

Conformity Declaration

Address: No.6, Riahi St., Karaj Makhsous Road, Tehran, Iran

Postal Code: 13919-47611

Tel: +98 (0) 21 44 63 44 00- 7

Fax: +98 (0) 21 44 64 02 24

Email: Sales@polfilm.net

RD@polfilm.net

Marketing@polfilm.net

Web site: www.polfilm.net

Hereby we declare that our produced BOPET films (Bi axially oriented Polyethylene terephthalate) 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 31 August 2023 including EU 2023/1627
2. Regulation (EC) No 1935/2004 and its amendment Regulation (EU) 2019/1381 and its latest consolidated version on 27 March 2021
3. Commission Directive 2002/72/EC and its amendment up to 28 January 2011 including Commission Directive 2011/8/EU
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 174.5 On general provisions applicable to indirect food additives under conditions of good manufacturing practice (GMP)
6. Code of Federal Regulations, FDA Section 21 CFR 177.1630 and its amendment up to Aug 30, 2024.
7. 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
8. 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)
9. 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.
10. Switzerland- Amendment of Regulation SR 817.023.21 of the EDI on Materials and Articles Intended to Come into Contact with Foodstuffs

OVERALL MIGRATION:**EUROPEN 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 31 August 2023.

Reference	Food Simulant	Abbreviation	Time & Temperatuer
EU	Acetic acid 3 % (w/v)	Simulant B	40°C / 10 days + 100°C / 4h
	Ethanol 50 % (v/v)	Simulant D1	40°C / 10 days + 100°C / 4h
	Vegetable oil	Simulant D2	40°C / 10 days + 175°C / 2h

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

- 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:**→ Chemical Substances:**

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	CAS No	Ref. No	SML (mg/kg)
Terephthalic acid	100-21-0	24910	7.5
Isophthalic acid	121-91-5	19150	5
Monoethyleneglycol (MEG)	107-21-1	16990	30
Diethyleneglycol (DEG)	111-46-6	13326	30
Antimony trioxide	1309-64-4	35760	0.04
Acetaldehyde	75-07-0	10060	6
Formaldehyde	50-00-0	17260/ 54880	15

→ Primary Aromatic Amines

Specific migration of Primary aromatic amines mentioned in EU 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.

→ Metals

Specific migration of metals were analyzed in acetic acid 3% (Simulant B, 10 days@60°C) according to Annex II of Directive (EU) No 10/2011.

The results for the specific migration of metals mentioned in the table is below the limit values.

Chemical Substance	Food Simulant	Abbreviation	SML (mg/kg)
Aluminum	Acetic acid 3 % (w/v)	Simulant B	1
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 177.1630 (Polyethylene phthalate polymers).

Reference	Chloroform soluble fraction of	Time & Temperature
FDA	(i) Distilled water	212 deg. F for 2 hours
	(ii) n- Heptane	150 deg. F for 2 hours
	iii) 50 % ethyl alcohol	120 deg. F for 24 hours

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.

Chemical Substance	CAS number	Ref Number	E Number
Silicon dioxide	7631-86-9	86240	E551

HEAVY METALS:

The heavy metals, cadmium, lead, mercury and chromium VI are not intentionally used for the production of our PET 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 **PET** products and NIAS do not exceed the limit value in our BOPET Films.

1) EPOXY Derivatives :

According to 1895/2005/ EC (Directive 01/61/ECC and 05/1895/CEE) the epoxy derivatives include BADGE, BFDGE AND NOGE are not intentionally used during the production.

- Bisphenol A Di- Glycidyl ether (BADGE)
- 2, 3-dihydroxypropyl ether (BADGE, H₂O)
- 2, 3-dihydroxypropyl glycidyl (BADGE.2 H₂O)
- 3-chloro-2-hydroxypropyl glycidyl (BADGE.HCl)
- 3-chloro-2-hydroxypropyl ether (BADGE.2HCl)
- (3-chloro-2-hydroxypropyl) -2, 3-dihydroxypropyl ether (BADGE.H₂O.HCl)
- Bis (4-hydroxyphenyl) methane (BFDGE)
- Novolac glycidyl ethers(NOGE)

2) PHTHALATES:

The phthalates (as listed in Decision 99/815/EC, Decision 2004/781/EC, Regulation 1907/2006/EC and Commission Regulation (EU) 2018/2005) are not intentionally added in the above mentioned films. However DIBP, DBP, DEP and ethyl isobutyl phthalate could be as minor components; maximum residuals are no more than 15 ppm.

- Bis (2 ethylhexyl) phthalate (DEHP)
- Dibutyl phthalate (DBP) Benzyl butyl phthalate (BBP)
- Di isononyl phthalate (DINP) Di- isodecyl phthalate (DIDP)
- Di-n-octyl phthalate (DNOP)
- Di-n-hexyl phthalate (DNHP)
- Di-n-ethyl phthalate (DEP)
- Di-n-methyl phthalate (DMEP)
- Di-n-pentyl phthalate (DPEP)

3) ALLERGENS:

Our films do not contain any allergic substances and we hereby confirm that our film complies with 2000/13/EC, amended with 2003/89 EC, 2007/68/ EC.

4) Nanomaterial:

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

5) GMO (*Genetically Modified Organism*):

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

6) OTHER ABSENCES:

We declare that in the recipes of films are not intentionally added the substances listed below:

- 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
- Benzotrile
- Benzyl butyl phthalate
- Benzyl Phenol
- Biocides
- Bisphenol-A (BPA)
- Bisphenol A diglycidyl ether (BADGE)
- Bisphenol-F (BPF)
- bisphenol F diglycidyl ether (BFDGE)
- Bisphenol-S (BPS)
- Black Carbon
- Brominated flame retardants
- Bumetizole
- 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)

- 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
- 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
- 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
- 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 naphthalenes (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)

- 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)
- 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
- Tributylamine
- 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)
- 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-ethoxynaphthalene 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
- 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-naphthylamine 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-xylydine with CAS number 87-62-7
- 2,4-xylydine with CAS number 95-68-1

- 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

- All the chemicals found in the EUPIA exclusion list:
 - Titanium
 - Lithium
 - Iron
 - Silicon
 - Chromium
 - Zinc
 - Copper
 - Manganese
 - Nickel
 - Thallium
 - Beryllium
 - Tin
 - Lead
 - Barium
 - Cobalt
 - Chromium VI
 - Polychlorobiphenyls (PCBs)

REACH / SVHC:

We hereby declare that our products fully comply with the European Union's 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).

- Our products do not contain any of the Substances of Very High Concern (SVHC) above the specified concentrations, as defined in Article 57 and Annex XIV (including all amendments).
- Our products do not contain any of the restricted substances, as defined in Article 67 and Annex XVII (including all amendments).

RECYCLABILITY:

BOPET films can be recycled.

Specification of the intended use or restrictions:

- ❖ Foodstuffs can be put in contact with these films by considering BOPET 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.*

This document is electronically generated and is valid without signature.