

PolIPET™ ECO 84SD RESIN GRADE

Last review: JUNE 2017

1. COMPLIANCE WITH EU REGULATIONS FOR FOOD CONTACT PLASTICS – FOOD CONTACT STATEMENT

Polisan Hellas hereby declares that the mentioned product **PolIPET ECO 84SD (ex 84SDR)**:

- is a high molecular weight *blend* of virgin PET resin (chips) and cleaned post-consumer recycled PET resin (chips).
- the cleaned post-consumer recycled PET resin (chips) used for the production of the product (blend), became only from an authorized recycling process, as is defined in Regulation EC No 282/2008 relating to recycled plastics materials and articles intended to come into contact with foodstuffs.
- the product (blend) produced under specific production conditions, using a super-clean recycling process which is in a position to produce recyclates which are in compliance with Article 3 of the EU Regulation 1935/2004. The maximum amount of cleaned post-consumer recycled PET resin which could be used is 33%
- the produced PET recyclate fulfils the requirements of Article 4 of the EU Regulation 282/2008.
- the applied quality assurance system (QAS) assures that the super-clean recycling process is in a position to fulfil the requirements of the GMP EC Regulation 2023/2006
- a challenge test regarding the super-clean process applied and proved to fulfill the above mentioned data regarding the recycled PET product.
- a request for the evaluation of POLISAN HELLAS S.A recycling process for PET for direct food contact (mandate and technical dossier) under EU Regulation 282/2008, submitted by POLISAN HELLAS S.A to European Food Safety Authority (EFSA).
- EFSA scientific opinion adopted on 21 June 2016, [*j.efsa.2016.4463*](#): This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) deals with the safety evaluation of the recycling process Polisan Hellas S.A. (EU register No RECYC128).The Panel concluded that the PET obtained from this process (containing at least 67% virgin PET input), intended to be used up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, with or without hot fill, is not considered of safety concern. Trays made of this PET are not intended to be used, and should not to be used in microwave and conventional ovens.

We hereby confirm that PolIPET ECO 84SD resin grade is in compliance with the requirements of the following regulations:

- EC Regulation 1935/2004 (general requirements, article 3) for all materials and articles intended to come into contact with food
- EU Regulation 10/2011 and all its amendments, on plastic materials and articles to come into contact with food
- EU Regulation 282/2008 on recycled plastic materials and articles intended to come into contact with foods
- EC Regulation 2023/2006 on good manufacturing practices for materials and articles intended to come into contact with food
- EC Directive 94/62 (article 11) and its amendments on packaging and packaging waste

Information on substances for which restrictions are in place in EU regulation 10/2011:

Substance	Technical function	CAS number	SML(T) mg/Kg	Notes
Terephthalic acid (PTA)	Monomer	100-21-0	7.5	Includes terephthalic acid dichloride & phthalic acid
Isophthalic acid (IPA)	Co-monomer	121-91-5	5	Includes isophthalic acid dichlorine
(Mono)-ethylene glycol (MEG)	Monomer	107-21-1	30 (MEG + DEG)	Includes stearic acid & esters with glycol
Di-ethylene glycol (DEG)	Co-monomer Plasticizer	111-46-6		
Antimony Trioxide (Sb ₂ O ₃)	Catalyst	1309-64-4	0.04	SML as antimony

The use of additives and other raw materials of PoliPET resin grades has as follows:

- Phosphoric acid (CAS number 7664-38-2): use as thermal stabilizer, is approved additive in the positive list under EU 10/2011 without any limit.
- Colorants Solvent Blue 104 (CI 61568) & Solvent Red 52 (CI 68210) comply with German BfR Recommendations IX, Council of Europe Resolution AP(89), French positive list (Brochure 1227 du Journal officiel) and purity criteria of Spanish Real Decreto 847/2011 and Italian Decreto Ministeriale 21/03/73.

Only those monomers and other starting substances mentioned above are used in the manufacture of PoliPET resin grades.

Tests performed in final articles (bottles) produced with PoliPET ECO 84SD resin grade, were in line with the requirements of the Regulation (EU) 10/2011 (regulatory status of components used in the PET resin, overall migration, relevant specific migrations and residual contents and relevant extraction tests). Furthermore, the investigated final articles (PET bottles) are in compliance with the sensory requirements according to 31 German "Lebensmittel und Futtermittelgesetzbuch" as well as Article 3 of EC Regulation 1935/2004 (sensory tests: odor and taste of water filled in PET bottles produced with PoliPET ECO 84SD resin).

Given the composition and the values obtained for the relevant overall and specific migrations and residual content, the *PoliPET ECO 84SD resin grade can be considered to be suitable for contact with all food types for any storage period at room temperature including heating up to 70°C for up to 2 hours, or heating up to 100°C for up to 15 minutes and any contact condition that can be considered as less severe in view of the relevant EU Regulations.*

As PET resin must be further processed in order to produce final articles, compliance with the migration requirements can only be demonstrated by tests carried out on the final article. So, *it is the responsibility of both the manufacturers of finished articles and the industrial packers to make sure that these articles in their actual use are in compliance with imposed specific and overall migration requirements.*

PoliPET ECO 84SD resin grade complies with the requirements for heavy metals as drawn up in the EC Directive 94/62/EC (article 11) and the amending Directive 2004/12/EC on Packaging and Packaging Waste: Lead, Cadmium, Mercury and hexavalent Chromium have not been intentionally added during the manufacture of these resins. The sum of the concentration levels of lead, cadmium, mercury and hexavalent chromium present in these resins does not exceed 100 parts per million by weight. Those results are in compliance with US CONEG Regulation too.

Trace amounts could be present in the starting substances (raw materials) used for resin manufacture, but their levels in the finished products are proved not to exceed the specified limits. **POLISAN HELLAS S.A** use raw materials for the production of all PoliPET resin grades and preforms which comply with the relevant Packaging and Packaging Waste legislation.

POLISAN HELLAS S.A applies an analytical method in order to check, control and verify the relative heavy metals content in raw materials and products (inductively coupled plasma-optical emission spectroscopy ICP-OES).

Regarding EC Regulation 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, article 3 defines as: “good manufacturing practice (GMP)” means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof. **POLISAN HELLAS S.A** is certified with ISO 9001 Quality Management System and PoliPET resin grades are manufactured to good manufacture practice standards (regulatory compliance, safety compliance, quality assurance system, quality control system, documentation etc.) complying with EC Regulation 2023/2006.

2. COMPLIANCE WITH FDA REGULATION FOR FOOD CONTACT PLASTICS

POLISAN HELLAS S.A PoliPET ECO 84SD resin grade is in compliance with the compositional requirements of the FDA Regulation 21CFR 177.1630 (Polyethylene Terephthalate Polymers) and 21CFR 174.5 (general provisions applicable to indirect food additives). A Letter of No Objection confirming the capability of proposed recycling process (super-clean recycling process) to produce postconsumer recycled polyethylene terephthalate (PCR-PET) material that is suitable for use at a level of up to 33% recycled content in the manufacture of PET containers in contact with all food types under Conditions of Use C through G, as described in Table 2, which can be accessed from the Internet in the Ingredients, Packaging & Labeling section under the Food topic of www.fda.gov. The finished (food contact) article is subject to extractive limitations. Compliance with the extractive limits can only be demonstrated by tests carried out on final article and *it is the responsibility of both the manufacturers of finished articles and the industrial packers to make sure that these articles in their actual use are in compliance to the extractive limitations.*

3. INFO REGARDING NIAS - ACETALDEHYDE

Acetaldehyde (CAS number 75-07-0) is a Non Intentionally Added Substance in Polyethylene Terephthalate resin. Is a foreseeable degradation by-product in the production of resin and may be further generated in downstream thermal treatment of PET resin (injection molding). Acetaldehyde is listed in Annex I of the EU Regulation 10/2011 with SML(T) (including propionic acid, vinyl ester) 6mg/Kg. Tests performed in final articles produced with PoliPET resin grades, were in line with the requirements of the Regulations (EU) No 10/2011 and the Regulation (EC) No 1935/2004 regarding specific migration of acetaldehyde in relative food simulants. **POLISAN HELLAS S.A** applies an analytical method in order to check, control and verify the relative acetaldehyde content in PoliPET resin grades. Due to possible further generation (injection molding) *it is the responsibility of both the manufacturers of finished articles and the industrial packers to make sure that these articles in their actual use are in compliance with imposed overall and specific migration requirements.*

4. EC DIRECTIVE 94/62 ON PACKAGING & PACKAGING WASTE AND PACKAGING MATERIALS

POLISAN HELLAS S.A states that to the best of our knowledge all packaging materials (big bags, cartoon octabins, pallets) used for packaging of all PoliPET resin grades and products, comply with the requirement for heavy metals as drawn up in the EC Directive 94/62/EC (article 11) and the amending EC Directive 2004/12 on Packaging and Packaging Waste. This statement is based on our packaging material supplier's relevant statements, which could be available to any concerned party upon request.

5. EC REGULATION 1907/2006 – REACH COMPLIANCE

Polyethylene Terephthalate (PET) polymers themselves are currently exempt from REACH Registration and Evaluation. For the monomers and additives used in the manufacture of PoliPET resin grades, **POLISAN HELLAS S.A** states that to the best of our knowledge all its major suppliers have registered their substances in accordance with REACH requirements. PET polymers are not classified as hazardous (no CLP number) according to EC Regulation 1272/2008.

6. SVHC (Substances of Very High Concern) COMPLIANCE

POLISAN HELLAS S.A declares that no substances of very high concern (SVHC) are intentionally added in the manufacture of any of its PoliPET resin grades. SVCH substances are listed in Candidate List of REACH Regulation. The Candidate List is dynamic and subject of periodical update, so new version(s) in the future or inclusion of other substances may occur. **POLISAN HELLAS S.A** periodically follows up and verify the Candidate List (SVCH substances) in order to be in compliance. *It is recommended to the manufacturers of finished articles to periodically verify if the final article (due to further process of the virgin resin) still meets the criteria of REACH Regulation concerning SVHC substances.*

7. BPA (Bisphenol A) and BPS (Bisphenol S) STATEMENT

POLISAN HELLAS S.A declares that no Bisphenols are used as additive or raw material for manufacturing of all PoliPET resin grades. More info regarding Bisphenols: EU Regulation 323/2011 (amendment on EU Regulation 10/2011)

8. PHTHALATES STATEMENT

POLISAN HELLAS S.A declares that no Phthalates (DEHP, DBP or any other chemical form) are used or added for manufacturing of all PoliPET resin grades. More info regarding Phthalates: EU Directive 2005/84.

9. ALLERGENS STATEMENT

POLISAN HELLAS S.A states that no allergens (substances, additives, raw materials) are used, added, participate in any stage of manufacturing process or included as residuals in any of PoliPET resin grades. More info regarding Allergens: EU Regulation 1169/2011.

10. GMO STATEMENT

POLISAN HELLAS S.A states that to the best of our knowledge of raw materials and supplier's information, PoliPET resin grades are considered as not genetically modified or not derived by a genetically modified organism, as defined by EC Directive 2001/18 and EU Regulations 1829/2003 & 1830/2003.

11. DISCLAIMER AND CONTACT INFO POLISAN HELLAS S.A:

All info contained in this document is based on current analytical data, knowledge and experience at the date of publication and could be change due to possible changes in law, regulations and other data. It is the responsibility of both the manufacturers of *finished articles* and the industrial packers to assure the compliance with law, regulations, safety and technical suitability of *final articles* produced with PoliPET resin grades.

For further info or queries, please contact **POLISAN HELLAS S.A**:

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