Polinas Plastik San. ve Tic. A.Ş.

Polinas Plastik Sanayi ve Ticareti A.Ş.
Manisa OSB 1. Kısım, Keçiliköy Mah.
Cumhuriyet Caddesi No:2 45030
Yunusemre/Manisa/Türkiye
Tel : +90 236 226 22 00
www.polinas.com

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# DECLARATION OF COMPLIANCE

We, Polinas Plastik Sanayi ve Ticaret A.Ş., hereby declare that **POLINAS BOPET PEELABLE** 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. USA :** American 21 CFR 174.5 (GMP for food contact materials and articles intended to come into contact with food)
**E.** FDA Section 21 CFR Ch. 177.1630 section (f), (g), (h)(1),(2) and (i), (j)
**F.** 21 CFR 175.105 Adhesives
**G.** 21 CFR 175.320 Resinous and polymeric coatings films
**H.** 21 CFR 175.320* Resinous and polymeric coatings for polyolefin films
**İ.** 21 CFR 176.170(b)* Components of paper and paperboard in contact with aqueous and fatty foods
**J.** 21 CFR 176.180 Components of paper and paperboard in contact with dry food
**K. 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)
**M. Swiss** Ordinance on materials and articles in contact with food (sr 817.023.21)
**N. Germany:** BgVV (ex BGA) Empfehlung XVII, BFR (July 2016)
**O. Italy:** D.P.R: 777/82 and D.M. 21/3/73 and amendments and changes,
**P. France:** Brochure n° 1227.

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 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**.

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**EU 10/2011:**

| **Solution** | | **Conditions** |
|---|---|---|
| 10% Ethyl alcohol solution | Simulant A | 40°C / 10 days + 100°C / 2h |
| 3% Acetic acid solution | Simulant B | 40°C / 10 days + 100°C / 2h |
| Vegetable oil | Simulant D2 | 40°C / 10 days + 100°C / 2h |

Results of the tests are available upon request. Tests are done biyearly.
Surface Volume ratio = 6 dm^2/kg food

**SPECIFIC MIGRATION LIMITS:**

During the production of our BOPET PEELABLE 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 amendments. 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.

| **FCM number** | ***Chemical Name*** | SML/SML T | ***Available at*** |
|---|---|---|---|
| 13326-263 | Diethyleneglycol | 30 mg/kg | Coated/uncoated |
| 16990-227 | Ethyleneglycol | | Coated/uncoated |
| 24910-785 | Terephthalic acid | 7,5 mg/kg | Coated/uncoated |
| 19150-291 | Isophtalic acid | 5 mg/kg | Coated/uncoated |
| 24970-288 | Dimethyl terephthalate (DMT) | 60 mg/kg | Coated/uncoated |
| 13395-484 | 2,2-bis(hydroxymethyl) propionic acid | 0.05 mg/kg | Coated |
| 13720-254 | 1.4 Butanediol | 5 mg/kg | Coated |
| 18700-361 | 1.6-Hexandiol | 0,05 mg/kg | Coated |
| 35760-398 | Antimony trioxide | 0,04 mg/kg | Coated/uncoated |
| 661-20-1 (cas number) | Isocyanade | 1 mg/kg | Coated |
| 68400-587 | Steary erucamide | 5 mg/kg | Coated/uncoated |
| Zin salt of 115 | Zinc Acetate | 5 mg/kg | Coated/uncoated |

**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** | **FCM Number** | **E Number** |
|---|---|---|
| Silicon dioxide | 504 | E551 |

**HEAVY METALS:**

The raw materials used in the production of said BOPET PEELABLE 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 PEELABLE 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 PEELABLE 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 peelable 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 the additives and PP homopolymers, terpolymers 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

**RECYCLING:**

BOPET PEELABLE 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 PEELABLE 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 PEELABLE 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 PEELABLE 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 PEELABLE films produced by Polinas.

**Chemical List of Proposition 65:**

We confirm that our BOPET PEELABLE 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 PEELABLE Films have been identified by using qualitative and quantitative test method. Some of the substances are listed on EC 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 PEELABLE 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 EC 10/2011).

We declare that NIAS substances in Polinas BOPET PEELABLE 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)

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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 Polinas' Peelable films are considered as "article" and exempt from UK REACH registrations.

**SVHC:**

Our BOPET PEELABLE 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 PEELABLE film production do not contain any animal derived substances. For this reason, it can be considered as Halal/Kosher. However, Polinas BOPET PEELABLE 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.

Ümit Sancar
Polinas R&D

Polinas

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