



INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.

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

Testing Laboratory No. 1004

accredited by ČIA according to ČSN EN ISO/IEC 17025:2018



Testing laboratory * Calibration laboratory * Product certification body * Quality management systems certification body
Inspection body * Authorized body * Notified body

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ACCREDITED LABORATORY TEST REPORT ref.No. 472112254-01

Client: Polypak, s.r.o.
ID: 04030630

Address: Osada Dukla 253, 415 01 Újezdeček, Czech Republic

Sample: Bio foil Polypak

Sample received on: May 6, 2019

Report elaborated by: Dipl. Ing. Šárka Kopečková

Place and date of issue: Zlín, November 18, 2019



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Dipl. Ing. Jiří Samsoněk, Ph.D.
Head of Accredited Testing Laboratory

Note: The results given in this Test Report apply only to the sample tested by our laboratory!
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**Sample description and identification:****Table I - Sample description and identification**

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

Sampling method used:

The test sample was collected and supplied to the laboratory by the client. The laboratory is not responsible for this way of sampling.

Work requested:

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.

Testing method used:

1. Overall migration into simulants A (10% ethyl-alcohol), B (3% acetic acid) and D2 (olive oil) according to EN 1186-2 and EN 1186-3
2. Specific migration of terephthalic acid, PM/Ref. No. 24910, CAS 100-21-6 into food simulants by UFLC method according to ITC's internal regulation A-96-35, method M
3. Specific migration of 1,4-butanediol, PM/Ref. No. 13720, CAS 110-63-4 into food simulants by GC-TCD method according to ITC's internal regulation A-12-103
4. Specific migration of 1,4-butanediol, PM/Ref. No. 13720, CAS 110-63-4 into food simulant D2 by GC-MS method according to ITC's internal regulation A-04-38
5. Specific migration of tetrahydrofuran, PM/Ref. No. 25150, CAS 109-99-9 into food simulants by GC-FID method according to ITC's internal regulation A-04-38
6. Determination of hexamethylene diisocyanate, PM/Ref. No. 18640, CAS 822-06-0 according to EN 13130-8
7. Specific migration of metals (Al, Ba, Co, Cu, Fe, Li, Mn, Ni and Zn) into 3% acetic acid by ICP-MS according to ITC's internal regulation A-10-97
8. Specific migration of primary aromatic amines into 3% acetic acid according to ITC's internal regulation No. A-07-69
9. Evaluation of organoleptic properties according to DIN 10955

Test conditions:

- ad 1 Simulants: A (10% ethanol), B (3% acetic acid) and D2 (olive oil)
Contact temperature and contact time: (40±2) °C / 10 days
Migration ratio: 100 cm² of the sample / 100 ml of simulant
- ad 2 Simulants: A (10% ethanol), B (3% acetic acid) and substitute fatty simulant (95% ethyl-alcohol)
Contact temperature and contact time: (40±2) °C / 10 days
Substitute fatty simulant – isooctane
Contact temperature and contact time: (20±2) °C / 2 days – these conditions correspond to the migration conditions into oil (40±2) °C / 10 days
Migration ratio: 60 cm² of the sample / 100 ml of simulant
- ad 3-5 Simulants: A (10% ethanol), B (3% acetic acid) and D2 (olive oil)
Contact temperature and contact time: (40±2) °C / 10 days
Migration ratio: 60 cm² of the sample / 100 ml of simulant

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- ad 6 According to EN 13130-8
- ad 7 Simulant: B (3% acetic acid)
Contact temperature and contact time: (40±2) °C / 10 days
Migration ratio: 60 cm² of the sample / 100 ml of simulant
- ad 8 Simulant: B (3% acetic acid)
Contact temperature and contact time: (40±2) °C / 10 days
Migration ratio: 300 cm² of the sample / 100 ml of simulant
The test results are expressed for migration ratio 60 cm² / 100 ml.
- ad 9 Food simulant: boiled and cooled drinking water
Contact temperature and contact time: (40±2) °C / 48 h
Migration ratio: 100 cm² of the sample / 100 ml of simulant
Number of assessors: 6
Sensory test: paired multi-comparison test

The laboratory is not responsible for information received from customer, which could have influence on the validity of the results. Further information required by the standard/standards and not given in this Test Report are available at a request at the Laboratory.

Testing laboratory:

Workplace no.: 1 - třída Tomáše Bati 299, Louky, 763 02 Zlín

Test results:

The test results are listed in the following tables:

Assessment of organoleptic properties

Table II: Sample No. 12254/1 – Bio foil Polypak

Food, contact conditions		Drinking water, (40±2) °C / 48 h	
Assessor No.	Unit	Odour	Taste
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 Commission Regulation (EU) 10/2011 the articles shall not cause a deterioration in organoleptic characteristics of food.

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Overall migration determination; (40±2) °C / 10 days
Table III: Sample No. 12254/1 – Bio foil Polypak

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
3% acetic acid	mg/dm ²	67; 69; 71	69	5	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 III:

- 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 Commission Regulation (EU) No 10/2011

Specific migration determination of monomers and additives
Table IV: Sample No. 12254/1 – Bio foil Polypak

Parameter	Unit ¹⁾	Test result ²⁾	Uncertainty	Limit ³⁾
Specific migration into 10% ethanol, (40±2) °C / 10 days				
Terephthalic acid, Ref. No. 24910, CAS 100-21-6	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 100-21-6	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 100-21-6	mg/kg	< 0.3	-	max. 7.5
Specific migration into isooctane, (20±2) °C / 2 days				
Terephthalic acid, Ref. No. 24910, CAS 100-21-6	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 IV:

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

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Test results of isocyanates determination
Table V: Sample No. 12254/1 – Bio foil Polypak

Parameter	Unit	Test result ¹⁾	Uncertainty	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 V:

- 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 dm² as QMA by calculation from the residual content in the mass for the surface weight 0.37 g/dm²

**Specific migration of metals and primary aromatic amines
according to Commission Regulation (EU) No 10/2011, Annex II**
Table VI: Sample No. 12254/1 – Bio foil Polypak

Parameter	Unit ¹⁾	Test result ²⁾	Uncertainty ³⁾	Limit ⁴⁾
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. 46
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 ⁵⁾	mg/kg	negative ⁶⁾	-	max. 0.01

Notes to the table VI:

- ¹⁾ Expressed as mg of element per kg of food simulant
- ²⁾ Symbol „<“ means LOD (limit of detection) of the analytical method
- ³⁾ 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%
- ⁴⁾ The limit values according to Commission Regulation (EU) No 10/2011
- ⁵⁾ Expressed as mg of aniline per kg of food stimulant

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- ⁶⁾ Negative = visual evaluation of the leachate coloration; the detection limit: less than 0.01 mg/kg of simulant for the migration ratio: 60 cm²/100 ml.

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

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