

**REGULATORY COMPLIANCE STATEMENT  
FOR FOOD CONTACT ARTICLES**

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

**Polinas® BOPET Film: PKC**

are suitable to come in contact with foodstuffs, being in conformity with:

**EEC Regulations and Directives:** 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

**U.S.A.:** F.D.A. Regulations Title 21 par. 177.1630 (April 2016):

- (f) (1) (i e ii) (2)

- (g) (1) (i e ii) (2)

- (h) (1) (ii) (2)

**Japan :** Food Sanitation Law

**Germany:** BgVV (ex BGA) Empfehlung XVII, BFR (July 2016)

**Italy:** D.P.R: 777/82 and D.M. 21/3/73 and amendments and changes,

**France:** Brochure n° 1227.

**Turkey :** Türk Gıda Kodeksi Gıda İle Temas Eden Plastik Madde Ve Malzemeler Tebliği (Tebliğ No: 2019/43 – 2019/44 - 25.12.2019 tarih 30989 nolu Resmi Gazete)

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

N° CAS	Component	SML
0000111-46-6	Diethyleneglycol	30 mg/kg
0000107-21-1	Ethyleneglycol	
0000100-21-0	Terephthalic acid	7,5 mg/kg
0000121-91-5	Isophtalic acid	5,0 mg/kg
000120-61-6	Dimethyl terephthalate (DMT)	60 mg/kg
126-30-7	2,2-dimethyl-1,3-propanediol	0,05 mg/kg
109-99-9	Tetrahydrofuran	0,6 mg/kg
75-21-8	Ethylene oxide	1 mg/kg
552-30-7	Trimellitic anhydride	5 mg/kg
146340-15-0	Alcohols, C12-C14 secondary, $\beta$ -(2-hydroxyethoxy), ethoxylated	5 mg/kg

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0005124-30-1	Dicyclohexylmethane-4,4'-diisocyanate	1 mg/kg
0001309-64-4	Antimony trioxide	0,04 mg/kg (expressed as antimony)

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

**Ethyl alcohol 10% (A simulant) at 60°C / 10 days + 100°C / 4h**

**Acetic acid 3% (B simulant) at 60°C / 10 days + 100°C / 4h**

**Refined olive oil (D<sub>2</sub> simulant) at 60°C / 10 days + 175°C / 2h**

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.

### **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.

### **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.

### **DUAL USE ADDITIVES:**

Our films contain following food additives

Chemical Name	Cas Number	PM Ref Number	E Number
Synthetic silica	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. **USA CONEG REGULATION**
- b. **2009/48/EC (Safety of toys)**
- c. **Directive 94/62/EC on packaging and packaging waste is amended by Directive 2004/12/EC.**
- d. **ROHS Regulation (2011/65/EC)**
- e. **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, asbestos, 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, American FDA regulation 21 CFR 174.5

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

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



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**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.

Polinas films are produced only from virgin resin and do not contain post-consumer recycled components, and no obligation exists under the **EC 282/2008**

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

### **RECYCLING:**

BOPET films can be recycled.

### **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.

Research Institues 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 institues/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.



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We, Polinas Plastik Sanayii ve Ticaret A.S., make two different laboratories do risk assesment. NIAS substances in some of Polinas BOPP and 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 OPP and 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 BOPP and 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 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.