

Conformity Declaration

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Hereby we declare that our produced BOPP films (bi-oriented polypropylene) with trade names

TBK 121, TBA 131, TBJ 131, LRT 13, LPB 132, LPO 532, TOK 521, TMK 721

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 and including 2019/1338
2. Regulation (EC) No 1935/2004
3. Directive 2002/72/EC
4. Code of Federal Regulations , FDA Section 21 CFR 177.1520

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 and including 2019/1338.

Reference	Food Simulant	Abbreviation	Time & Temperatuer
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:

- 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

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 in FDA 21 CFR 177.1520

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)
CAS No : 71786-60-2 Ref No: 39090	Vegetable oil	Simulant D2	1.2
CAS No : 002082-79-3 Ref No: 68320	Vegetable oil	Simulant D2	6
PAAs (primary aromatic amines)	Acetic acid 3 % (w/v)	Simulant B	0.01
Barium (Ba)	Acetic acid 3 % (w/v)	Simulant B	1
Cobalt (Co)			0.05
Copper (Cu)			5
Iron (Fe)			48
Litium (Li)			0.6
Manganese (Mn)			0.6
Zink (Zn)			25

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 DIRECTIVE 2004/19/EC.

Chemical Substance	CAS number	Ref Number	E Number
Mono/diglycerides of fatty acids	-	30610	E471
Synthetic silica	007631-86-9	86240	E551

HEAVY METALS:

The sum of the heavy metals cadmium, lead, mercury and chromiumVI incidentally present in this product is below 100 ppm as declared by the raw material suppliers and our films, therefore, comply with the limits set out in EC Directive 94/62/EC (Article 11) on packaging and packaging waste (amended with Directive 2004/12/EC, Directive 2005/20/EC and Regulation (EC) No 219/2009).

- ❖ The following substances are not intentionally used in the manufacture or formulation of **POLILUX** products.

1) EPOXY Derivatives : (include BADGE, BFDGE AND NOGE)

According to 1895/2005/ EC these substances are not intentionally used.

2) PHTHALATES:

The phthalates 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.

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) OTHER ABSENCES:

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

Acetyl acetone	Biocides	Formaldehyde	Organo-tin compounds
Acryl amide	Bisphenol A	ITX	PFOA/PFOS
Aromatic amines	CMR substances	Latex	PVC/PVDC
Asbestos	Dimethyl fumarate	Melamine	Triclosan
Azocolorants	Dioxins and furans	Nanoparticles	Vinyl chloride
Benzophenone	ESBO	Nonylphenol	
BHA, BHT	Flame retardants	nonylphenol ethoxylate	

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 regularly by ECHA (European Chemicals Agency).

RECYCLABILITY:

All POLILUX BOPP films are recyclable and can be effectively disposed of through incineration. Full combustion of polypropylene yields almost entirely carbon dioxide and water.

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.*