Polinas Plastik San. ve Tic. A.Ş.

Polinas Plastik Sanayi ve Ticareti A.Ş.
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DECLARATION OF COMPLIANCE

We, Polinas Plastik Sanayi ve Ticaret A.Ş., hereby declare that **POLINAS BOPET (chemical coated, corona treated [uncoated], metallized)** films comply with the following legislations,

A. EU : Regulation 1935/2004/EC and its amendment including EU 2019/1381
B. Regulation 2023/2006/EC,
C. Commission Regulation EU 10/2011 and its successive amendments including EU 2026/245
D. Regulation 2025/40 on Packaging and Packaging Waste Regulation (PPWR) EU 2019/1020 and Directive EU 2019/904, and repealing Directive 94/62/EC except for metallized films (according to Recylass' latest guidelines)
E. USA : American 21 CFR 174.5 (GMP for food contact materials and articles intended to come into contact with food)
F. FDA Section 21 CFR Ch. 177.1630 section (f), (g), (h)(1),(2) and (i), (j)
G. TR : Türk Gıda Kodeksi Gıda İle Temas Eden Plastik Madde Ve Malzemeler Tebliği (Tebliğ No: 2019/44 – 2023/33 – 06.05.2024 tarih ve 32538 Sayılı Resmi Gazete)
H. China:

- GB 4806.1-2016 - General Food Contact Materials and Articles
- GB 4806.7-2023 - National Food Safety Standard - Food Contact Plastics Materials and Articles
- GB 31604.1-2023 - National Food Safety Standart-General Principles for Food Contact Materials Migration Tests.
- GB 31604.59-2023 - National Food Safety Standart – Genral Principles for Validation of Chemical Analysis Methods for Food contact Materials and Products.
- GB9685-2025 -National Food Safety standard -Standards for uses of additives in food contact material and product
- GB31603-2015 - General specification of production for food contact material and product

İ. MERCOSUR

All materials and/or raw materials used are in accordance with the requirements listed in:

a. MERCOSUR / GMC / RES No. 03/92. General criteria for food packaging and equipment in food contact.
b. MERCOSUR / GMC / RES No. 20/21. Modification of GMC Resolution No. 56/92 General provisions for plastic containers and equipment in contact with food
c. MERCOSUR / GMC / RES No. 28/99. Technical regulation on the positive list for packaging and elastomeric equipment in food contact.
d. MERCOSUR / GMC / RES No. 02/12. Technical regulation on the positive list of Monomers, other starting substances and authorized polymers for the production of plastic containers and equipment in food contact.

e. MERCOSUR / GMC / RES N ° 39/19 and RES N ° 22/2024 . Technical regulation on positive list of additives for plastic materials destined to the elaboration of containers and equipment in food contact.
f. MERCOSUR / GMC / RES N ° 15/10 Technical Regulation on Colorants in food contact plastic packaging and equipment
g. MERCOSUR / GMC / RES N ° 34/2025 Technical Regulation on Silicones for the Manufacture of Materials, Packaging, Coatings and Equipment

J. Japan: Food Sanitation Law and Japanese (MHLW) Positive List of 1st June 2025
K. Swiss Ordinance on materials and articles in contact with food (sr 817.023.21, 1 Februar 2024)
L. Germany: BgVV (ex BGA) Empfehlung XVII, BFR (July 2016)
M. Italy: D.P.R: 777/82 and D.M. 21/3/73 and amendments and changes,
N. France: Brochure n° 1227.
O. UK :

a. The Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025, Part 4
b. The Materials and Articles in Contact with Food (England) Regulations 2012, Part 6
c. The Packaging (Essential Requirements) Regulations 2015 (SI 2015 No. 1640)

Polinas films are intended for single use only. Our films were not tested for repeated contact usages.

OVERALL MIGRATION LIMITS:

We confirm that to produce our films listed, we use only monomers, starting substances and additives listed in the Union List of Authorized Substances of EU 10/2011 and its successive amendments.

All polymers and additives in the composition of above-mentioned films appear in the positive list of products accepted for the fabrication of packaging materials intended for food contact, as published by the Food and Drug Administration (USA) FDA 21 CFR 177.1630 section (f), (g), (h)(1),(2) and (i), (j)

Films were tested according to latest directives (EU 10/2011) in the following simulants to obtain overall migration values for **all food types**.

EU 10/2011:

Solution		**Conditions**
10% Ethyl alcohol solution	Simulant A	40°C / 10 days + 100°C / 4h
3% Acetic acid solution	Simulant B	40°C / 10 days + 100°C / 4h
Vegetable oil	Simulant D2	40°C / 10 days + 100°C / 4h

Results of the tests are available upon request. Tests are done biyearly.

SPECIFIC MIGRATION LIMITS:

During the production of our BOPET films, we use the following additives which are included in the Union List of Authorized Monomers and other starting substances in Annex I of EC Directive 10/2011 and its successive amendment. The theoretical calculation method was used according to EC directive of 10/2011 in order to find the level of specific migrations for the compounds below.

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FCM&PM number	*Chemical Name*	SML/SML (T)	*Available at chemical*
263-13326	Diethyleneglycol	30 mg/kg	Coated/uncoated
227-16990	Ethyleneglycol		Coated/uncoated
785-24910	Terephthalic acid	7,5 mg/kg	Coated/uncoated
291-19150	Isophtalic acid	5 mg/kg	Coated/uncoated
288-24970	Dimethyl terephthalate (DMT)	60 mg/kg	Coated/uncoated
484-13395	2,2-bis(hydroxymethyl) propionic acid	0.05 mg/kg	Coated
254-13720	1.4 Butanediol	5 mg/kg	Coated
361-18700	1.6-Hexandiol	0,05 mg/kg	Coated
398-35760	Antimony trioxide	0,04 mg/kg	Coated/uncoated
475-19110	1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	1 mg/kg	Coated

Results of the tests are available upon request.

Surface Volume ratio = 6 dm^2/kg food

For metallized films : Metallized surface should not be in contact with foodstuffs

DUAL USE ADDITIVES:

Our films **may contain** following food additives. We confirm that the migration of those dual use additives are in the limits of our overall migration limits.

Chemical Name	E Number
Silicon dioxide	E551

HEAVY METALS:

The raw materials used in the production of said BOPET films do not contain heavy metals such as cadmium, hexavalent chromium, lead, nickel, tin, arsenic and mercury, as declared by the suppliers of the above-mentioned raw materials.

Neither the said heavy metals nor their compounds are intentionally added during the production of the said BOPET films, nor they are used, directly or indirectly, in the production process itself.

Any incidental amount of heavy metals contained does not exceed 100 ppm (by weight). For these reasons, we hereby declare that the said BOPET films comply with the following regulations:

a. USA CONEG REGULATION
b. 2009/48/EC (Safety of toys) and its amendment EU 2025/2509
c. Regulation 2025/40 on packaging and packaging waste amending Regulation EU 2019/1020 and Directive EU 2019/904, and repealing Directive 94/62/EC
d. ROHS Regulation (EU 2011/65) and its amendment EU 2023/1526
e. WEEE Regulation (EU 2012/19)

SPECIFIC MIGRATION OF HEAVY METALS:

Specific migration analysis of *aluminum, ammonium, antimony, arsenic, barium, cadmium, calcium, chromium, cobalt, cupper, europium, iron, gadolinium, mercury, lanthanum, lead, lithium, magnesium, manganese, nickel, potassium, sodium, terbium, zinc* in the table 1 of Annex II of EC Directive 2020/1245 were tested in the simulant of 3% acetic acid solution (Simulant B, 10 days @ 60 °C). Test results comply with the table 1 of Annex II. Results are available upon request.

SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINES:

Specific migration of 22 Primary aromatic amines mentioned in EU 2020/1245 were tested in the simulant of 3% acetic acid solution (Simulant B, 10 days @ 60 °C). Test results comply with the relevant regulation. Results are available upon request.

PPWR:

Polinas BOPET films meet the requirements of the Regulation 2025/40 Article 5 of the European Parliament and the Council of 19 December 2024 on packaging and packaging waste (PPWR).

The sum of the concentrations of lead, cadmium, mercury and hexavalent chromium does not exceed 100 mg/kg.

Our film comply with PFAS requirements of PPWR as stated below.

25 ppb **for any PFAS** as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) , 250 ppb for **the sum of PFASs** measured as sum of targeted PFAS analysis, 50 ppm for PFAS **(total fluorine)**.

GMP:

Polinas operates in conformity to the Good Practices of Manufacture according to European Regulation 2023/2006/CE, American FDA regulation 21 CFR 174.5

GMO – DIOXINE – RESTRICTIONS-ALLERGENS – RECYCLED RAW MATERIAL USAGE-MICROPLASTICS , IRRADIATION:

According to the information received from our suppliers PET Chips, additives and coating materials used to produce said films do not contain any genetically modified organisms (GMO)

EC 2003/11 (restrictions on the marketing and use of certain dangerous substances and preparations)**:** please refer absence list given below.

EC 1895/2005 (restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food): please refer absence list given below.

EU 252/2012 (related with dioxine and dioxine related PCB's in the food chain) is not applicable to our products.

Our films do not contain any allergic substances and we hereby confirm that our film complies with **EU 1169/2011** and its amendments.

Polinas films are produced only from virgin resin and do not contain post-consumer recycled components, and no obligation exists under the **EU 2022/1616.**

Our films do not contain nanoparticles, so **EU 2011/696** is inapplicable.

Our films do not contain Active and intelligent additives, so **EC/450/2009** is inapplicable.

Our films do not contain biocides, so **EU 528/2012** is inapplicable.

Our films do not contain Bisphenol A, and comply with Commission Regulation (EU) **2026/250** which is corrected regulation of **EU 2024/3190**

(EU) 2019/1021 (persistent organic pollutants) and its latest ammendment : Our films do not contain the substances listed in Annexes I, II, III and IV.

All our raw materials are free from **microplastic** and we do not intentionally add it during the production process of our films. Hence our films are in compliance with **Entry 78 of Annex XVII REACH,** as introduced by **Commission Regulation (EU) 2023/2055**. Please note that this regulation does not cover microplastics coming from the fragmentation of our films in the environment by time

We confirm that no Irradiation (ionizing, radiofrequency, ultraviolet, pulsed light radiation) is not applied to any material produced at Polinas

REGULATION (EC) No 1272/2008 on cosmetic products

Article 15 of the Cosmetics Regulation 1223/2009 contains provisions on the use of CMR in cosmetic products. As a general principle, substances classified as CMR substances of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 are banned for use in cosmetic products.1223/2009 does not directly apply to the packaging components of cosmetic products except where that packaging is in direct contact with the cosmetic product.

None of the components of our films, including the active substance, are listed on CMR substances of category 1A, 1B, or 2 the list of substances prohibited in cosmetic products.

Therefore, our BOPET films should be used as a secondary packaging.

RECYCLING:

BOPET films can be recycled.

GENOTOXICITY:

In accordance with the requirements of Regulation 10/2011/EC Annex IV, part 6, OUR BOPP films do not contain genotoxic substances which would migrate from a final material at a level exceeding 0.15 ppb in food or food simulant.

ABSENCE OF SUBSTANCES:

The raw materials used in the production of said BOPET films do not contain the following substances, as declared by the relevant raw materials suppliers:

*Latex**, Bisphenol A,S,F,AP,AF,B,BP,C,E,G,M,P,PH,TMC,Z**, BHT, BHA, Polychlorinated biphenyls, 2-Ethylhexyl Acrylate, Polychlorinated napthalates, Chlorinated Paraffins, Polybrominated biphenyls, Polybrominated diphenylethers, Organic Tin Compounds (tributyl or triphenyl tin), Asbestos, Azo Compounds, Formaldehyde, Mirex (perchloredecone), Alkyl Phenols – Octyl & Nonyl, Alkyl Phenol Ethoxylates, , CFC, HCFC, Triclosan, PVC, PVDC, Acrylamide, Dioxin etc, BADGE, BFGDE, NOGE, Melamine, Ammeline, TXIB , PCDD (polychloride dibenzo-p-dioxin), PCDF(polychloride dibenzo-p- furan), PCB (Polychloride biphenyl), PAH (Polycyclic aromatic hydrocarbon), SCCP (Chlorinated paraffin short chain), HCH (Hexachlorocyclohexane), Hexabromocyclododecane (HBCD), PCP (Pentachlorophenol), Semicarbazide, Adipates, ESBO (Epoxidised Soybean Oil), Cyanuric acid, Dimethylfumarate, Isocyanates, Titanium Acetyl Acetonate (TAA), 2-4 pentandione, pentabromodiphenyl ether, octabromo-diphenyl ether,*

halogenated compounds, conflict minerals (gold, wolframite, casserite, columbite-tantalite, and their derivative metals, which include tin, tungsten, and tantalum), active and intelligent substances, ozone depleting substances, PFOA (perfluorooctanoic acid), PFOS (perfluorooctane sulfonate), nano particles, Per- and Polyfluorinated Surfactants (PFS), - Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances, Perfluorooctane sulfonic acid (PFOS), its salts and PFOS-related compounds, Undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances, Polytetrafluoroethylene (PTFE, CAS No. 9002-84-0), Perfluorononanoic acid (PFNA), Perfluorohexane sulfonic acid (PFHxS), MOAH/MOSH/POSH, melamine, glycol ethers, polycarbonate, nitrosamine, mancozeb, cholecalciferol, Radioactive Substances,

Neither the said substances are intentionally added during the production of the said BOPET films, nor they are used, directly or indirectly, in the production process itself.

We also would like to emphasize that we did not tested the films for such substances.

ENDOCRINE DISRUPTORS

We, Polinas Plastik Sanayi ve Ticareti A.S., hereby declare that the raw materials used in the production of the BOPET films do not contain substances given in SINLIST substances (can be reached https://sinlist.chemsec.org/endocrine-disruptors/), as declared by the relevant raw material suppliers.

Our films do not contain the below mentioned chemicals as declared by the relevant raw material suppliers: Substances identified as endocrine disruptors at EU level and included in the EU Endocrine disruptor list (List I) [https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu]

PHTHALATES

We hereby state that no phthalates of whichever chemical form are intentionally added as modifiers, plasticizers additives, or processing aids to BOPET films produced by Polinas.

Chemical List of Proposition 65:

We confirm that our BOPET films are manufactured with raw materials which do not contain purposely the chemicals mentioned on the California Proposition 65 list, except Antimony trioxide (CAS-No. 1309-64-4, PM Ref Number: 35760) and Ethylene Glycol (CAS –No. 107-21-1).

Polycondensation catalysis using antimony-based compounds represents a general technology for polyester production for more than 50 years. The substance is entirely incorporated in the polymer matrix in catalytic amounts and the extractable Sb amount is well below the Oeko-Tex Class 1 limit of 30 ppm.

Information reported above are based on technical knowledge of our products of our raw materials. Complete list can be downloaded from;

https://oehha.ca.gov/sites/default/files/media/downloads/proposition-65//p65chemicalslist.pdf

NIAS:

Non-intentionally added substances (NIAS) is that the substances are not added intentionally during the production. They may be present as impurities, reaction intermediates, decomposition or reaction products.

The legislators/law makers like FDA and EC / European Food Safety Authority (EFSA) do not specify the test method for NIAS. It means there is no 'STANDARD TEST METHOD' for NIAS risk assessment.

Research Institutes like Fraunhofer, Rapra and the laboratories like CSI, Campden, SGS have no specified test method for NIAS risk assessment. Film or injection grade homopolymer / terpolymer producers in the world (polypropylene, polyethylene, polyester, polystyrene etc.) have no risk assessment test method.

Even the NIAS subject is studied for almost 15 years, the technique cannot be defined by neither legislators/law makers nor the research institutes/laboratories. To identify NIAS substances, all substances in the film are extracted by using a solvent. Then the solvent is analyzed by instrumental method to define the substances.

Because of there is no standard test method and solvent, different solvents and test methods are used to identify the NIAS substances. Depends on these differences, the results are different for each technique.

For all these reasons, NIAS still is a difficult subject.

We, Polinas Plastik Sanayii ve Ticaret A.S., make two different laboratories do risk assessment. NIAS substances in some of Polinas BOPET Films have been identified by using qualitative and quantitative test method. Some of the substances are listed on EU 10/2011 and some of them are not.

The amount of NIAS substances which is not seen in EU 10/2011 list, that may be accepted as 'non-authorized' or 'non-listed', in the said BOPET films. The migration amount may be calculated by using worst case scenario and should be < 0,01 mg to 1 kg food (The detection limit for non-authorized or non-listed substances acc to EU 10/2011).

We declare that NIAS substances in Polinas BOPET Films do not exceed the limit value. The said films are also analyzed for the toxicological evaluation by means of Cramer Classifications. The films have no substance which is classified in Cramer Toxicology Class.

REACH:

Under the REACH regulation, all the products of POLINAS (plastics films) are manufactured items obtained from polymers, and so exempted from REACH registration. (including February 16th update)

POLINAS have taken all the necessary steps to ensure that the chemical components from which POLINAS' products are obtained fulfill the obligation of the REACH registration, with specific requests of declarations from POLINAS' raw material suppliers.

Raw material suppliers to POLINAS are:

· Producers of Polymers
· Producers of Polymer Masterbatches (admixtures of Polymers and other components)

Polymers are exempted from the provisions of registration of Title II of REACH (Article 2(9)).

Polymer Masterbatches are considered, in regulatory terms, “preparations”, and are exempted from the provisions of registration.

Nevertheless, the obligation of registration of the individual chemical substances used by the raw material suppliers to POLINAS (Producers of Polymers and Producers of Polymer Masterbatches) goes down in the supply chain to the obliged parties that supply the base chemicals and monomers (namely, propylene monomer) to the Producers of Polymers and Producers of Polymer Masterbatches that are the present suppliers to POLINAS.

For UK REACH, same principles are applied and Polinas’ BOPET films are considered as “article” and exempt from UK REACH registrations.

SVHC:

Our BOPET film do not contain in their composition more than 0,1% (w/w) concentration of the substances listed in SVHC (substances very high concern), which is updated regularly by ECHA. New list is updated regularly, if necessary, on our web site.

HALAL/KOSHER STATUS:

According to the information received from our raw material suppliers, raw material used in BOPET film production do not contain any animal derived substances. For this reason, it can be considered as Halal/Kosher. However, Polinas BOPET plant has not been certified by any external authority for Halal/Kosher and we do not provide any certificate.

DISCLAIMER

When our films are converted, since conversion activity is out of Polinas’s control, it is our customers responsibility to assure regulatory compliance, recyclability and suitability for food contact. Polinas does not give any warranty/guaranty and do not accept responsibility for converted products about food contact compliance.

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Polinas R&D

Polinas

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