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Conformity Declaration

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Hereby we declare that our produced BOPP films (bi-oriented polypropylene) with trade names **POLABLE 141 WA8, POLABLE 542 L86, POLER 381 S, 381 D2 & POLET 142 NM8** have a composition that complies with the following requirements for food contact applications.

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1. Commission Regulation (EU) No 10/2011 and its successive amendments up to 23 September 2020 including Regulation (EU) 2020/1245
2. Regulation (EC) No 1935/2004 and its amendment up to 20 June 2019 and including Regulation (EU) 2019/1381
3. Commission Regulation (EC) No 2023/2006 and its amendment up 27 March 2008 and including Commission Regulation (EC) No 282/2008 (*GMP for materials and articles intended to come into contact with food*)
4. Commission Directive 2002/72/EC and its amendment up to 19 October 2009 including Commission Regulation (EC) No 975/2009
5. Code of Federal Regulations , FDA Section 21 CFR 177.1520 and its amendment up to 20 May 2022

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:

- 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)
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	0.002
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
Calcium carbonate	00471-34-1	-	E170
Titanium dioxide	0013463-67-7	93440	E171

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 **POLFILM** 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:

We confirm that our films comply with the Directive 2011/65/EC amended by Directive (EU) 2020/366. Referred to Annex II of RECAST, below-mentioned restricted substances do not exceed the limit value (0.1%) in our BOPP Films

- **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 POLFILM 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.

- Acetyl acetone
- Active and intelligent materials and article
- Acryl amide
- Acryl amide
- Aromatic amines
- Asbestos
- Azo colorants
- Benzene
- Benzophenone
- Benzonitrile
- Benzyl butyl phtalate
- BHA, BHT
- Brominated flame retardants
- Carbon black
- CRM compounds
- Chlorophenols
- Chlorofluorocarbons (CFC)
- Hydrochlorofluorocarbons (HCFC)
- Hydrofluorocarbons (HFC)
- 2-ethylhexanoic acid
- Dimethyl fumarate
- Dioxins and furans
- Epoxidised Soya Bean Oil (ESBO)
- Ethyl benzene
- Flame retardants
- Formaldehyde
- Genotoxic substances
- ITX
- Latex
- Melamine
- Microplastics
- Nanoparticles
- Nonylphenol
- Nonylphenol ethoxylate
- Mineral Oil Aromatic Hydrocarbon (MOAH)
- Mineral Oil Saturated Hydrocarbon (MOSH)
- Nitrate
- Nitrosamine
- Organic Tin Compounds (tributyl or triphenyl tin)
- Perfluorooctanoic acid(PFOA)
- Perfluorooctane sulfonate (PFOS)
- Polybrominated biphenyls
- Polybrominated diphenylethers
- Polycarbonate
- Polychloride dibenzo-p- furan (PCDF)
- Polychloride biphenyl (PCB)
- Polychloride dibenzo-p-dioxin (PCDD)
- PVC/PVDC
- Silicone
- Titanium Acetyl Acetone (TAA)
- Triclosan
- Toluene
- Vinyl chloride
- Xylene

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 8 July 2021 by ECHA (European Chemicals Agency).

RECYCLABILITY:

All POLFILM 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.*