

## **EUROPEAN REGULATORY INFORMATION SHEET**

## RAMAPET N1(S), N180, R1, R180(S), R180, R182(C), R182(C)PlantPET, P184, S184, W176, L1 and AH62

Aflatoxins and Ochratoxin A	In regards to EU Regulation 1881/2006/EC (on contaminants in foodstuffs)
EU Regulation 1881/2006/EC	and amendments, IVL Europe does not analyze for the presence of aflatoxins and ochratoxin A. However, based on our knowledge of the raw materials and manufacturing process, we have no reason to expect that materials that produce aflatoxins and ochratoxin A were used in this product or that this product would have contacted materials that produce aflatoxins.
Alkyl phenols	The long-chain alkyl phenols are used extensively as precursors to the detergents, as additives for fuels and lubricants, polymers, and as components in phenolic resins. These compounds are also used as building block chemicals that are also used in making fragrances, thermoplastic elastomers, antioxidants, oil field chemicals and fire retardant materials.
	Although we have not specifically analyzed RAMAPET polymers for the presence of alkyl phenols, it is our believe based on our current knowledge of the raw materials and processes used in the manufacture of PET, that we have no reason to expect that these compounds are present in the above products.
Amines	IVL Europe does not analyze its products for primary aromatic amines. However, primary aromatic amines are not used as a raw material, nor are they added to the manufacturing process or the end product. Further, we do not expect these amines to be formed during manufacturing or under normal handling, storage and use conditions. Therefore, we have no reason to expect that primary aromatic amines are present.
Biocides EU Regulation 528/2012	IVL Europe does not analyze its products for biocides. However, biocides as listed in EU Regulation 528/2012 (Biocides Regulation), and amendments, are not used as a raw material, nor are they added to the manufacturing process or the end product. Therefore, we have no reason to expect that these substances would be present.
CMRs and skin sensitizers EU Regulation 1272/2008	IVL Europe does not analyze its products for the carcinogens, mutagens, reproductive toxins (CMRs) or skin sensitizers that are classified as such by the EU Regulation 1272/2008. However, these substances are not added to the manufacturing process or the end product and we do not expect that these substances will be formed during manufacturing or under normal handling, storage and use conditions of our product. We have no reason to expect that these substances would be present.
Colourants Resolution AP 89(1) German BfR Recommendation IX	The composition of the colorant system used in this product is proprietary. The colorant system complies with the purity and migration requirements of the Council of Europe Resolution AP (89) 1 (on the use of colourants in plastic materials coming into contact with food) and the German BfR Recommendation IX (Farbmittel zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände). In migration experiments on articles made from a polyester representative of this product, the colorants were not detected in the food simulants using an analytical method with a limit of

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Cosmetic Regulation Fragrances EU Regulation 1223/2009	Annex 2 in the Cosmetic Regulation EU 1223/2009 refers to components used in cosmetics. Antimony and its compounds are on this Annex 2 list. PET contains Antimony at such level that migration is not a problem for food contact. Sb2O3 is on the positive list of EU 10/2011 for articles in direct contact with food and migration tests should confirm that migration does not exceed the SML. The Cosmetic Regulation EU 1223/2009 does not specify migration limits. IVL Europe does not analyze its products for fragrances. Fragrances as described in EU 1223/2009 are not used as a raw material, nor are they added to the manufacturing process or the end product. We have no reason to expect that fragrances would be present in PET.
Bis(2-ethylhexyl)phthalate (DEHP, DOP)	Although we have not specifically analyzed RAMAPET polymers for the presence of DEHP, it is our believe based on our current knowledge of the raw materials and processes used in the manufacture of PET, that we have no reason to expect that compounds stated are present.
Dimethylformamide (DMF) and Dimethyl fumarate	Although we have not specifically analyzed RAMAPET polymers for the presence of DMF (Dimethylformamide) and dimethyl fumarate, it is our believe based on our current knowledge of the raw materials and processes used in the manufacture of PET, that we have no reason to expect that compounds stated are present.
Emulsifiers EU Directive 2003/53/EC	In regards to Directive 2003/53/EC (restricting nonylphenol and nonylphenol ethoxylates), amending Directive 76/769/EEC, IVL Europe does not analyze this product for nonylphenol and nonylphenol ethoxylates. Emulsifiers are not used as a raw material, nor are they added to the manufacturing process or the end product. Therefore, we have no reason to expect that these substances are present.
Epoxides EU Directive 2005/1895/EC	IVL Europe does not analyze its products for the following epoxy substances: Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE); 2,2-bis(4- hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE); Novolac glycidyl ethers (NOGE); Bisphenol-A; Bisphenol-F. However, these substances are not used as a raw material, nor are they added to the manufacturing process or the end product. This product complies with EU Regulation 2005/1895/EC (on epoxy derivatives in materials and articles intended to come into contact with food), and amendments, which replaced EU Directive 2002/16/EC.
Fatty Acids	IVL Europe does not analyze its products for fatty acids. Fatty acids are not used as a raw material, nor are they added to the manufacturing process. We have no reason to expect that fatty acids would be present.
Flavourings EU Regulation 1334/2008/EC	Based on our knowledge of the raw materials and manufacturing process, this product does not contain flavouring ingredients as described in EU Regulation 1334/2008/EC ( <b>o</b> n flavourings and certain food ingredients with flavouring properties for use in and on foods), and amendments. We have no reason to expect that these substances are present.
Genetically modified organism (GMO) EU Directive 2001/18/EC EU Regulation 1829/2003 EU Regulation 1830/2003	Based on our knowledge of the raw materials or based on supplier information, this product is considered not genetically modified or not derived from a genetically modified organism as defined by EU Directive 2001/18/EC (deliberate release into the environment of genetically modified organisms), and amendments, EU Regulation 1829/2003 (on genetically modified food and feed) and 1830/2003 (on labeling and traceability of genetically modified organisms), and amendments.



ISO 9001	Article 4 of regulation 2023/2006/EC states: "Conformity with good
EU Regulation 2023/2006/EC	manufacturing practice. The business operator shall ensure that manufacturing operations are carried out in accordance with the general rules on ISO 9001 as provided for in Article 5, 6, and 7." Article 5 refers to the Quality Assurance System, Article 6 refers to Quality Control System and Article 7 Documentation. These provisions are accounted for in the ISO 9001 Quality Management System of which the manufacturing sites Indorama Ventures Europe, Indorama Ventures Poland and Orion Global PET, Indorama Ventures Química are certified.
Heavy Metals	This statement covers the following heavy metals (or their compounds):
EU Directive 2006/1907/EC	- Arsenic (As)
EU Directive 2009/48/EC	- Barium (Ba)
EU Directive 94/62/EC	- Cadmium (Cd)
EU Directive 2000/53/EC	- Copper (Cu)
EU Directive 2010/75/EC	- Hexavalent chromium (Cr (6+))
CEN EN 71, Part 3	- Lead (Pb)
US CSG (CONEG)	- Mercury (Hg)
	- Nickel (Ni)
	- Selenium (Se)
	- Strontium (Sr)
	- Thallium (TI)
	- Vanadium (V)
	For the listed heavy metals, this product complies with the heavy metal content limits of the following regulations:
	- EU Directive 2006/1907/EC relating to restrictions on the marketing and use of certain dangerous substances and preparations, and amendments;
	- EU Directive 2009/48/EC concerning the safety of toys, and amendments;
	- EU Directive 94/62/EC on packaging and packaging waste, and amendments. Based on our knowledge of the raw materials and manufacturing process, no Cadmium (Cd), Hexavalent chromium (Cr (6+)), Lead (Pb), Mercury (Hg) are intentionally added to RAMAPET. According to data from analysis of a representative sample, the sum of any heavy metals do not exceed limit of 100 ppm.
	- EU Directive 2000/53/EC on end-of life vehicles, and amendments;
	- European Standard CEN EN 71, Safety of Toys - Part 3: Migration of certain elements;
	- US CONEG (or TPCH or CSG) Model Toxics in Packaging Legislation.
	Antimony (Sb), may be used in the manufacture of this product and may be present a level around 300 ppm.
	The presence of these metals may have consequences for compliance with the EU Directive 2010/75/EC (on the incineration of waste). As laid down in Annex II of this directive, limits for air emissions and discharge of waste water must be observed.



Heavy Metals - RoHS	EU Directive 2011/65/EC (on the restrictions of the use of certain hazardous
EU Directive 2011/65/EU COMMISSION DELEGATED DIRECTIVE (EU) 2015/863	substances in electrical and electronic equipment - RoHS) states that "Member States shall ensure that from 1 July 2006 new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)".
	COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances. Additions: bis(2- ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP).
	To our knowledge, these substances listed are not used as raw materials in this product, nor are they added during the production process or the end product. Although we do not routinely analyze our product for these substances, we have no reason to expect that they are present.
Heavy Metals - WEEE EU Directive 2012/19/EC	The purpose of EU Directive 2012/19/EC (on waste electrical and electronic equipment - WEEE), as a first priority, is the prevention of waste electrical and electronic equipment. In addition, it addresses the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste. It also seeks to improve the environmental performance of all operators involved in the life cycle of electrical and electronic equipment, e.g. producers, distributors and consumers, and in particular those operators directly involved in the treatment of waste electrical and electronic equipment. We have no reason to expect that the products as marketed by Indorama would contain substances that will obstruct the reuse, recycling or other forms of recovery of the waste of electrical and electronic waste.
Ozone Depleting Substances	IVL Europe does not analyze its products for ozone depleting substances
EU Directive 2002/215/EC	(ODS) that are classified as such by the following: EU Council Decision 2002/215/EC concerning the conclusion of the Fourth Amendment to the
EU Regulation 1005/2009	Montreal Protocol on substances that deplete the ozone layer; EU Regulation 1005/2009 on substances that deplete the ozone layer, and amendments. Based on our knowledge of the raw materials and our manufacturing process, we do not expect the listed substances to be present in our products.
Organotin Compounds	IVL Europe does not analyze its products for organotin compounds. However, these substances are not used as a raw material, nor are they added to the manufacturing process or the end product. We have no reason to expect that organotin compounds are present in our products.
Parabens	Parabens are a class of chemicals widely used as preservatives in the cosmetic and pharmaceutical industries. Parabens are effective preservatives in many types of formulas. These compounds, and their salts, are used primarily for their bactericidal and fungicidal properties. They can be found in shampoos, commercial moisturizers, shaving gels, personal lubricants, topical/parenteral pharmaceuticals, spray tanning solution, makeup and toothpaste. They are also used as food additives. IVL Europe does not analyze its products for Parabens. However, these substances are not used as a raw material, nor are they added to the manufacturing process or the end product. We have no reason to expect that Parabens are present in our products.



Polivinyl chloride (PVC) and Polivinylidene chloride (PVDC) Chlorinated Plastics	IVL Europe does not analyze its products for Chlorinated Plastics, (PVC, and PVDC). However, these substances are not used as a raw material, nor are they added to the manufacturing process or the end product. Further, we do not expect that these substances will be formed during manufacturing or under normal handling, storage and use conditions. We have no reason to expect that these substances would be present.
Phthalates Commission Decision 1999/815/EC	Regarding the presence of phthalates in this product, we declare that the generic term 'phthalate' actually refers to three different classes of chemicals, each with different physical-chemical properties: orthophthalates, isophthalates and terephthalates. Phthalates as discussed for endocrine effects in public literature, refer to orthophthalates. It should be noted that only select orthophthalate materials have been reported to have endocrine activity. One of the starting materials for copolyesters is terephthalic acid. This product, as sold by IVL Europe, contains no orthophthalates. We do not routinely analyze for orthophthalates in our product, but based on our knowledge of the manufacturing process and starting materials, we would not expect any orthophthalates to be present.
Polycyclic Aromatic Hydrocarbons EU Regulation 850/2004 EU Regulation 1907/2006 EU Regulation 1272/2013 US EPA	<ul> <li>IVL Europe does not analyze its products for the following polycyclic aromatic hydrocarbons (PAH): Acenaphthene; Acenaphthylene; Anthracene; Benzo[a]anthracene; Benzo[b]fluoranthene; Benzo[a]anthracene; Benzo[ghi]perylene; Benzo[a]pyrene; Chrysene; Cyclopenta[c,d]pyrene; Dibenzo[a,h]anthracene; Dibenzo[a,e]pyrene; Dibenzo[a,h]pyrene; Dibenzo[a,i]pyrene; Dibenzo[a,l]pyrene; Fluoroanthene; Fluorene; Indeno[1,2,3-cd]pyrene; Naphthalene; Phenanthrene; Pyrene; 5-methylchrysene. These substances are not used as a raw material, nor are they added to the manufacturing process or the end product. We have no reason to expect that the listed PAHs would be present in this product.</li> <li>References:</li> <li>EU Regulation 850/2004 on persistent organic pollutants;</li> <li>EU Regulation 1907/2006 and 1272/2013 on polycyclic aromatic hydrocarbons;</li> <li>US EPA.</li> </ul>
Bovine spongiform encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) EU Regulation 999/2001 (EMEA 410/01 Rev. 3)	The European Commission has adopted a decision on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies (EU Regulation 999/2001 and amendments, laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies). Based on our knowledge of the raw materials and processes used in the manufacture of this product, we have no reason to expect that bovine-derived materials are present in this product. This product is manufactured using non-animal-derived raw materials. Additionally, this product does not contain, and is not derived from, specified risk materials as defined in EU regulations. This product is not derived from any constituent of animal origin, including ruminants, excluding milk or milk derivatives and derivatives of wool and hair of ruminants. The equipment used in the manufacturing process of the product did not come into contact with a substance derived from animal origin.



Triclosan 2,4,4'-trichloro-2'- hydroxydiphenyl ether	Although IVL Europe has not specifically analyzed RAMAPET polymers for the presence of Triclosan, it is our believe based on our current knowledge of the raw materials and processes used in the manufacture of PET, that we have no reason to expect that compounds stated are present.
Commission decision 2010/169/EU	
VOC EU Directive 2004/42/EC Swiss OVOC	This product is not considered to be a volatile organic compound (VOC), nor does it contain a VOC, as defined in Article 5 of EU Directive 2004/42/EC (an organic substance with an initial boiling point less than or equal to 250 °C at a standard pressure of 101,3 kPa). Also, it is not considered a VOC, nor does it contain one, as defined in the Swiss ordinance on incentive taxes on volatile organic compounds (OVOC): "volatile organic compounds (VOC) are organic compounds with a vapour pressure of at least 0.1 mbar at 20°C or a boiling point of maximum 240°C at 1013.25 mbar".

## Disclaimers

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Revision date: February 2021

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