Polinas

Polinas Plastik San. ve Tic. A.Ş.

Polinas Plastik Sanayi ve Ticareti A.Ş.
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DECLARATION OF COMPLIANCE

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

TEAR TAPES

comply with the following legislations,

A. EU : Regulation 1935/2004/EC and its amendment including EU 2019/1381
B. Regulation 2023/2006/EC,
C. Commission Regulation EU 10/2011 and its successive amendments including EU 2026/245
D. TR : Türk Gıda Kodeksi Gıda İle Temas Eden Plastik Madde Ve Malzemeler Tebliği (Tebliğ No: 2019/44 – 2023/33 – 06.05.2024 tarih ve 32538 Sayılı Resmi Gazete)

OVERALL MIGRATION LIMITS:

Tear Tape Film of Polinas consists of PP film, ink and adhesive.

We confirm that for the production of tear tape films reffering to suppliers' declaration:

Film:

We use only monomers, starting substances and additives listed in the Union List of Authorized Substances of 10/2011 and its successive amendments .

Inks and adhesives:

Adhesive & coatings and inks are subject to the **EU framework Regulation (EC) 1935/2004** (materials and articles intended to come into contact with food).

This regulation refers specifically to food contact materials and articles rather than to inks and associated coatings. Key requirements are:

Article 3 (General requirements) require that 'Material and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food which could:

a) Endanger human health
b) Bring about an unacceptable change in the composition of the food
c) Brind about deterioration in the organoleptic characteristic thereof

This regulation refers to finished materials and articles i.e. the finished packaging. The ink manufacturer has a responsibility under the GMP Regulation (Article 3 above) to manufacture the inks under GMP and to formulate products which – if correctly applied – should allow the other members of the packaging chain - i.e. converter, packer/filler etc to meet their responsibilities under the legislation.

We confirm that inks are manufactured in accordance with ***the European Printing Ink Trade Association – EuPAI – Good Manufacturing Practice*** referring to ink supplier's declaration.

A copy of the Exclusion Policy for Printing Inks and related Products is available form the EuPIA website – http://www.eupia.org

Commission Regulation EC 2023/2006 – on good manufacturing practice for materials and articles intended to come into contact with food: The Annex refers to processes involving the application of printing inks formulated to the non-food contact side of a material or article.

Ink suppliers confirm that ink is manufactured in accordance with EuPIA 'Good Manufacturing practices for the production of packaging inks formulated for use on the non-food contact surfaces of food packaging and articles intended come into contact w,th food (GMP)'.

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (as amended): The European Commission has confirmed the legislation to relate to plastic packaging rather than to inks and associated coatings and adhesives.

Polinas confirms that "Tear Tape films" are suitable to be in contact with all food types.

SPECIFIC MIGRATION LIMITS:

Film does not contain any SML substances referring to suppliers' declarations.

Ink manufacturer supplies adequate information concerning potentially migratable substances along with the Swiss Ordinance status of the product via a statement of composition (SOC). These formulation – specific documents are available to customers following to signing of ink suppliers' mutual confidentiality agreement.

Following SML substances come from the adhesive given below.

Theoretical calculation method and worst case scenario were used to find the level of specific migrations for the substances below.

PM Ref Number	Restrictions
17260	SML (T)* = 15 mg/kg
18670	SML (T)* = 15 mg/kg
33801	SML* = 30 mg/kg
66755	SML* = 0,5 mg/kg
11500	SML= 0,05 mg/kg
- (acrylic acid, and its esters)	SML (T)* = 6 mg/kg

- (methacrylic acid, and its esters)	SML (T)* = 6 mg/kg
91530	SML* = 5 mg/kg
91815	SML* = 2 mg/kg
43730	SML* = 0,15 mg/kg
- (peroxides)	SML* = 0,05 mg/kg

*** adhesive's supplier declares for 19 gr/m2 coating (Polinas coating 5 gr/m2, 5 times lower than that of declaration): substances present at such a low concentration in the product that restrictions cannot be reached even assuming 100% migration in the worst case scenario.**
SML = Specific migration limit
SML (T) = Specific migration limit expressed as total of moiety or substances indicated

DUAL USE ADDITIVES:

Film does not include dual use additives.

Ink supplier's disclose dual use additives under a completed Non Disclosure Agreement, relevant adequate information on the composition in the ink.

Dual use additive come from the adhesive:

Chemical Name	Cas or PM Ref Number
Hexamethylenetetramine	PM/Ref: 18670

HEAVY METALS:

Film:
We confirm that PP film of tear tape does not contain heavy metals such as cadmium, hexavalent chromium, lead, antimony, nickel, tin, arsenic, PBB, PBDE and mercury, as declared by the suppliers of raw materials referring to suppliers' declaration.

Neither the said heavy metals nor their compounds are intentionally added during the production of the said PP 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 PP films comply with the following regulations:

a. USA CONEG REGULATION
b. 2009/48/EC (Safety of toys) and its amendment EU 2025/2509
c. Regulation 2025/40 on packaging and packaging waste amending Regulation EU 2019/1020 and Directive EU 2019/904, and repealing Directive 94/62/EC
d. ROHS Regulation (EU 2011/65) and its amendment EU 2023/1526
e. WEEE Regulation (EU 2012/19)

Ink:

Level of specific heavy metals present in packaging is restricted and additionaly require that certain dangerous substances be minimized by **The Packaging and Packaging Waste Directive 94/62/EC** (as amended). This directive relates to plastic packaging rather than to inks, coatings or adhesives.

Ink manufacturer's confirm that ink for tear tape film does not intentionally contain those heavy metals (cadmium, chromium (VI), lead or mercury) as specified in the Directive. The total content of these four metals present in a dried ink will be less than 100ppm limit.

As a result of this, the ink will support finished printed packaging materials in meeting with the requirements of **Directive EU 2025/40.**

SPECIFIC MIGRATION OF HEAVY METALS:

Film:

Specific migration analysis of *aluminum, ammonium, antimony, arsenic, barium, cadmium, calcium, chromium, cobalt, cupper, 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 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.

Ink:

Ink supplier declares that the limit of the following metals (soluable in 0.1 M hydrochloric acid) in the dried ink is as follow:

Antimony (Sb) < 60 ppm

Arsenic (As) < 25 ppm

Cadmium (Cd) < 25 ppm

Chromium (Cr VI) < 50 ppm

Lead (Pb) < 50 ppm

Mercury (Hg) < 12 ppm

Selenium (Se) < 50 ppm

The Packaging and Packaging Waste Directive EU 2025/40; The combined total of specified heavy metals: cadmium, chromium (VI), lead and mercury will not exceed 100 ppm referring to suppliers' declaration.

PPWR:

Polinas Tear Tapes meet the requirements of the Regulation 2025/40 Article 5 of the European Parliament and the Council of 19 December 2024 on packaging and packaging waste (PPWR).

The sum of the concentrations of lead, cadmium, mercury and hexavalent chromium does not exceed 100 mg/kg.
Our film comply with PFAS requirements of PPWR as stated below.

25 ppb **for any PFAS** as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification) , 250 ppb for **the sum of PFASs** measured as sum of targeted PFAS analysis, 50 ppm for PFAS **(total fluorine)**.

CONEG Regulation – This US legislation identifies the same heavy metals as does EU 2025/40. The combined 100 ppm limit is also the same.

GMO – DIOXINE – RESTRICTIONS-ALLERGENS – RECYCLED RAW MATERIAL USAGE-MICROPLASTICS, IRRADIATION:

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

EU 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 **EU 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 **EU 2022/1616.**

Our films do not contain nanoparticles, so **EU 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 **EU 528/2012** is inapplicable.

Our films do not contain Bisphenol A, and comply with Commission Regulation (EU) **2026/250** which is corrected regulation of **EU 2024/3190**.

(EU) 2019/1021 (persistent organic pollutants) and its latest ammendment : Our films do not contain the substances listed in Annexes I, II, III and IV.

All our raw materials are free from **microplastic** and we do not intentionally add it during the production process of our films. Hence our films are in compliance with **Entry 78 of Annex XVII REACH,** as introduced by **Commission Regulation (EU) 2023/2055**. Please note that this regulation does not cover microplastics coming from the fragmentation of our films in the environment by time .

We confirm that no Irradiation (ionizing, radiofrequency, ultraviolet, pulsed light radiation) is not applied to any material produced at Polinas

ABSENCE OF SUBSTANCES:

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

*Latex**, **Bisphenol A,S,F,AP,AF,B,BP,C,E,G,M,P,PH,TMC,Z**, BHT, BHA, Polychlorinated biphenyls, 2-Ethylhexyl Acrylate, Polychlorinated napthalates, 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, , CFC, HCFC, 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), PAH (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 Acetonate (TAA), 2-4 pentandione, pentabromodiphenyl ether, octabromo-diphenyl ether, halogenated compounds, conflict minerals (gold, wolframite, casserite, columbite-tantalite, and their derivative metals, which include tin, tungsten, and tantalum), active and intelligent substances, ozone depleting substances, PFOA (perfluorooctanoic acid), PFOS (perfluorooctane sulfonate), nano particles, Per- and Polyfluorinated Surfactants (PFS), - Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances, Perfluorooctane sulfonic acid (PFOS), its salts and PFOS-related compounds, Undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances, Polytetrafluoroethylene (PTFE, CAS No. 9002-84-0), Perfluorononanoic acid (PFNA), Perfluorohexane sulfonic acid (PFHxS), MOAH/MOSH/POSH, melamine, glycol ethers, polycarbonate, nitrosamine, mancozeb, cholecalciferol, Radioactive Substances,*

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 also would like to emphasize that we did not tested the films for such substances.

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.

Our films do not contain the below mentioned chemicals as declared by the relevant raw material suppliers: Substances identified as endocrine disruptors at EU level and included in the EU Endocrine disruptor list (List I) [https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu] except DBP and DIBP.

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/sites/default/files/media/downloads/proposition-65//p65chemicalslist.pdf

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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 16th 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 (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:

Our Tear Tape 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.

Ümit Sancar
Polinas R&D