



# Polinas

Polinas Plastik San. ve Tic. A.Ş.

Date: 26/09/2020

**REGULATORY COMPLIANCE STATEMENT  
FOR FOOD CONTACT ARTICLES**

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

**Polinas® BOPET Films KMP – KMPO- KMX - KMXE**

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

**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 (Jul 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/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

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

Organize Sanayi Bölgesi 45030 Manisa Türkiye T\_ +90 236 226 22 00 F\_ +90 236 233 25 25 www.polinas.com.tr



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<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.

Specific migration of metals:

<b>Acetic acid 3%</b>	<b>(B simulant)</b>	<b>at</b>	<b>60°C / 10 days and 100°C / 4h</b>
<b>Ethyl alcohol 50%</b>	<b>(D<sub>1</sub> simulant)</b>	<b>at</b>	<b>60°C / 10 days and 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>

### General list of migration limits for substances migrating from plastic materials and articles

<b>NAME</b>	<b>Salts allowed in accordance with Article 6(3)(a)</b>	<b>Specific (mg/Kg food or food simulant)</b>	<b>Remark</b>	<b>Test result (mg/Kg food simulant)</b>
Aluminum	yes	1 mg/kg		< 0,5
Antimony	no	0,04	<b>(2)</b>	< 0,02
Barium	yes	1		< 0,02
Cobalt	yes	0,05		< 0,02
Copper	yes	5		< 1
Iron	yes	48		< 1
Lithium	yes	0,6		< 0,02
Manganese	yes	0,6		< 0,02
Zinc	Yes	5 mg/Kg		< 1

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(2) The note in Annex I, Table 1, FCM No 398 applies: SML might be exceeded at very high temperature

The same simulants (B, D1, D2) and conditions as for OML, are used for SML testing for all food types, therefore SML testing with Tenax (Simulant E) for dry foods is not required at all. Migration test in simulant Tenax have not yet been carried out in compliance with the article 22 – Reg. 10/2011.

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. 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 and 2018/852.****d. ROHS Regulation (2011/65/EC)****e. WEEE Regulation (2002/96/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 derivatives (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 butyrolactone (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,

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photoinitiators, adipates and mineral oils, ozone depleting substances, PFOA (perfluorooctanoic acid), PFOS (perfluorooctane sulfonate), nano particles

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)

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

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

**252/2012 EC** (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 **2003/89 EC**.

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

**RECYCLING :**

BOPET films can be recycled.

**NIAS :**

Non-Intentionally added substances (NIAS) are under ongoing risk assessment using recognized method.

**REACH :**

Under the REACH regulation, all Polinas products are manufactured items which are obtained from polymers, and so exempted from REACH registration.(including February 16<sup>th</sup> update)

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)



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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.