaging Clearinghouse"

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.

EU Packaging and Packaging Waste

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste ("Packaging and Packaging Waste Directive"), as amended up to Commission Directive 2018/852 of 30 May 2018.

Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended, including Commission Delegated Directive (EU) 2015/863 of 31 March 2015 also known as RoHS 3.

Contact us:

Customer Service: 1-800-527-5419 Technical Service: 1-800-338-0489

www.ineos-op.com

Page 7 of 11 Revision date: January 2024



Regulatory Position Statement

Nanomaterials

This intermediate plastic raw material as supplied as well as all substances used in its manufacture do not fall under the definition of "nanomaterial" as provided in the Commission Recommendation on the definition of nanomaterial 2022/C 229/01 (updating Commission Recommendation 2011/696/EU).

Waste

Waste Electrical and Electronic Equipment (WEEE)

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment, as amended.

End of Life Vehicles

Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles, as amended.

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 in the table below are intentionally added to this product.

We do not conduct routine analytical testing for the presence of these substances in our products and we cannot guarantee that there are no trace amounts of these substances, as impurity or otherwise, in this product.

Absence of Substances and Chemicals	
■ 1,4-Dioxane	 Asbestos
3-MCPD (3-monochloropropane)	 Azo dyes/ Colorants/Pigments
 Acrylamide 	Azodicarbonamide or semi-carbazide compounds
 Alkyphenols and Ethoxylates: Octylphenol and Nonylphenol ethoxylates 	 Benzophenones, hydroxybenzophenone and 4-methyl benzophenone
 Allergens or allergen derivatives 	 Benzoate Preservatives (e.g., BHA, BHT, TBHQ)
 Animal or Human Derived Material/TSE/BSE¹ 	Bisphenols (e.g., A, AF, AP, B, BP, C, E, F, FL, G, M, P, PH, S, TMC, Z)
 Antimicrobial agents/ Biocides/ Fungicides/ Pesticides (Substances identified as such and used for such purpose)² 	Bromine or Bromine Compounds
 Aromatic Amines 	 Carboxymethylcellulose

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www.ineos-op.com



Regulatory Position Statement

Absence of Substances and Chemicals				
 Chlorinated paraffins (Short Chain (SCCPs), Medium Chain (MCCPs), and Long Chain (LCCPs)) 	Heavy Metals (e.g., As, Ba, Cd, Cr, Hg, Ni, Pb, Sb, Se)			
Chlorine or Chlorinated Compounds	 International Council for Harmonisation (ICH) Q3D Elemental Impurities 			
 Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC) 	"Intelligent packaging" materials			
CITES Appendix (I, II, III)	 IUCN Red List of Threatened Species 			
Cobalt or Cobalt Compounds	 Jatropha Oil 			
Cocamide diethanolamide	 Latex or Natural Rubber 			
 Conflict Minerals: columbite-tantalite, coltan, niobium, tantalum, cassiterite (tin), gold, and wolframite (tungsten)³ 	Melamine and cyanuric acid			
 Decabromodiphenyl ether (Deca) 	 Methylisothiazolinone (MI / MIT) & Methylchloroisothiazolinone (MCI / CMIT) 			
 Diethanolamine salts of mono- and bis 	Microbeads			
 Dimethyl Fumarate (DMF) 	 Mineral Oils – MOAH or MOSH⁴ 			
 Dioxins and furans 	 Nanoparticles 			
■ Endocrine Disruptors ⁵	 N-Ethyl-toluenesulfonamide (Ortho/Para) 			
■ Epoxidized Soybean Oil (ESBO)	Nickel or Nickel compounds			
 Flame Retardants (e.g., Brominated, Halogenated, Phosphorous- or Nitrogen-based, Chlorinated, etc.) 	Nitrates			
 Formaldehyde 	 Nitrocellulose 			
Fragrances	 Nitrosamines 			
 GADSL, "Global Automotive Declarable Substance List," as amended, listed as Declarable or Prohibited above 0.1% wt. 	 Organotin Compounds, such as tributyl tin, trimethyl tin oxide, triphenyl tin, and trialkyl tin 			
 Halogens (e.g., fluorine, chlorine, bromine, iodine, astatine) or Halogenated Compounds containing these elements 	 Ozone Depleting Chemicals (ODCs)⁶ 			
 Hazardous Air Pollutants (HAPs) Section 112(b) of the US Clean Air Act 	Polycyclic Aromatic Hydrocarbons (PAHs)			

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Customer Service: 1-800-527-5419 Technical Service: 1-800-338-0489

www.ineos-op.com

Page 9 of 11 Revision date: January 2024



Regulatory Position Statement

(Living Future Bldg. Materials List)
ive Substances
Annexes XIV and XVII
ts (e.g., Chemicals of Concern, including Maine, usetts, Minnesota, Oregon, Vermont, Washington)
Mix
Acetyl Acetonate (TAA)
(2,4,4' -trichloro-2'-hydroxy-diphenyl ether)
nylphenyl) phosphite (TNPP)
oride monomer (VCM) and its polymers or copolymers /DC)
chlo

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Page 10 of 11 Revision date: January 2024



Regulatory Position Statement

Classification and Labelling Information

Classification and labelling information according to latest legislation requirements can be found in the Safety Data Sheets (SDS) for relevant product / country combinations and can be found here: Product SDS

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

As agent for INEOS O&P USA,

Carolyn Panader

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.

Contact us:

Customer Service: 1-800-527-5419 Technical Service: 1-800-338-0489

> Page 11 of 11 Revision date: January 2024

¹ 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.

² Biocidal Products (as defined in art.3 of Regulation (EU) No 528/2012 of 22 May 2012 as amended, specifically as any substance or mixture, in the form in which it is supplied to the user, consisting of, containing, or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action") are not used in the manufacture of or formulation of this product. The above product is not listed in the Annex "Active Substances Approved for Use in Plant Protection Products (i.e., fungicides, insecticides, plant growth regulators, rooting hormones, preserving plant products, herbicides, weed killers …) of the Commission Regulation No 540/2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances - Amendments - Commission implementing Regulation (EU) 2018/1915 of 6 December 2018.

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 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.

⁵ 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.

⁶ Materials listed in the Clean Air Act Amendments of 1990 (Class I, CFCs and Class II, HCFCs, Halons and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) and ozone-depleting substances (ODS), listed in the Annexes I & II of the Regulation (EC) No 1005/2009 of 16 September 2009, are not intentionally used in the production of this product.

⁷ 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.