INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.

třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

TESTING LABORATORY - TESTING DIVISION

issues

ATTEST

No. 472112254-01

On sample:

Bio foil Polypak

Client:

Polypak, s.r.o.

Osada Dukla 253, 415 01 Újezdeček, Czech Republic; ID: 04030630

Evaluation of the measured parameters:

The evaluated parameters mentioned on the pages 3 – 5 of the Attest **meet** hygienic requirements for the **products made of plastics** given by **Czech Health Ministry Decree No. 38/2001 Coll.,** relating to hygienic requirements for the articles intended to come into contact with foodstuffs, as amended and **Commission Regulation (EU) No. 10/2011 of 14th January 2011** on plastic materials and articles intended to come into contact with food, as amended.

Food contact conditions:

- All storage times of all foodstuff types except of acidic food with pH<4.5 at refrigerated and frozen conditions including heating up to 70 °C ≤ T ≤ 100 °C for up to the maximum contact time t = 120/2^((T-70)/10) minutes and/or
- Contact with all foodstuff types except of acidic food with pH<4.5 for up to 30 days at temperatures up to 40 °C
- Ratio: 6 dm^2 of product surface / 1 kg (liter) of food (or more)

The evaluated sample meets requirements for the limit values of the substances limited by their specific migration limits (SML) and/or limited by their quantity in the mass of the final product (QM):

- According to the Annex I of Commission Regulation 10/2011: see page 2
- According to the Annex II of Commission Regulation 10/2011: metals (Al, Ba, Co, Cu, Fe, Li, Mn, Ni, Zn) and primary aromatic amines.

The evaluated sample does not cause a deterioration in organoleptic characteristics of food.

The evaluated sample meets requirements of the article 3 of **Regulation (EC) No. 1935/2004 of the European Parliament and of the Council** on materials and articles intended to come into contact with food.

This Attest was issued on the basis of the accredited test report Ref. No. 472112254-01 issued on November 18, 2019.

Issued on: November 18, 2019
Valid till: November 30, 2022

ZKUŠEBNÍ LABORATOŘ * Institut pro testování a certifikaci, a.s. *

Dipl. Ing. Jiří Samsonek, Ph.D.
Head of the testing laboratory

Conditions for use of the Attest and associated information:

1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*

ATTEST
No. 472112254-01
Bio foil Polypak

The substances limited by their specific migration limits (SML) and/or limited by their quantity in the mass of the final product (QM) according to the Annex I of Commission Regulation 10/2011:

- Terephthalic acid PM/Ref. No. 24910, CAS 100-21-0, SML = 7,5 mg/kg;
- 1,4-Butanediol, PM/Ref. No. 13720/40580, CAS 110-63-4, SML = 5 mg/kg;
- Tetrahydrofuran, PM/Ref. No. 25150, CAS 109-99-9, SML = 0.6 mg/kg;
- Hexamethylene diisocyanate, PM/Ref. No. 18640, CAS 822-06-0, QM = 1 mg/kg and QMA = 0.01 mg/kg (expressed as sum of isocyanate moiety).

Notes:
QM = Content in the mass of final product (Quantity in mass)
QMA = Residual content per food contact surface area (Quantity in mass per area)

ZKUŠEBNÍ LABORATOŘ * Institut pro testování a certifikaci, a.s. *

Conditions for use of the Attest and associated information:

1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*

ATTEST
No. 472112254-01
Values obtained:

Assessment of organoleptic properties

Food, contact conditions		Drinking water, (40±2)°C / 48 h	
Assessor No.	**Unit**	**Odour**	**Flavour**
1	level	1	1.5
2	level	1.5	1.5
3	level	2 (oleic)	2 (oleic)
4	level	1	1.5
5	level	1	2 (chemical)
6	level	1.5	1.5
Mean	**level**	**1.5**	**1.5**

Off-odour and off-taste scale:
0 = No perceptible off-odour or off-taste
1 = Just perceptible off-odour or off-taste (off-odour and off-taste determination is very difficult)
2 = Moderate off-odour or off-taste
3 = Strong off-odour or off-taste
4 = Very strong off-odour or off-taste

According to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) 10/2011 the articles shall not cause a deterioration in organoleptic characteristics of food.

Overall migration determination, 40°C / 10 days

Food simulant	Unit	Value obtained		Uncertainty [1]	Limit [2]
		Single results	Average		
10% ethanol	mg/ dm^2	4.4; 3.9; 4.0	**4.1**	0.4	max. 10
Olive oil	mg/ dm^2	2.9; 2.6; 1.9; 1.8	**2.3**	0.6	max. 10

Notes to the table:
[1] The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%.
[2] Limit values according to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) No 10/2011.

ZKUŠEBNÍ LABORATOŘ * Institut pro testování a certifikaci, a.s. *

Conditions for use of the Attest and associated information:
1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*

ATTEST
No. 472112254-01

Specific migration of additives and monomers

Parameter	Unit [1]	Test result [2]	Limit [3]
Specific migration into 10% ethanol, (40±2)°C / 10 days			
Terephthalic acid, Ref. No. 24910, CAS 100-21-0	mg/kg	< 0.3	max. 7.5
1,4-Butanediol, Ref. No. 13720, CAS 110-63-4	mg/kg	< 4.5	max. 5
Tetrahydrofuran, Ref. No. 25150, CAS 109-99-9	mg/kg	< 0.2	max. 0.6
Specific migration into 3% acetic acid, (40±2)°C / 10 days			
Terephthalic acid, Ref. No. 24910, CAS 100-21-0	mg/kg	< 0.3	max. 7.5
1,4-Butanediol, Ref. No. 13720, CAS 110-63-4	mg/kg	< 4.5	max. 5
Tetrahydrofuran, Ref. No. 25150, CAS 109-99-9	mg/kg	< 0.2	max. 0.6
Specific migration into 95% ethanol, (40±2)°C / 10 days			
Terephthalic acid, Ref. No. 24910, CAS 100-21-0	mg/kg	< 0.3	max. 7.5
Specific migration into isooctane, (20±2)°C / 2 days			
Terephthalic acid, Ref. No. 24910, CAS 100-21-0	mg/kg	< 0.3	max. 7.5
Specific migration into olive oil, (40±2)°C / 10 days			
1,4-Butanediol, Ref. No. 13720, CAS 110-63-4	mg/kg	< 0.3	max. 5
Tetrahydrofuran, Ref. No. 25150, CAS 109-99-9	mg/kg	< 0.2	max. 0.6

Notes to the table:

1) Expressed as mg of substance/element per kg of simulant.
2) Symbol „<" means less than LOD (limit of detection) of the analytical method.
3) The limit values according to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) No 10/2011.

Test results of isocyanates determination

Parameter	Unit	Test result [1]	Limit [2]
Determination of isocyanates expressed as NCO groups in the mass of the sample (QM)			
Hexamethylene diisocyanate, PM/Ref. No. 18640, CAS 822-06-0	mg/kg [3]	< 0.05	-
Sum of isocyanates expressed as NCO groups	mg/kg [3]	< 0.05	max. 1
Content of residual isocyanates expressed as NCO groups – QMA (recalculation for contact surface)			
Hexamethylene diisocyanate, PM/Ref. No. 18640, CAS 822-06-0	mg/6 dm^2 [4]	< 0.0002	
Sum of isocyanates expressed as NCO groups	mg/6 dm^2 [4]	< 0.0002	max. 0.01

Notes to the table:

1) Symbol „<" means less than LOD (limit of detection) of the analytical method.
2) The limit values according to Commission Regulation (EU) No 10/2011
3) Expressed as mg NCO groups per kg of the sample
4) Expressed as mg NCO groups per 6 dm^2 as QMA by calculation from the residual content in the mass for the surface weight 0.37 g/dm^2

Conditions for use of the Attest and associated information:

1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*

ATTEST
No. 472112254-01

Specific migration of metals and primary aromatic amines according to Annex II to Commission Regulation (EU) 10/2011

Parameter	Unit [1]	Test result [2]	Limit [3]
Specific migration into 3% acetic acid, (40±2)°C / 10 days			
Al	mg/kg	< 0.10	max. 1
Ba	mg/kg	< 0.05	max. 1
Co	mg/kg	< 0.005	max. 0.05
Cu	mg/kg	< 0.05	max. 5
Fe	mg/kg	0.11±0.01	max. 48
Li	mg/kg	< 0.01	max. 0.6
Mn	mg/kg	0.011±0.001	max. 0.6
Ni	mg/kg	< 0.01	max. 0.02
Zn	mg/kg	< 0.10	max. 5
Primary aromatic amines [4]	mg/kg	negative [5]	max. 0.01

Notes to the table:

1) Expressed as mg of substance / element per kg of food simulant.
2) Symbol „<" means less than limit of detection of the analytical method. The test results are expressed including the expanded uncertainty based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%.
3) The limit values according to Commission Regulation (EU) No 10/2011.
4) Expressed as mg of aniline/kg of food simulant.
5) Negative = visual evaluation of the leachate coloration; the detection limit: less than 0.01 mg/kg of simulant for the migration ratio: 60 cm^2/100 ml.

ZKUŠEBNÍ LABORATOŘ * Institut pro testování a certifikaci, a.s. *

Conditions for use of the Attest and associated information:

1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*

INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
Testing Laboratory – D2

Attest No. 472112254-01

Sample description and identification:

ITC's number	Sample identification by client	Description of submitted sample
12254/1	**Bio foil Polypak**	Colourless plastic foil

Together with the sample the following document was supplied:

D1 – conformity declaration of foil material "Biodolomer® F" with the Commission Regulation (EU) No 10/2011, issued by GAIA BioMaterials AB, Sweden, on July 1, 2018

Request

Evaluation of hygienic properties of the sample according to Decree of Health Ministry No. 38/2001 Coll. *for articles intended into a contact with foodstuffs,* as amended, in compliance with Law of Czech Republic No. 258/2000 Coll. *about protection of the public health*, as amended.
The evaluation of hygienic properties of the sample is based on European legislation in the sense of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council *on materials and articles intended to come into contact with food*, according to Commission Regulation EU No. 10/2011 *on plastic materials and articles intended to come into contact with food,* as amended.

Opinions and interpretations:

The evaluated sample **"Bio foil Polypak "** is intended to come into direct contact with foodstuffs.

The requirements for products intended to come into direct contact with foodstuffs are given by Decree of the Health Ministry No. 38/2001 Coll., as amended (hereinafter referred to as Decree 38/2001), by Commission Regulation EU No. 10/2011 (hereinafter referred to as Regulation 10/2011) and by European Parliament and Council Regulation No. 1935/2004 (hereinafter referred to as Regulation 1935).

General requirements - Decree 38/2001, Regulation 10/2011 and Regulation 1935

The products intended to contact with foodstuffs shall be manufactured so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: endanger human health or bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof. The performed tests verified that the evaluated sample does not influence the organoleptic properties of the food (see the table on the page 3 of this attest). The constituent transferring is discussed further.

Requirements on plastic products - Decree 38/2001, Regulation 10/2011

Only the monomers and other basic substances listed in the supplement Regulation 10/2011 can be used for the manufacturing of the plastic products intended to come into contact with foodstuffs, complying with defined limitation. The client submitted the document declared the conformity of raw materials used for manufacturing with the requirements for plastic composition.

Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm^2) (limit of overall migration). The test results of overall migration including migration conditions are mentioned on the page 3 of this attest. All measured values of overall migration meet the required limit values except of the migration into simulant B (3% acetic acid). The foil is not suitable for acidic foods with pH value less than 4.5.

INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
Testing Laboratory – D2

Attest No. 472112254-01

Migration of components from plastic materials and products shall not exceed specific migration limits (SML) or other restrictions included in the list of substances. There are the substances restricted by SML: see the list on the page 2. The test results of the specific migration of these substances including migration conditions are mentioned in the table on the page 4 of this attest. All measured values of specific migration meet the required limit values.

The test results of determination of hexamethylene diisocyanate, PM/Ref. No. 18640, CAS 822-06-0 in the sample are mentioned in the table on the page 4. The measured value meets the required limit for this substance content in the final product (QM) and the residual content of the substance calculated for the contact surface area (QMA). Recalculation for contact surface area was carried out for the surface weight 0.37 g/dm^2.

General restrictions on plastic materials and articles according to the Commission Regulation No. 10/2011/EC

Materials and articles shall not release metals: Al, Ba, Co, Cu, Fe, Li, Mn, Ni and Zn and primary aromatic amines in foods or food simulants in quantities exceeding the specific migration limits set out in the Annex II to this Regulation. Compliance with specific migration limit of these substances was verified experimentally and is shown in the table on the page 5 of this attest.

Tests results of overall and specific migration meet the above mentioned requirements under following conditions:

- **All storage times of all foodstuff types except of acidic food with pH<4.5 at refrigerated and frozen conditions including heating up to 70 °C ≤ T ≤ 100 °C for up to the maximum contact time t = 120/2^((T-70)/10) minutes and/or**
- **Contact with all foodstuff types except of acidic food with pH<4.5 for up to 30 days at temperatures up to 40 °C**
- **Ratio: 6 dm^2 of product area / 1 kg (liter) of food (or more)**

The opinion expressed and interpretation made by:
Dipl. Ing. Šárka Kopečková, November 18, 2019

Conclusion:
Comparison of the obtained results with the limits of Decree No. 38/2001 Coll., as amended, of Commission Regulation (EU) No. 10/2011 and of the article 3 of European Parliament and Council Regulation No. 1935/2004 and evaluation of the conformity with these regulations are mentioned on the page 1 of this attest.

Dipl. Ing. Věra Vilímková
Head of the laboratory of analytical chemistry and microbiology

Conditions for use of the Attest and associated information:

1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*