



Polinas Plastik San. ve Tic. A.Ş.

Date: 01/06/2021

**REGULATORY COMPLIANCE CERTIFICATE**

We, Polinas Plastik Sanayi ve Ticaret A.Ş., hereby declare that the OPP films of the types:

**POLIKAP PVDC COATED FILMS 0Y26, 0X26, 0X48**

comply with the following legislations,

- A. Commission Regulation 10/2011 and its successive amendments up to and including 2020/1245**
- B. Regulation 1935/2004/EC and its amendment up to and including 2019/1381**
- C. Regulation 2023/2006/EC, American 21 CFR 174.5 (GMP for food contact materials and articles intended to come into contact with food)**
- D. FDA Section 21 CFR Ch. 175.300 and 176.170**
- E. 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)**

**OVERALL MIGRATION LIMITS:**

We confirm that for the production of 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 up to and including 2020/1245.

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 177.1520(c)1.1a (Polyolefins)

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

**EU 10/2011:**

10% Ethyl alcohol solution	Simulant A	10 days @ 60 °C
3% Acetic acid solution	Simulant B	10 days @ 60 °C
Veg. oil containing less than 1% unsaponified matter	Simulant D2	10 days @ 60 °C

**SPECIFIC MIGRATION LIMITS:**

During the production of our coated BOPP films, we use 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 up to and including 2020/1245. Theoretical calculation method was used according to latest EC directive of 10/2011 in order to find the level of specific migrations for the compounds below.

PM Ref Number	SML
68320	6 mg/kg
16600	ND(0.01) mg/kg
16630	
25210	
25240	

### **DUAL USE ADDITIVES:**

Our films may contain following food additives

Chemical Name	Cas or PM Ref Number	E Number
Mono/diglycerides of fatty acids	PM/Ref: 56486	E471
Synthetic silica	CAS no 7631-86-9	E551

### **HEAVY METALS:**

The raw materials used in the production of said coated OPP films, namely: PP homopolymers, PP copolymers, PP terpolymers, masterbatches and coatings, based on the above mentioned resins do not contain heavy metals such as cadmium, hexavalent chromium, lead, antimony, nickel, tin, arsenic, PBB, PBDE 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 coated OPP 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 coated OPP 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 (2012/19/EC)**

### **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.



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### **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.

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

According to the information received from our suppliers the additives and PP homopolymers, terpolymers and coating materials 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.

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 EC 528/2012 is inapplicable.

### **RECYCLING:**

BOPP films can be recycled.

### **PHTHALATES:**

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

In fact, Polypropylene films and BOPP in particular, do not need phthalates as modifier, plasticizer, additive, or processing aid. Phthalates in general, are peculiar modifiers, plasticizers, additives, or processing aids of plastics materials totally different from polypropylene. Even in the case of such (different) plastics



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materials, the food contact legislation allows anyhow the use of certain phthalates in food contact, stating in certain cases SML for their use.

During the production of catalysts for PP, Dibutyl phthalate (DBP) Diisobutyl phthalate (DIBP) or Bis(2-ethylhexyl) phthalate (DEHP) are used to improve the efficiency of the catalyst and those are essential for the control of isotacticity of polymer and therefore has major impact on mechanical properties of the final product

If completely surviving the polymerization process, the used phthalates could theoretically be present in concentrations of about 1 mg/kg in the final pellets. However, test results have shown phthalate values not exceeding 0,15 mg/kg PP and often even below the threshold of the analytical method of 0,01 mg//kg PP.

The potential residual traces of phthalates in polypropylenes are decades below the limits defined by REACH (0,1 wt%), thus no commercial polypropylene is subject to any restriction or ban in that respect.

The sunset date for these phthalates in 2015 does not prohibit the import or use of any products containing them in concentrations below 0.1 wt%.

As a reference, one of our film has been tested for DBP and DEHP in simulants A, B and D2 at 60C, 10 days. Results for those phthalates shown that it is well below the measurable limit of 0,1 mg/kg.

The following phthalates are absent in our film.

*Di(2-ethylhexyl) phthalate, n-butyl benzyl phthalate Octyl & Nonyl phthalates, Butyl Benzyl Phthalate, Diisodecylphthalate, Diisononylphthalate, Diisooctylphthalate, Dioctyl phthalate,*

### **Chemical List of Proposition 65:**

We certify that during the production of our films, we do not use or intentionally incorporate into them, any of the chemicals as restricted by Chemical Lists of Proposition 65 of the State of California and subsequent amendments. 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.

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.

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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 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 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 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 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 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 16<sup>th</sup> 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 (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 (namely; propylene monomer) to the Producers of Polymers and Producers of Polymer Masterbatches that are the present suppliers to POLINAS.



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**SVHC:**

Our BOPP, BOPET, CPP, Coated and Barrier Films 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.