

**REGULATORY COMPLIANCE STATEMENT**  
**FOR FOOD CONTACT ARTICLES**

We, Polinas Plastik Sanayi ve Ticareti A.Ş. declare that,

**Polinas® BOPET Films PGX, PGM**

comply with the following legislations,

- A. Commission Regulation 10/2011 and its successive amendments up to and including 2020/1245, Regulation 1935/2004/EC and its amendment up to and including 2019/1381, Regulation 2023/2006/EC, American 21 CFR 174.5 (GMP for food contact materials and articles intended to come into contact with food)
- B. FDA Section 21 CFR Ch. 177.1630 section (f), (g), (h)(1),(2) and (i), (j)
- C. Japan: Food Sanitation Law and Japanese Positive Lists
- D. Germany: BgVV (ex BGA) Empfehlung XVII, BFR (July 2016)
- E. Italy: D.P.R: 777/82 and D.M. 21/3/73 and amendments and changes,
- F. France: Brochure n° 1227.
- G. China: GB 9685-2016 National Food Safety Standard – Standards for uses of additives in food contact material and product  
GB 4806.6-2016 National Food Safety Standard – Food Contact Plastic Resin  
GB 4806.1-2016 National Food Safety Standard – General safety requirement for food contact material and product  
GB 4806.7- National Food Safety Standard – Food Contact Plastic Material and Product
- H. Türk Gıda Kodeksi Gıda İle Temas Eden Plastik Madde Ve Malzemeler Tebliği (Tebliğ No: 2019/43 – 2019/44 – 25.12.2019 tarih ve 30989 Sayılı Resmi Gazete)
- J. 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. Technical regulation on positive list of additives For plastic materials destined to the elaboration of containers and equipment in food Contact
- K. SWISS ORDINANCE ON MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SR 817.023.21)



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The film contains the following substances subjected to restrictions in accordance with the laws above mentioned:

N° CAS	Component	SML/QM	Test results
0000111-46-6	Diethyleneglycol	30 mg/kg	< 5 mg/kg
0000107-21-1	Ethyleneglycol		
0000100-21-0	Terephthalic acid	7,5 mg/kg	< 1 mg/kg
0000121-91-5	Isophtalic acid	5 mg/kg	< 1 mg/kg
000120-61-6	Dimethyl terephthalate (DMT)	60 mg/kg	< 1 mg/kg
0004767-03-7	2,2-bis(hydroxymethyl)propionic acid	0.05 mg/kg	< 0.01 mg/kg
0005124-30-1	dicyclohexylmethane-4,4'-diisocyanate	ND (not detected) Content max 1 mg/kg	ND
PM REF:91530	Sulphosuccinic acid alkyl (C4-C20) or cyclohexyl diesters, salts	5 mg/kg	<1 mg/kg
0001309-64-4	Antimony trioxide	0,04 mg/kg (expressed as antimony)	< 0,02 mg/kg

### **OVERALL MIGRATION LIMITS:**

The film respects the limits of overall migration and specific migrations in the following conditions:

<b>Acetic acid 3%</b>	<b>(B simulant)</b>	<b>at</b>	<b>60°C / 10 days + 100°C / 4h</b>
<b>Ethyl alcohol 50%</b>	<b>(D<sub>1</sub> simulant)</b>	<b>at</b>	<b>60°C / 10 days + 100°C / 4h</b>
<b>Veg. oil containing less than 1% unsaponified matter</b>	<b>(D<sub>2</sub> simulant)</b>	<b>at</b>	<b>60°C / 10 days + 175°C / 2h</b>

The overall and specific migrations (including primary aromatic amines and metals according to Annex II of Regulation (EU) No 10/2011), whose the monomers or/and the additives are subjected, are respected in accordance with the usage conditions above mentioned. The assertion is supported by analytical tests, carried out in accordance with EC10/2011 and with the DM 21/03/73 or on the basis of calculations carried out considering the content of the substances subjected to migration limits. The computations have been arranged assuming that 1 kg of food comes in contact with 6 dm<sup>2</sup> of film.

This product complies with relevant requirements contained in the FDA Regulation part. 177.1630 and shall be applicable for the contact direct access to food products of the type of 21 CFR § 176 170 (c) Table 1 and with conditions for use of 21 CFR § 176.170 (c) Table 2.



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## **SPECIFIC MIGRATION OF HEAVY METALS:**

Specific migration analysis of *aluminum, ammonium, antimony, astatine, barium, cadmium, calcium, chromium, cobalt, copper, 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 which is the last amendment of EC10/2011, 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. Antimony is available as Sb<sub>2</sub>O<sub>3</sub> form, as declared by our raw material supplier.

## **SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINES:**

Specific migration of 22 Primary aromatic amines mentioned in 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.

### **Restrictions:**

To avoid colorants migration, avoid keeping in contact the film with the foodstuffs at temperature higher than 80°C.

The overall and specific migrations (including primary aromatic amines and metals according to Annex II of Regulation (EU) No 10/2011), whose the monomers or/and the additives are subjected, are respected in accordance with the usage conditions above mentioned. The assertion is supported by analytical tests, carried out in accordance with EC10/2011 and with the DM 21/03/73 or on the basis of calculations carried out considering the content of the substances subjected to migration limits. The computations have been arranged assuming that 1 kg of food comes in contact with 6 dm<sup>2</sup> of film.

*The above statement is valid only for the not metallized side.*

## **DUAL USE ADDITIVES:**

Our films contain following food additives

Chemical Name	Cas Number	PM Ref Number	E Number
Silicon dioxide	CAS no 7631-86-9	86240	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, PBB, PBDE and mercury, as declared by the suppliers. 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. 2009/48/EC (Safety of toys)
- b. Directive 94/62/EC on packaging and packaging waste is amended by Directive 2004/12/EC and 2018/852.
- c. ROHS Regulation (2011/65/EC) and its amendment 2015/863
- d. WEEE Regulation (2012/19/EC)

### **ABSENCE OF SUBSTANCE**

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

*Hazardous substances (reported in the "N" list of Directive 67/548/ECC and successive modifications), Epoxidic derivates (B.A.D.G.E. – B.F.D.G.E. – N.O.G.E.) (Directive 01/61/ECC and 05/1895/CEE), phthalates (as listed in Decision 99/815/EC, Decision 2004/781/EC and Regulation 1907/2006/EC), Di(2-ethylhexyl)phthalate (DEHP), melamine and cyanuric acid, alkylphenols, parabens, PVC, PVDC, latex, Substances derived from animal, vegetable and human sources, Acrylamide (CAS # 79-06-1), Substances regulated by Directives 96/5/CE and amendments (presence of pesticides as listed in Directive 2006/125/EC annex VI e VII), fluorinated substances, Gamma butirrolactone (GBL) CAS n. 96-48-0, bisphenol A (CAS 80-05-07) & F, benzene, toluene, acetylacetone CAS 123-54-6, titanium acetylacetonate CAS 17927-72, absence of Organic Tin Compounds, absence of halogenated compounds, nanotechnology, formaldehyde, photoinitiators, adipates and mineral oils, ozone depleting substances, PFOA (perfluorooctanoic acid), PFOS (perfluorooctane sulfonate), nano particles, MOSH/MOAH*

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

### **GMP:**

Polinas operates in conformity to the Good Practices of Manufacture according to European Regulation 2023/2006/CE

### **GMO – DIOXINE – RESTRICTIONS-ALLERGENS – RECYCLED RAW MATERIAL USAGE:**

According to the information received from our suppliers PET Chips, additives used for the production of 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.

**EC 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 EC **1169/2011** and its amendments.



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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 **EC 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 **EC 528/2012** is inapplicable.

### **RECYCLING:**

BOPET films can be recycled.

### **ENDOCRINE DISRUPTORS:**

We, Polinas Plastik Sanayi ve Ticareti A.S., hereby declare that the raw materials used in the production of the BOPP 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.

### **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/media/downloads/proposition-65//p65chemicalslistsingletable2021p.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 assesment.

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

Even the NIAS subject is studied for almost 15 years, the technique can not 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 analized 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 assesment. 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 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 films. The migration amount may be calculated by using worst case scenorio and should be < 0,01 mg to 1 kg food (The detection limit for non-authorized or non-listed substabces acc to EC 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 Toxigology Class.

### **REACH:**

Under the REACH regulation, all Polinas products are manufactured items which are obtained from polymers, and so exempted from REACH registration.

POLINAS have taken all necessary steps to ensure that 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 (admixture 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



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down in the supply chain to the obliged parties that supply the base chemicals and monomers to the Producers of Polymers and Producers of Polymer Masterbatches that are the present suppliers to POLINAS.

**SVHC:**

Our films do not contain substances of very high concern (SVHC) of the candidate list which is frequently renewed by ECHA. New list is updated regularly, if necessary, on our web site.