

Conformity Declaration

Address: Ulaş OSB Mh. 105 Sok. NO:3/1 ERGENE-TEKİRDAĞ

Tel: (+90) 282 686 70 00

Fax: (+90) 282 686 12 12

Email: rd@polilux.com
marketing@polilux.com

Web site: www.polilux.com

Hereby we declare that our produced BOPP films (bi-oriented polypropylene) with trade names
TMK 811, TMJ 832, LPM 932

Have a composition that complies with the following requirements for food contact applications.

1. Commission Regulation (EU) No 10/2011 and its successive amendments up to 11 July 2023 including Regulation (EU) 2023/1442
2. Regulation (EC) No 1935/2004 and its amendment up to 20 June 2019 and including Regulation (EU) 2019/1381
3. Commission Directive 2002/72/EC and its amendment up to 19 October 2009 including Commission Regulation (EC) No 975/2009
4. Commission Regulation (EC) No 2023/2006 of 22 December 2006 (*on good manufacturing practice for materials and articles intended to come into contact with food*) amended by Commission Regulation (EC) No 282/2008 of 27 March 2008
5. Code of Federal Regulations, FDA Section 21 CFR 177.1520 and its amendment up to 20 May 2022
6. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
7. France Decree no. 2020-105 of February 10, 2020 relating to the fight against waste and the circular economy (*Decree of September 28, 2023, ANNEX I- list of substances presenting endocrine disruptive properties mentioned in I AND II OF ARTICLE L. 5232-5 OF THE PUBLIC CODE*)
8. French Decree no. 2007-766 of May 10, 2007 implementing the Consumer Code with regard to materials and objects intended to come into contact with foodstuffs.
9. Switzerland- Amendment of Regulation SR 817.023.21 of the EDI on Materials and Articles Intended to Come into Contact with Foodstuffs

OVERALL MIGRATION:

EUROPEAN UNION:

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 23 September 2020 including Regulation (EU) 2020/1245.

Reference	Food Simulant	Abbreviation	Time & Temperature
EU	Acetic acid 3 % (w/v)	Simulant B	10 days, 50°C
	Vegetable oil	Simulant D2	
	Ethanol 50 % (v/v)	Simulant D1	10 days, 40°C

☒ authorized maximum limits defined in EC Directive 2002/72/E and EU Regulation 10/2011:

Regulatory Compliance Certificate

Doc No: TS19

Review Date: 16.05.2018

Revision Date: 25.09.2024

Revision No: 22

- for aqueous simulants: 10 mg/dm² with an analytical tolerance 2 mg/dm²
- for fatty simulants: 10 mg/dm² with an analytical tolerance 3 mg/dm²

SPECIFIC MIGRATION:

The same simulants as for OML are used for SML testing and the results for the specific migration of chemical substances mentioned in the table is below the limit values.

Chemical Substance	Food Simulant	Abbreviation	SML (mg/kg)
Ref No: 39090	Vegetable oil	Simulant D2	1.2
CAS No : 002082-79-3 / Ref No: 68320	Vegetable oil	Simulant D2	6
PAA's (primary aromatic amines)	Acetic acid 3 % (w/v)	Simulant B	0.002
Aluminum	Acetic acid 3 % (w/v)	Simulant B	1
Ammonium			-
Antimony			0.04
Arsenic			N.D
Barium			1
Cadmium			N.D
Calcium			-
Chromium			N.D
Cobalt			0.05
Copper			5
Europium			0.05
Gadolinium			0.05
Iron			48
Lanthanum			0.05
Lead			N.D
Lithium			0.6
Magnesium			-
Manganese			0.6
Mercury			N.D
Nickel			0.02
Potassium			-
Sodium			-
Terbium			0.05
Zinc			5
N.D: Not Detectable			

United States of America (FDA):

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 (Olefin polymers)

Reference	Extract in Solvents	Time & Temperatuer
FDA	n-hexane	(2 hours at reflux)
	xylene	(dissolving in 120 °C cooling at 25 °C)

- ☒ authorized maximum limits set by paragraph (a)(1)(ii) Code of Federal Regulations 177.1520
- n-hexane : 6.4%
 - Xylene : 9.8%

The results for the extraction tests are below the limit values given inFDA21CFR177.1520

DUAL USE ADDITIVES:

We confirm that in the above mentioned films there are no food additives or flavorings subject to a restriction in food.

Our films contain the following food additives that may be used in the manufacture of plastic material and articles and comply with Annex III DIRECTIVE 2002/72/ EC as amended by Commission Regulation (EC) No 975/2009.

Chemical Substance	CAS number	Ref Number	E Number
Synthetic silica	007631-86-9	86240	E551

HEAVY METALS:

The heavy metals, cadmium, lead, mercury and chromium VI are not intentionally used for the production of our PP films. The sum of the heavy metals incidentally present in our mentioned products are below 100 ppm as declared by the raw material suppliers. Therefore our films comply with the following regulations:

- Directive 94/62/EC on packaging and packaging waste is amended by Directive (EU) 2018/852
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)
- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)

NIAS:

Non-intentionally added substances (NIAS) comprise all substances that have not been added for a technical reason during manufacturing of food contact materials and articles. They have various sources and can be grouped into side products, breakdown products, and contaminants.

We declare that no intentionally added substances are formed or introduced in the manufacture or formulation of **POLILUX** products and NIAS do not exceed the limit value in our BOPP Films.

EPOXY Derivatives:

We confirm that our films comply with Commission Regulation (EC) No 1895/2005/ EC, on the restriction of use of certain epoxy derivatives in materials and articles intended to come in to contact with food. Epoxy derivatives including:

- **BADGE** [Bisphenol-A diglycidyl ether]
- **BADGE, H2O** [Bisphenol-A (2,3-dihydroxypropyl) glycidyl ether]
- **BADGE.2 H2O** [Bisphenol-A bis(2, 3-dihydroxypropyl ether)]
- **BADGE.HCL** [Bisphenol –A (3-chloro-2-hydroxyprpyl glycidyl ether)]
- **BADGE.H2O.HCL** [Bisphenol –A (3-chloro-2-hydroxyprpyl) - 2, 3-dihydroxypropyl ether]
- **BADGE.2HCL** [Bisphenol-A (3-chloro-2-hydroxyprpyl ether)]
- **BFDGE** [Bisphenol-F (diglycidyl ether)]
- **NOGE** [novolac glycidyl ether]

ALLERGENS:

Our films do not contain any allergic substances and we hereby confirm that our film complies with EC 1169/2011 and its amendments.

PHTHALATES:

Polypropylene films, do not need phthalates as modifier, plasticizer, additive, or processing aid. We confirm that no phthalates are intentionally added to BOPP films produced by POLILUX and our films comply with the Regulation (EU) No 10/2011 amended by Regulation (EU) 2023/1442 (11 July 2023).

- **PBB** (Polybrominated biphenyls)
- **PBDE** (Polybrominated diphenyl ethers)
- **DEHP** (Bis(2-ethylhexyl) phthalate)
- **BBP** (Butyl benzyl phthalate)
- **DBP** (Dibutyl phthalate)
- **DIBP** (Diisobutyl phthalate)

Nanomaterial:

We declare that our BOPP films have a composition that complies with Commission Recommendation 2011/696/EU on the definition of nanomaterial.

GMO (Genetically Modified Organism):

We confirm that our films manufactured from starting substances or additives which are not in grade genetically modified organism.

OTHER ABSENCES:

The raw materials used in the production of Polilux films do not contain the following substances, as declared by the raw materials suppliers. So we do not intentionally add the substances listed below in manufacturing of our BOPP films.

- Acetaldehyde
- Acetyl acetone
- Active and intelligent materials and article
- Acryl amide
- Acrylonitrile
- Alkyl benzenes
- Alkyl phenols (APs)
- Alkyl tin derivatives
- Ammonia
- Anthraquinone
- Antimony
- Antimony trioxide
- Aromatic amines
- Asbestos
- Arsenic
- Asbestos
- Azo colorants
- Azo compounds
- Azodicarbonamide
- Benzene
- Benzidine
- Benzoic acid
- Benzophenone
- Benzonitrile
- Benzyl butyl phthalate
- Benzyl Phenol
- Biocides
- Bisphenol-A (BPA)
- Bisphenol A diglycidyl ether (BADGE)
- Bisphenol-B (BPB)
- Biphenyl-4-ylamine
- Dioxins
- Disodium metasilicate
- Epichlorhydrin (ECH)
- Epoxidised Soya Bean Oil (ESBO)
- Epoxy derivatives
- Ethers de glycol
- Ethyleneimine
- Ethyl benzene
- Ethyl benzoate
- Formaldehyde
- Glycol ethers
- Glyoxal Heavy metals-based pigments
- Heavy metals including Aluminum, Barium, Cobalt, Copper, Iron, Lithium, Manganese, and Zinc
- Bisphenol-F (BPF)
- bisphenol F diglycidyl ether (BFDGE)
- Bisphenol-S (BPS)
- Black Carbon
- Brominated flame retardants
- Bumetrizole
- Butyl benzoate
- Butylated Hydroxyanisole (BHA)
- Butylated Hydroxytoluene (BHT)
- Carbon black
- Carcinogenic and mutagenic compounds
- Chlorine
- Chloroalkanes
- Chlorobenzenes
- Chlorofluorocarbons (CFC)
- Chlorophenols (TCP-PCP)
- Chloropropanols
- Cholecalciferol CAS N° 200-673-2
- CMR substances
- CRM compounds
- DEAB (= 4,4'- Bis(diethylamino)benzophenone)
- Dibutyl phthalate
- Di(ethylhexyl) adipate (DEHA)
- Di(ethylhexyl) maleate (DEHM)
- Di-isopropyl naphthalenes (DIPN)
- Diantimony trioxide
- Diarsenic pentaoxide
- Diarsenic trioxide
- Dibutyl sebacate (DBS)
- 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one
- Dimethyl Fumarate (DMF)
- Dinitrogen oxide
- Endocrine disrupting substances
- Organo-tin compounds:
 - Dibutyl-tin (DBT)
 - Monobutyl-tin (MBT)
 - Tributyl-tin (TBT)
- O-toluidine
- Oxygen absorbers
- p-(1,1-dimethylpropyl) phenol
- Palm Oil and its derivatives
- Paraben
- Parachlorobenzotrifluoride (PCBTF)
- Paraffin wax CAS N° 8002-74-2

Regulatory Compliance Certificate

Doc No: TS19

Review Date: 16.05.2018

Revision Date: 25.09.2024

Revision No: 22

- 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol
- Hexabromocyclododecane (HBCDD)
- Hexamethylenetetramine
- Hydroquinone
- Linear Alkylbenzenes
- Mancozeb CAS number 8018-01-7
- Melamine
- MEK (Methyl Ethyl Ketone or 2- butanone)
- MIBK (Methyl Isobutyl Ketone)
- Michler's ketone
- Mineral oils including:
- POSH (polyolefinic oligomeric saturated hydrocarbons)
- MOAH (Mineral Oil Aromatic Hydrocarbon)
- MOSH (Mineral Oil Saturated Hydrocarbon)
- Nanoparticles
- NETSA (N-ethyl toluene sulfonamide)
- Nitrate
- Nitrite de sodium
- Nitrocellulose
- Nitrosamine (freenitrosamines, N- nitrosable substances)
- Nitrofurazone
- Nonylphenols
- Nonylphenol ethoxylate
- Nonylphenol and its derivatives
- novolac glycidyl ethers (NOGE)
- O-aminoazotoluene
- O-anisidine
- Octabromodiphenyl ether
- Octyl tin chemicals
- Optical brighteners
- Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol
- Perchloric acid, salts
- Phthalates (including DEHP and DBP)
- Poly & Perfluoroalkyl substances
- Polyhydroxyalkanoates
- POSH (Polyolefin oligomeric saturated hydrocarbons)
- POPs (Persistent Organic Pollutants)
- Primary aromatic amines
- Rhodamine-based pigments
- Pyrene
- Recycled products by Regulation (EC) 2022/1616
- Salicylic acid (FCM No 121)
- Semi-carbazide compounds
- Silicic acid, sodium salt
- Sintered expanded polystyrene (EPS)
- Para-phenylenediamine (PPD)
- Pentabromodiphenyl ether
- Pentachlorophenol
- Pentachlorothiophenol (PCTP)
- per- and polyfluoroalkyl compound substances (PFAS)
- Perchlorate
- Perfluorinated tenside (PFT)
- Perfluorooctane sulfonate (PFOS)
- Perfluorooctanoic acid (PFOA)
- Perfluorobutane sulfonic acid (PFBS)
- Phenanthrene
- phenols
- PhenylPhenole
- Photoinitiators
- Phthalates
- Plasticisers
- Poly (aromatic hydrocarbons)
- Polyacrylonitrile
- Polybrominated biphenyls (PBBs)
- Polybrominated diphenyl ethers (PBDEs)
- Polybrominated terphenyls (PBTs)
- Polycarbonate
- Polychloride dibenzo-p- furan (PCDF)
- Polychloride biphenyl (PCB)
- Polychloride dibenzo-p-dioxin (PCDD)
- Polychlorinated biphenyls (PCBs)
- Polychlorinated naphtalenes (PCNs)
- Polychlorinated diphenyl ethers (PCDEs)
- Polychlorinated terphenyls (PCTs)
- Polycyclic aromatic hydrocarbons [PAHS (I.E Benzo(a)pyrene, benzo(a)anthracene, chrysene, benzo(b)fluoranthene)]
- Polyethylene Glycol (PEG)
- Polytrimethylene naphthalate (PTN)
- Polyglycolic acid (PGA)
- Polystyrene
- Polyvinyl Chloride
- Polylactic acid
- Polycarbonates
- 2,4-Pentanedione with CAS number 123-54-6
- 2-Isopropylthioxanthone (ITX) with CAS number 5495-84-1
- 4-Methylbenzophenone with CAS number 134-84-9
- 6-amino-2-ethoxynaphthaline with CAS number 293733-21-8
- 4-amino-3-fluorophenol
- 4-aminoazobenzene with CAS number 60-09-3
- 4-chloroaniline with CAS number 106-47-8
- 4-chloro-o-toluidine with CAS number 95-69-2

Regulatory Compliance Certificate

Doc No: TS19

Review Date: 16.05.2018

Revision Date: 25.09.2024

Revision No: 22

- Styrene
- Short chained chlorinated paraffins
- Sodium bromide
- Sodium fluoride
- Sodium metasilicate nonahydrate
- Sodium metasilicate pentahydrate
- Synthetic latex
- Radioactive substances, as defined by Directive 96/29/Euratom (In 1223/2009)
- Silicone
- Tertiary Butylhydroquinone (TBHQ)
- Toluene
- Thiobenzoate
- Thiuram mix
- Titanium Acetyl Acetone (TAA)
- Titanium Dioxide
- 2,4,6-tri-tert-butylphenol
- Tributyltin
- Trichloroethylene
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether)
- triphenyl phosphate CAS 115-86-6
- tri-o-cresyl phosphate CAS 78-30-8
- tri-m-cresyl phosphate CAS 563-04-2
- tri-p-cresyl phosphate CAS 78-32-0
- Tris(2-chloroethyl) phosphate (TCEP)
- Tris (4-nonylphenyl, branched and linear) phosphite (TNPP)
- Tris(nonylphenyl)phosphite
- Toluene
- Untreated wood flour or fibres from a specific wood:
 - FCM No. 1080 (triethanolamineperchlorate, sodium salt)
 - FCM No. 1081 (N, N-bis (2-hydroxyethyl) stearylamine partially esterified with saturated C16/C18 fatty acids)
 - FCM No. 1082 (Phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate)
 - FCM No. 1083 (BTDA)
- Vinyl acetate
- Vinyl chloride monomer (VCM) and its polymers or copolymers:
 - Polyvinylidene chloride (PVDC)
 - Chlorinated polyvinyl chloride (CPVC)
 - Vinyl chloride monomer (VCM)
 - Vinyl chloride polymer (PVC)
 - Vinylidene Chloride (VDC)
 - Vinyl chloride
- Xylene
- Zinc di(acetate)
- 1-3 Butadiene with CAS number 106-99-0
- 3,3'-d-dichlorobenzidine with CAS number 91-94-1
- 3,3'-dimethoxybenzidine with CAS number 119-90-4
- 3,3'-dimethylbenzidine with CAS number 119-93-7
- 6-methoxy-m-toluidine with CAS number 120-71-8
- 4-methoxy-m-phenylenediamine with CAS number 615-05-4
- 4,4'-methylenebis(2-chloroaniline) with CAS number 101-14-4
- 4,4'-methylenedianiline with CAS number 101-77-9
- 4,4'-methylenedi-o-toluidine with CAS number 838-88-0
- 4-methyl-m-phenylenediamine with CAS number 95-80-7
- 2-naphtylamine with CAS number 91-59-8
- 5-nitro-o-toluidine with CAS number 99-55-8
- 4,4'-oxydianiline with CAS number 101-80-4
- 4,4'-thiodianiline with CAS number 139-65-1
- 2,4,5-trimethylaniline with CAS number 137-17-7
- 2,6-xylidine with CAS number 87-62-7
- 2,4-xylidine with CAS number 95-68-1

- All the chemicals found in the EUPIA exclusion list:

- Titanium
- Lithium
- Iron
- Silicium
- Chromium
- Zinc
- Copper
- Manganese
- Nickel
- Thallium
- Beryllium
- Tin
- Lead
- Barium
- Cobalt
- Chromium VI
- Polychlorobiphenyls (PCBs)

SVHC:

We confirm that our BOPP 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 on **27 June 2024** by ECHA (European Chemicals Agency).

RECYCLING:

Our films are produced only from virgin resins and do not contain post-consumer recycled components, and no obligation exists under the 2022/1616/EC.

We declare that our products do not contain any out-sourced recycled material and we only use in-house recycled material in our production at a limited percentage.

Also, we declare that our BOPP films can be recycled.

Specification of the intended use or restrictions:

- ❖ Foodstuffs can be put in contact with these films by considering BOPP specifications.
- ❖ Customers must check that our films are safe and technically suitable in their applications.

➤ *This Declaration is valid starting from the issue date, and will be modified in the case of significant modification in our products formula structure or in the case of legislation amendments.*