

**DECLARATION OF COMPLIANCE
FOR PET PLASTIC PRODUCTS AND CONTAINERS
INTENDED TO COME INTO CONTACT WITH FOOD**

20 September 2023, Revision 08

PLASTIKSE is the producer of **clear PET bottles, containers, and jars**, which can be used for different applications including packaging all types of food dry and liquid products, beverages, alcohol, cosmetics, pharmaceuticals, chemicals, and others.

This declaration covers all PET bottles, containers, and jars produced and supplied by PLASTIKSE and is not designed to be item-specific.

Monomers and Starting Substances

PLASTIKSE confirms that PET bottles, containers, and jars are manufactured only with monomers and other starting substances and additives that are authorized under Plastics Regulation No 10/2011¹ and all its amendments for plastics used in contact with food.

We hereby confirm

that PET bottles, containers, and jars produced and supplied by PLASTIKSE comply with the relevant requirements as follows:

We hereby confirm, that amber PET packaging produced and supplied by PLASTIKSE complies with the relevant requirements as follows:

- a) the Plastics Regulation No 10/2011¹ with all amendments: No. 321/2011, No. 1282/2011, No. 1183/2012, No 202/2014, No 2015/174, No 2016/1416, No 2017/752, No 2018/79, No 2018/213, No 2018/831, No 2019/37, No 2019/1338, No 2020/1245, No 2023/1442 and No 2023/1627.
- b) the Framework Regulation No 1935/2004/EEC² Article 3, 11(5), 15 and 17.
- c) the Commission Regulation No 2023/2006³ on good manufacturing practice (GMP).
- d) Requirements of Food Safety Standard Certification (FSSC) 22000 version 5.1 (based on ISO 22000:2018 and relevant technical standards for sector-specific PRPs).

Overall and Specific Migration Limits (OML and SML)

Overall Migration Limits (OML) testing has been carried out on samples of our PET packaging under conditions of Plastics Regulation No 10/2011 using appropriate simulants for the food product. The ratio of the sample area to the volume of the food simulant is 1.8 dm²/200 ml.

Test conditions	Test method	Overall migration limits (OML)
10 % ethanol, 10 days, 40 °C	LST EN 1186-9:2002	Do not exceed 10 mg/dm²
3 % acetic acid 10 days, 40 °C		
Isooctane, 10 days, 40 °C	LST EN 1186-14:2002 except 4.5	
95 % ethanol. 1 dav. 50 °C		

The analysis result of OML of our products shown to meet overall migration limits laid down in Plastics Regulation No 10/2011.

According to Regulation (EU) No 10/2011, Annex V, chap 2, paragraph 2.2.3 each stage of manufacture, supporting documentation, substantiating the Declaration of Compliance in PLASTIKSE are kept available for the enforcement authorities. As migration testing is time-consuming, costly, and may be complex, it is accepted to demonstrate compliance by calculations or modeling, or other analysis, and

¹ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food with all amendments.

² Commission Regulation (EC) No 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

³ Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

scientific evidence or reasoning if these render results, which are at least as severe as the migration testing. Our production process is strongly controlled and OML does not exceed limits, therefore Specific Migration Limits (SML) testing is not monitored continuously and compliance with the SML is based on the data provided by the suppliers of PET raw materials. The Suppliers have conducted tests on sample containers made from PET polymers resins using good manufacturing practices. Samples were analyzed by an outside party and results were shown to meet migration limits (OML and SML) of monomers and additives into the food simulants:

Substances	PM/Ref. No	CAS No	Simulant	Specific migration limits (SML)	Test results
Terephthalic Acid (PTA)	24910	000100-21-0	3 % acetic acid (B) 50 % ethanol (D1) Olive oil (D2)	7.5 mg/kg	< 0.8 mg/kg
Isophthalic Acid (IPA)	19150	000121-91-5		5 mg/kg	< 0.8 mg/kg
Monoethylene Glycol (MEG) and Diethylene Glycol (DEG)	16990 and 15760	000107-21-1 and 000111-46-6		30 mg/kg of MEG+DEG	< 6.2 mg/kg
Antimony Trioxide	35760	0001309-64-4	3 % acetic acid (B)	0.04 mg/kg of antimony	< 0.04 mg/kg
			Simulant	Overall migration limits (OML)	Test results
			3 % acetic acid (B) 50 % ethanol (D1) Olive oil (D2)	10 mg/dm ²	< 1 mg/dm ²

The OML and SML determinations are the responsibility of the manufacturer of the finished product (bottled product) if it would be used for the specific application. PLASTIKSE would suggest to, that the manufacturers of the bottled product must verify that the finished material/article, manufactured according to GMP, does not modify the properties of the final product.

Non – intentionally Added Substances (NIAS)

PLASTIKSE confirms that reaction intermediates, decomposition or reaction side products comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 of the Plastics Regulation has been performed. We performed the analysis of NIAS in accordance with internationally recognized scientific principles⁴ on risk assessment. Our production process is fully automatized and controlled, every step is described in the HACCP plan.

Substances	CAS No	SML limits/ Restrictions (SML/QM)	Comments
Terephthalic Acid (PTA)	000100-21-0	7.5 mg/kg	Starting monomers ⁴
Isophthalic Acid (IPA)	000121-91-5	5 mg/kg	
Monoethylene Glycol (MEG) and Diethylene Glycol (DEG)	000107-21-1 and 000111-46-6	30 mg/kg of MEG+DEG	
Polyethylene glycol mono alkyl ether	25322-68-3	1.8 mg/kg Restrictions (SML/QM)	
Antimony Trioxide	0001309-64-4	-	Polymerization catalyst ⁴
Acetaldehyde (AA)	000075-07-0	6 mg/kg Restrictions (SML/QM)	Side products of decompositions Break-down products / Thermo-oxidative and thermo-mechanical degradation of PET ⁴
Acetic acid, Vinyl ester	000108-05-4	12 mg/kg Restrictions (SML/QM)	

PLASTIKSE confirms, according to the opinion of our NIAS risk assessment that our products do not intentionally contain any substances based on (are not as a part of the recipe):

- Bisphenol A (BPA), (CAS 80-05-7) (complied with EU Regulation 2018/213⁵);
- Azodicarbonamide (E927);
- Polyvinyl Chloride (PVC);
- Substances listed in Table 1 of Annex II of Regulation No 10/2011 (consolidated versions 23/09/2020). Substances (metals) listed in point 1 of Annex II to the Plastics Regulation do not migrate in detectable concentrations.

⁴S. De Cort, F. Godts, A. Moreau, Packaging materials 1. Polyethylene terephthalate (PET) for food packaging applications. Updated Version 2017, the International Life Sciences Institute (ILSI), ISBN 9789078637431.

⁵Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials

Primary Aromatic Amines (PAAs)

Raw materials (food grade PET pellets) do not release PAAs covered by point 2 of Annex II of Regulation No 10/2011. In the CPME industry test program for NIAS, where our suppliers of raw materials are attended, no PAAs were found. PAAs are not as a part of the recipe of PLASTIKSE products.

Metals in Annex II

PET raw material does not intentionally contain metals listed or their salts – listed point (1), Table 1 of Commission Regulation (EU) No 10/2011. Antimony is present in the PET polymer at a level of < 300 ppm, - expressed as Antimony (Sb).

Sb has an SML of 0.04 mg/kg food or food simulant – listed above.

Heavy metals

Heavy metals such Pb, Hg, Cd, and Cr (VI) are not intentionally added in the manufacture of our products. Based on the chemical analysis of our products, we confirm that the content of mentioned substances do not exceed the limits laid down in 94/62/EC⁶ Article 11.

Migration of substances subject to restrictions in national legislation

PLASTIKSE confirms that the substances mentioned in the sections above do not migrate in detectable concentrations. Overall Migration Limits (OML) comply with the Plastics Regulation No 10/2011 requirements.

Substances of very high concern (SVHC)

PLASTIKSE and our supplier of raw materials confirm that products and ingredients do not contain any of the Annex XIV substances on the Authorisation list or Annex XIV candidate chemicals proposed to be SVHC (list as of 14th June 2023) above the 0.1 % threshold as stated in REACH (published in accordance with Article 59(10) of the REACH Regulation No 1907/2006⁷). The current list of all SVHCs can be found at the ECHA website link listed below:

<https://www.echa.europa.eu/candidate-list-table>

Dual use additives

PET packaging may contain the dual-use additive a phosphorus compound - phosphoric acid (E338), which is used in the manufacture of PET polymer. The compound is listed in Table 6 of Part 6 of Commission Regulation (EU) No 1130/2011⁸.

Specific of the use of the supplied PET packaging and containers

PET bottles, containers, and jars are fully food contact compliant as sold and can be used for food contact applications with dry and liquid food products as follows: beverages, soft drinks, juices and mineral water; beer, wines, and alcoholic beverages (up to 95 % alcohol), acetic acid; species extracts; vegetable oil; mayonnaise; stored at room and at a lower temperature. Packaging is not suitable for hot filling over 55 °C, microwave, and conventional ovens.

Further Compliance Work required by Customers

There will be a need for further steps of compliance work to be performed by the downstream in order to prevent migration of some of the potentially migrating substances into the final filled goods. The producer of the final article (bottled product) is fully responsible for substance stability in filled packaging and shall demonstrate the safety of the packaging in relation to the specific food for which it should be used.

⁶ European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

⁷ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

⁸ Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavorings and nutrients.

Shelf life

PET products do not have any specified shelf life and can be used without any problem during the long period (2-3 Years) after the production and storage under ambient conditions, if it is stored and transported on recommended conditions (pleased see below). How a product is stored, distributed, and used by consumers will affect food safety and shelf-life. Also, we have performed OML analysis of our PET bottles after 3 Years from the production date:

Test conditions	Test method	Overall migration limits (OML)	Test results	Test results after 3 Years
95 % ethanol, 10 days, 40 °C	LST EN 1186-9:2002	10 mg/dm²	< 0.3 mg/dm²	< 0.3 mg/dm²
3 % acetic acid, 10 days, 40 °C				
Isooctane, 10 days, 40 °C	LST EN 1186-14:2002 except 4.5			
95 % ethanol, 1 day, 50 °C				

Storage & Transportation of PET bottles and containers

The packaged product(s) should be stored indoors at temperatures in the range of -30 °C to +30 °C. The product shall be protected from direct sunlight, UV light, high temperature, and rain. Packages and containers shall be closed when stored. Exposure to high temperatures (> 60 °C) and sunlight for a long time may deform PET bottles, jars, and containers.

Recycling & Sustainability of clear PET packaging

Clear PET packaging is fully recyclable and highly sustainable. PET packaging is identified by its polymer code 01. The PET bottle recycling industry is well-established. Collected PET bottles can be recycled into fibers, personal care products – or into carpet and clothing fibers, also into automotive parts, construction materials, industrial strapping, or other packaging materials.

<http://www.petresin.org/faq.asp>

https://www.petcore-europe.org/images/news/pdf/factsheet_the_facts_about_pet_dr_frank_welle_2018.pdf

Sincerely,
Quality Manager
Milda Šulcienė
20th September 2023

Should you have any further questions
concerning our products, please contact
us at e-mail:
milda@plastikse.com

