

Biopack & Logistics BV  
Konijnenboslaan 21  
B-8470 Gistel

## Declaration of conformity

<b>Code</b>	<b>BLOKV0018 + BLOKV0024 + BLOKV0027 with window BLOKZ0022 + BLOKZ0023 without window</b>
<b>Product</b>	Paper kraft bags with or without window
<b>Material</b>	Lined brown kraft paper 80 gsm + PE coating 30 micron + optional polyethylene terephthalate (PET) window 19 micron

The manufacturer declares that the above mentioned products may come into contact with food.

The goods were made according to the following **recommendations**:

COMMISSION REGULATION EC No 2023/2006 (from 22 December 2006) concerning good manufacturing practice for materials and articles intended to come into contact with food European Parliament and Council Directive 94/62/EC on packaging and packaging waste.

COMMISSION REGULATION (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

COMMISSION REGULATION EC No 1935/2004 (from 27 October 2004) concerning materials and product for contact with food and repealing Directives 80/590/EEC and 89/109/EEC, Official Journal of the European Union L 338/4 of 13.11.2004, modified by app. No. 5.17 of the regulation (EC) No 596/2009 of 18 June 2009, Official Journal of the European Union L 188 July 2009, article 3.

COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and its last amended regulation (EU) No 1282/2011

Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code – LFGB) in the version of the notification of 3 June 2013 (BGBl.p.1426), last amendment by article 4 section 20 of the law of 7 August 2013 (BGBl. I p. 3154), §§ 30 and 31).

German Recommendation XXXVI for the health-related evaluation of materials and objects for the contact with foodstuffs in the frame of the Foodstuffs and Animal Feed Code, 34<sup>th</sup> memorandum, Bundesgesundheitsblatt 10, 14 (1967), including the 215<sup>th</sup> memorandum, Bundesgesundheitsblatt 56, 1017-1022 (2013), state of 1 June 2013.

### Migration limits and testing:

The plastic materials are not fully inert and there are substances, which can transfer or migrate from the plastic packaging into the food and vice versa. This migration of substances is regulated by regulation (EU) 10/2011 and it's amendment (EU) 2016/1416 with two different migration limits:

### Overall Migration Limit

Polyester films comply for overall migration test as per below test condition. The test method is based on BS E1186-1(2002) and EU-10/2011.

Testing	Stimulant used	Test condition	Result (mg/dm <sup>2</sup> )	Limit as per std.(mg/dm <sup>2</sup> )
Overall migration test (OML)	Simulant-A (10% Ethanol)	10 days at 40 °C	<5	10
	Simulant-B (3% Acetic acid)		<5	10
	Simulant-D1 (50% Ethanol)		<5	10
	Simulant-D2 (Rectified olive oil)		<5	10
	Simulant E (MPP-Tenax)	2 hrs at 70 °C	<5	10

### Specific Migration Limits (SML)

Directive (EU) 10/2011 also stipulates specific migration limits (given in mg/kg food) for certain substance. Polyester film meets the specific migration limits accordingly under the test conditions set out in Annex III in accordance with the rules set out in chapter 2, section 2.1 of Annex V. The specific migration values given in mg/kg food are converted to mg/dm<sup>2</sup> film surface by multiplying with the standard conversion factor 6, since by definition 1 kg food is enclosed by 6dm<sup>2</sup> of film.

Sr. No.	Name of test	CAS Nos.	Result	Unit	Detection Limit	Limit as per standard
1	Mono Ethylene glycol	107-21-1	N.D	mg/kg	10	30
2	Di Ethylene glycol	111-46-6	N.D	mg/kg	10	30
3	Terephthalic acid	100-21-0	N.D	mg/kg	1.0	7.5
4	Isophthalic acid	121-91-5	N.D	mg/kg	1.0	5.0
5	Antimony trioxide	01309-64-4	N.D	mg/kg	<0.04	0.04
6	Acetaldehyde	0000075-07-0	N.D.	mg/kg	1.0	6.0

The test condition for above test is 60 °C/10 days with stimulant A, B and Olive oil.

### Specific Migration of Phthalates

Polyester film is in compliance to the directive 2005/84/EC amending directive 76/769/EEC regarding uses of phthalates.

Sr. No.	Name of Test	Result (mg/kg)	Detection Limit (mg/kg)	Limit as per standard (mg/kg)
1	Dibutyl Phthalate (DBP)	<0.25	0.25	0.30
2	Benzyl butyl Phthalate (BBP)	<2.5	2.5	30.0
3	Bis(2-ethylhexyl) Phthalate (DEHP)	<1.0	1.0	1.50
4	Diisononyl Phthalate (DINP)+ Diisodecyl phthalate (DIDP)	<2.50	2.50	9.0
5	Di-n-octyl Phthalate (DNOP)+ Di-n-decyl	<2.50	2.50	5.0
6	Diallyl Phthalate (DAP)	<0.01	0.01	0.01

The test condition is 70°C/2hrs with stimulant 95% ethanol & Iso octane

### Specific Migration Limit of Heavy Metals

Polyester film side passes the specific migration test with reference to commission regulation (EU) No. 2017/752 amending and correcting regulation EU no.10/2011 Annex II for selection of Simulant and conditions, EN13130part1:2004 for selection of test method with test condition of 3% acetic acid,10 days@ 60°C. Test pass for heavy metals Aluminum, Barium, Cobalt, Copper, Iron, Lithium Manganese and Zinc. For Nickel, selection of test method with test condition of 3% acetic acid,100°C for 4hrs.

Sr. No.	Name of Test	Result	Unit	Detection limit	Limit as per Annexure II of EU-10/2011
1	Aluminium	<LOQ	mg/kg	0.2	1.00
2	Barium	<LOQ	mg/kg	0.2	1.00
3	Cobalt	<LOQ	mg/kg	0.02	0.05
4	Copper	<LOQ	mg/kg	0.2	5.00
5	Iron	<LOQ	mg/kg	0.2	48.0
6	Lithium	<LOQ	mg/kg	0.2	0.60
7	Manganese	<LOQ	mg/kg	0.2	0.60
8	Zinc	<LOQ	mg/kg	0.2	5.0
9	Nickel	ND	mg/kg	0.01	0.02

### Specific Migration of Primary Amine

Our films pass the specific migration test with reference to commission regulation (EU) No.10/2011, EN 13130- 1:2004 for selection of test method with test condition of 3% acetic acid, 70°C for 2 hrs.

Sr. No.	Name of Test	Result	Unit	Limit as per Annexure II of EU-10/2011
1	Specific Migration of Aromatic Amines	<0.01	Mg/kg	0.01

### Specific Migration of Bisphenol A

Polyester film does not contain any substances that are derived from “Bisphenol A and its derivatives so our polyester film products complied with EU directive 2018/213.

### Dual Additives

Based on our current manufacturing practice and information provided by our raw material suppliers, polyester film does not contain the dual additives (also called multiple function additives), which are covered by articles 5 of directive 2011/10/EU Annex-1.

### Dispersion adhesive based on synthetic polymers

According to paragraph 6 of the plastic regulation’s (EU) No 10/2011 preamble and article 2, paragraph 2, this regulation specifically is not valid for adhesives and coatings, but only applies to the plastic layers in multi-material multi-layers and does not regulate monomers and other components specially used for adhesives. An adhesive in indirect food contact can be considered as a part of a laminated plastic packaging. In this case monomers with specific migration limits used in the formulation of the adhesive have to be considered.

In accordance with article 12 of the regulation (EU) No 10/2011 the overall migration limit (OML) for all substances without any restrictions shall not exceed 10 mg of total constituents released per dm<sup>2</sup> of food contact surface (mg/dm<sup>2</sup>). The maximum value for materials for infants and young children is 60 mg of total of constituents released per kg of food simulatant. For many substances specific migration limits (SML) or other restrictions are specified in the regulation (EU) no 10/2011 and must be respected.

### Non-intentionally added, restricted and unlisted substances

Information on constituents with specific and/or group restrictions is listed in a table. All other constituents are subject to the overall migration limit (OML).

#### NIAS<sup>1)</sup> and substances not listed or with restrictions

Constituent	Conc.	EU 10/2011	BfR
Vinyl acetate	<0,09 %	SML 12 mg/kg	SML 12 mg/kg
Acetaldehyde <sup>1)</sup>	<0,015%	SML(T) 6 mg/kg	SML(T) 6 mg/kg
Acetic acid <sup>1)</sup>	<0,100 %	listed	listed
Ethyl acetate <sup>1)</sup>	<0,020 %	listed	not applicable
Formaldehyde <sup>1)</sup>	<0,025 %	SML(T) 15mg/kg	SML(T) 15 mg/kg
Methanol <sup>1)</sup>	<0,030 %	listed	not applicable
Methyl acetate <sup>1)</sup>	<0,010 %	not listed	not applicable
5-Chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4isothiazolin-3-one (mixture in a ratio of 3:1)	<0,0015 %	not listed	in total max. 4 µg / dm <sup>2</sup> in dispersion film
2-Bromo-2-nitropropane-1,3-diol	<0,0100 %	not listed	max. 0,032 mg / dm <sup>2</sup> in dispersion film
Dodecylguanidine hydrochloride	<0,015 %	not listed	max. 0,03%

<sup>1)</sup> NIAS: non-intentionally added substances

SML: the Specific Migration Limit applicable for the substance. It is expressed in mg substance per kg food.

SML(T): Group restriction for migration

ND: if the substance shall not migrate in detectable quantities [<10 ppb=10µg/kg].

### Dual use additives and flavourings

This product contains the following dual use additives or flavourings according to European Legislation on additives, (EC) 1333/2008, and flavourings (EC) No 1334/2008.

Substance	CAS	Concentration	E number
Glyceryl triacetate	102-76-1	< 8 %	E1518
Carbamide	57-13-6	< 2 %	E927

Adhesive are separated from food by a functional barrier, or has only trace exposure of the adhesive to aqueous or fatty foods at seams or edges of the laminate.

### **Hotmelt adhesive**

Hotmelt adhesive developed for use in the hygiene industry. They are not recommended for direct food contact applications, due to a high content of mineral oils that are not listed in the Regulation (EU) No 10/2011 and therefore not approved for direct food contact. An exception is given when the migration of MOH components out of the adhesive layer into the packaged foodstuff is excluded in the final application by using an adequate

functional barrier. In such a case, no transfer of MOH components into the filled goods is possible and a zero exposition can be assumed. Thus, the general requirements of Article 3, Paragraph 1 (a) of the Framework Regulation (EC) No 1935/2004 can be met.

Hotmelt adhesive is in compositional compliance with the Indirect Food Additives regulation 21 CFR 175.105 'Adhesives'.

Paragraph 175.105 of the 21 CFR of the FDA regulation is a specific paragraph for adhesives. This paragraph contains requirements for adhesives followed by a table with substances allowed in adhesive formulations and their specific restrictions.

Additionally, to the compositional compliance, 21 CFR 175.105 requires either a functional barrier between the adhesive and the filling good or incidental contact of the adhesive with dry foodstuff and the quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice (GMP). If the adhesive has incidental contact with fatty and aqueous foods, the quantity of adhesive that contacts the filling good shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.

Thus, 21 CFR 175.105 allows only a limited direct food contact for dry, fatty and aqueous foodstuffs.

The manufacturer confirms that the amount of hotmelt adhesive used for whole packaging has no direct food contact or do not exceed the limits of good manufacturing practice.

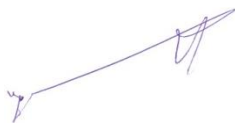
### **Heavy Metals**

We confirm that heavy metals as cadmium, mercury, lead and chromium as such and their compounds are not used in the manufacturing. The sum of these heavy metals from possible contaminations is below 100ppm (DIN 38 406) and complies with article 11 of EU Directive 2002/95/EC and 2004/12/EC amending directive 94/62/EEC (packaging and packaging waste).

### **The goods can be used in the following conditions:**

- Can come into contact with dry and non-fatty foods as well as moist and fatty foods.
- Any long-term storage at room temperature or below.
- Material is not suitable for heating
- Unlimited material shelf-life in use of the room temperature

Gistel, 20/09/2021



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