

PolIPET™ RESIN GRADES

Last review: JAN 2017

(PolIPET 76W, PolIPET 80GP, PolIPET 84SD, PolIPET 84F)

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

POLISAN HELLAS S.A PolIPET resins are copolymers produced by using only the monomers and additives listed in below given EU Directives and Regulations. We hereby confirm that PolIPET resin grades: PolIPET 76W, PolIPET 80GP, PolIPET 84SD, PolIPET 84F are 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
- 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.
- PolIPET 84F resin grade contains amount of a fast reheat additive (CAS number 64365-11-3) <10mg/Kg of polymer (resin) which is listed in Annex I of the EU Regulation 10/2011 without SML. This fast reheat additive is permitted only for use in PET at maximum 10 mg/kg of polymer.

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

Tests performed in final articles produced with PoliPET resin grades, were in line with the requirements of the Regulations (EU) 10/2011 and the Regulation (EC) 1935/2004 (check of the composition of the samples, check for the use of dual use additives, overall migration, relevant specific migrations and residual contents and relevant extraction tests).

Given the composition and the values obtained for the relevant overall and specific migrations and residual content, the *PoliPET resin grade products 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.*

All PoliPET resin grades comply 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 resin grades are in compliance with the compositional requirements of the FDA Regulation 21CFR 177.1630 (Polyethylene Terephthalate Polymers). 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. CALIFORNIA PROPOSTION 65

POLISAN HELLAS S.A PoliPET resin grades do not contain any substance listed by the “California Safe Water and Toxic Enforcement Act of 1986” (California Proposition 65), as being a carcinogen or reproductive toxicant *in an amount* that would require a warning statement under the provisions of the Act.

4. COMPLIANCE WITH SWISS REGULATION FOR FOOD CONTACT PLASTICS

POLISAN HELLAS S.A PoliPET resin grades are in compliance with Swiss Regulations 817.02 (article 34) & 817.023.21 (section 3, plastics) Ordinance on Materials and Articles in Contact with Food.

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.*

5. 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.*

6. 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.

7. EC REGULATION 1907/2006 – REACH COMPLIANCE – EU REGULATION 1272/2008

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. **POLISAN HELLAS S.A** states that no other CMR substances or other skin sensitizers are intentionally added in the manufacture of any of its PoliPET resin grades and therefore to the best of our knowledge no CMR substances and skin sensitizers are expected to be present to our products.

8. 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.*

9. 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)

10. PHTALATES 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.

11. 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.

12. PRIMARY AROMATIC AMINES STATEMENT

POLISAN HELLAS S.A states that no Primary Aromatic Amines (PAA) are used or added in any stage of manufacturing process in any of PoliPET resin grades. Tests performed in final articles produced with PoliPET resin grades were in line with the requirements of EU Regulation No 10/2011 (Annex II) – no PAA detected.

13. 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.

14. EU DIRECTIVE 2011/65 (RoHS)

EU Directive 2011/65 set restrictions of the use of certain hazardous substances in electrical and electronical equipment as follows (maximum concentration): Lead (0,1 %/1000ppm) Mercury (0,1 %/1000ppm) Cadmium (0,01 %/100ppm) Hexavalent chromium (0,1 %/1000ppm) Polybrominated biphenyls (PBB) (0,1 %/1000ppm) Polybrominated diphenyl ethers (PBDE) (0,1 %/1000ppm). Based on data given on paragraph 1 (regarding heavy metals and 94/62 EC Directive) and that no PBB or PBDE are used or added for manufacturing of all PoliPET resin grades, **POLISAN HELLAS S.A** states that to the best of our knowledge heavy metals content are in compliance with EU Directive 2011/65 and no PBB or PBDE are expected to be present in PoliPET resin grades.

15. EUROPEAN PHARMACOPOEIA – POLYETHYLENE TEREPHTHALATE FOR CONTAINERS FOR PREPARATIONS NOT FOR PARENTERAL USE

POLISAN HELLAS S.A declares that PoliPET resin grades which is Polyethylene Terephthalate copolymer, complies with European Pharmacopoeia, paragraph 3.1.15 as far as concern chemical composition.

Moreover, chemical analyses performed on resin material, are in agreement with the standards established by European Pharmacopoeia, paragraph 3.1.15, *subject to compliance of the finished article with the requirements of the paragraph 3.1.15 pertaining to converter and end user obligation*. **POLISAN HELLAS S.A** applies the relevant analytical methods (as described in 3.1.15) in order to check, control and verify the specified control limits (UV-Vis, ICP-OES and others).

POLISAN HELLAS S.A. cannot assure that the final articles made with Polyethylene Terephthalate identified by the brand PoliPET will be in compliance, as regards chemical and physicochemical tests, with the standards established by European Pharmacopoeia, paragraph 3.1.15, since it is unaware of the subsequent processing treatment PoliPET will be subjected to before its final use.

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 European Pharmacopoeia.

European Pharmacopoeia is dynamic and subject of periodical update. **POLISAN HELLAS S.A** periodically follows up and verify the above mentioned data.

16. EU REGULATION 1223/2009 (COSMETIC-FRAGRANCES)

Cosmetic Regulation EU 1223/2009 refers to components used in cosmetics. Antimony and its compounds are included on Annex II. PET contains Antimony Trioxide at such level that migration (expressed as Antimony) is in limits specified for food contact packaging materials. Sb₂O₃ is on the positive list of EU 10/2011 for articles in direct contact with food and specific migration tests confirm that migration does not exceed the SML. The Cosmetic Regulation EU 1223/2009 does not specify migration limits. **POLISAN HELLAS S.A** states that fragrances, as described in EU 1223/2009, are not used as a raw material and they are not added to the manufacturing process or the end product, so to the best of our knowledge no fragrances are expected to be present in PoliPET resin grades.

17. 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.

18. 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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