

# **Conformity Declaration**

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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 and including 2019/1338
- 2. Regulation (EC) No 1935/2004 its amendments Directive 80/590/EEC and 89/109/EEC
- 3. Directive 2002/72/EC and its amendments up to Commission Regulation (EC) No 975/2009
- 4. Code of Federal Regulations, FDA Section 21 CFR 177.1630

### **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
	Acetic acid 3 % (w/v)	Simulant B	60°C / 10 days + 100°C / 4h
EU	Ethanol 50 % (v/v)	Simulant D1	60°C / 10 days + 100°C / 4h
	Vegetable oil	Simulant D2	60°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/dm<sup>2</sup> with an analytical tolerance 2 mg/dm<sup>2</sup>
- For fatty simulants: 10 mg/dm<sup>2</sup> with an analytical tolerance 3 mg/dm<sup>2</sup>



# **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).

According to this Code of Federal Regulation, Chloroform-soluble extractives shall not exceed 0.2 (mg/inch <sup>2</sup>) of food-contact surface when exposed to the following solvents at temperatures and times indicated:

Reference	Chloroform soluble fraction of	Time & Temperatuer
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

The results for the extraction tests are below the limit values given in FDA 21CFR 177.1630

## **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
Ethylene glycol	107-21-1	16990	30
Di- Ethylene glycol	111-46-6	13326	30
Antimony trioxide	1309-64-4	35760	0.04

# → 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	SML (mg/kg)
Barium (Ba)		1
Cobalt (Co)		0.05
Cupper (Cu)		5
Iron (Fe)	Acetic acid 3 % (w/v) ( Simulant B)	48
Litium (Li)		0.6
Manganese (Mn)		0.6
Zink ( Zn)		25
Aluminuim (Al)		1



#### **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 Directive 2011/8/EU.

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

#### **HEAVY METALS:**

The sum of the heavy metals cadmium, lead, mercury and chromium VI 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 on packaging and packaging waste (amended with Directive 2004/12/EC, 2018/852).

The following substances are not intentionally used in the manufacture or formulation of PETCO products.

# 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-dihydroxyprypl glycidyl (BADGE.2 H₂O)
- 3-chloro-2-hydroxyprpyl glycidyl (BADGE.HCl)
- 3-chloro-2-hydroxyprypl ether (BADGE.2HCl)
- (3-chloro-2hydroxyprypl) -2, 3dihydroxypropyl ether (BADGE.H<sub>2</sub>O.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-penthyl 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) OTHER ABSENCES:

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

**Biocides** Formaldehyde Acetyl acetone Organo-tin compounds Acryl amide Bisphenol A ITX PFOA/PFOS PVC/PVDC Aromatic amines CMR substances Latex Asbestos Dimethyl fumarate Melamine Triclosan Azocolorants Dioxins and furans Nanoparticles Vinyl chloride

Benzophenone ESBO Nonylphenol

BHA, BHT Flame retardants nonylphenol ethoxylate

# **REACH / SVHC:**

We confirm that our BOPET 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:**

Our BOPET films are recyclable and can be effectively disposed of through incineration.

# 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.