



## **REGULATORY COMPLIANCE CERTIFICATE**

We, Polinas Plastik Sanayii ve Ticareti A.S., hereby declare that the OPP films of the types:

### **POLI-M 514, 519W, 525, GIFT-X, C11X, 515W, 524EF, 514O**

comply with the following legislations,

- A. **Commission Regulation 10/2011, that will be in force 1<sup>st</sup> May 2011,(See disclaimer below.)**
- B. **Commission Directive 2002/72/EC and its successive amendments up to and including 2009/975/EC**
- C. **Regulation 1935/2004/EC**
- D. **Regulation 2023/2006/EC (GMP for food contact materials and articles intended to come into contact with food)**
- E. **FDA Section 21 CFR Ch. 175.300 and 176.170**
- F. **Decreto Ministeriale 21.03.1973 and its subsequent amendments up to and including DM of 23.04.2009, No. 144**

Films were tested according to latest directives in the following simulant to obtain global migration values.

Olive Oil	10 days @ 40 °C
Distilled water	10 days @ 40 °C
3% acetic acid solution	10 days @ 40 °C
10% Ethyl alcohol solution	10 days @ 40 °C
Heptane	30 minutes @ 70 °F
Distilled water	24 hours @ 120 °F
10% Ethyl alcohol solution	24 hours @ 120 °F

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)

During the production of our BOPP films we use additives which are included in the incomplete list of additives in Annex I of EC Directive 10/2011

### **SPECIFIC MIGRATION LIMITS**

We inform that for some of the additives that are used during BOPP film production has Specific Migration Limits. We confirm that, according to our calculations, we do not exceed the specific migration limits.

<b>Chemical Name</b>	<b>Cas or PM Ref Number</b>	<b>SML</b>
Antioxidant	38820 – 38840 -68320	0,6 – 5 – 6 mg/kg
Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	83595	18 mg/kg

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*All the information given in this document is the best of our knowledge. Since the conditions under which our products may be used are beyond our control, Polinas A.Ş. makes no warranties and assumes no liability.*

Polinas Plastik Sanayii ve Ticareti A.S. Organize Sanayi Bölgesi 45030 - Manisa - Türkiye  
Tel: 90-236-2262200 Fax: 90-236-2332525 E-mail: info@polinas.com.tr



## **DUAL USE ADDITIVES :**

We confirm that our films may contain following food additives

Chemical Name	Cas or PM Ref Number	E Number
Synthetic silica	CAS no 7631-86-9	E551

## **HEAVY METALS :**

We declare that the raw materials used in the production of said OPP films, namely: PP homopolymers, PP copolymers, PP terpolymers, and masterbatches based on the above mentioned resins do not contain heavy metals such as, and not limited to: cadmium, hexavalent chromium, lead, antimony, nickel, tin, arsenic, PBB, PBDE and mercury, as declared by the suppliers of the above mentioned raw materials.

We also declare that neither the said heavy metals nor their compounds are intentionally added during the production of the said 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 OPP films comply with the following regulations:

- a. USA CONEG REGULATION
- b. CEN Standard EN 71/3 and its successive amendments.
- c. 1994/62/CE (Packaging Waste Management)
- d. ROHS Regulation (2002/95/EC)
- e. WEEE Regulation (2002/96/EC)
- f. 2003/11/EC

## **GMO – DIOXINE – 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)

1895/2005 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 :**

BOPP films can be recycled.

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## **ABSENCE OF SUBSTANCES :**

We declare that the raw materials used in the production of said OPP films do not contain the following substances, as also declared by the relevant raw materials suppliers:

*Latex, Bisphenol A&F, BHT, BHA, Polychlorinated biphenyls, Bis(2-ethylhexyl)phthalate, di(2-ethylhexyl) phthalate, 2-Ethylhexyl Acrylate, Polychlorinated naphthalates, n-butyl benzyl phthalate, 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, Octyl & Nonyl phthalates, Buthyl Benzyl Phthalate, Dibutyl Phthalate, Diethyl Hexyl Phthalate, CFC, HCFC, Pentachlorophenol, 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), HAP (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 Acetate (TAA)*

We also declare that neither the said substances are intentionally added during the production of the said OPP films, nor they are used, directly or indirectly, in the production process itself.

We certify that during the production of these products, 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.

## **REACH :**

Under the REACH regulation, all the products of POLINAS (plastics films) are manufactured items obtained from polymers, and so exempted from REACH registration.

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.

## **SVHC :**

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

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## **DISCLAIMER**

- *As it is written in 10/2011, in force on 1 May 2011, it contains a grace period (till 31 December 2012) that allows the implementation of the correct analysis procedures. In most of the cases, as indicated in the notes of the 10/2011, the 2002/72 SML limits have still legal validity.*
- *Until 31 December 2012, the 10/2011 accepts the results of the old methods and implementation of the new ones will take place between 1 January 2013 and December 2015).*
- *The 10/2011 will be completed during the grace period, with a more detailed description of test conditions and methods; the specific type of simulant to be used for testing a specific packaged foodstuff will have also to be indicated. Due to this reason, it is impossible for the time being to set up a comprehensive set of SML analysis.*
- *The standard food packaging materials commercially supplied by POLINAS comply with all the EU food contact conformity legislation in force at the date of this disclaimer.*

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