



INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.

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

TESTING LABORATORY - TESTING DIVISION

issues

ATTEST

No. 472111113

On samples:

PE-LD foil and bags

material: Lotréne FD0274

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 2 – 4 of the Attest meet hygienic requirements for the **products made of plastics** given by 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 at refrigerated and frozen conditions including heating up to 70 °C $\leq T \leq 100$ °C for up to the maximum contact time $t = 120/2^{((T-70)/10)}$ minutes and/or
- Contact with all foodstuff types for up to 30 days at room or lower temperatures.
- Ratio: 60 cm² of product area/100 g (ml) of food (or more)

The evaluated sample meet requirements for the substances limited by their specific migration limits (SML):

- According to the Annex I of Commission Regulation 10/2011: octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate, PM/Ref. No. 68320, CAS 2082-79-3, SML=6 mg/kg.
- 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 the 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.


Assessment of raw materials as required under the article 5 and the Annex I to Commission Regulation 10/2011 is not a part of this attest.

This Attest was issued on the basis of the accredited test reports Ref. No. 472111113 issued on May 17, 2018.

Issued on: May 17, 2018

Valid till: May 31, 2021




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

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ATTEST

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PE-LD foil and bags; material: Lotréne FD0274

Values obtained:

Assessment of organoleptic properties

Food, contact conditions		Overdone drinking water, 40 °C / 48 hours	
Assessor No.	Unit	Odour	Flavour
1	level	1	1
2	level	1	1
3	level	1	0
4	level	0	0
5	level	1	1
6	level	0	0
Mean	level	0.5	0.5

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 the organoleptic characteristics of food

Identification of low-molecular substances by method TD-GC-MS

Substance name	CAS No	Ref No	Limit ¹⁾
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxy-phenyl) propionate	2082-79-3	68320	SML=6 mg/kg
Oleamide	301-02-0	68960	No restriction

Note to the table:

- ¹⁾ Limit value according to Commission Regulation (EU) No 10/2011, Annex I;
SML = specific migration limit



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Test results of the toxic elements determination

Parameter	Unit	Test result ¹⁾	Uncertainty
Pb	mg/kg	< 10	-
Cd	mg/kg	< 10	-
Hg	mg/kg	< 10	-
Cr	mg/kg	< 10	-
Sb	mg/kg	< 10	-
As	mg/kg	< 10	-
Ba	mg/kg	< 30	-
Se	mg/kg	< 10	-

Notes to the table:

¹⁾ Symbol „<“ means less than LOD (limit of detection) of used analytical method

Overall migration determination, (40±2) °C / 10 days

Food simulant	Unit	Value obtained ¹⁾		Uncertainty ²⁾	Limit ³⁾
		Single results	Average		
10 % ethanol	mg/ dm ²	2.0; 2.1; 1.9	2.0	0.2	max. 10
3 % acetic acid	mg/ dm ²	1.8; 2.0; 1.9	1.9	0.2	max. 10
Olive oil	mg/ dm ²	1.5; 1.7; < 0.5; 1.8	- ⁴⁾	- ⁴⁾	max. 10

Notes to the table:

¹⁾ Symbol „<“ means less than limit of detection of the analytical method.

²⁾ 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%.

³⁾ Limit values according to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) No 10/2011.

⁴⁾ Average and uncertainty values are not mentioned because some of measurement result values are below the detection limit of the method



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ATTEST
No. 472111113

Test results of specific migrations

Parameter	Unit ¹⁾	Value obtained ²⁾	Limit ³⁾
Specific migration into 10% ethanol, (40±2) °C / 10 days			
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate, PM/Ref. No. 68320, CAS 2082-79-3	mg/kg	< 1	max. 6
Specific migration into 3% acetic acid, (40±2) °C / 10 days			
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate, PM/Ref. No. 68320, CAS 2082-79-3	mg/kg	< 1	max. 6
Al	mg/kg	< 0.05	max. 1 ⁴⁾
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	< 0.10	max. 48
Li	mg/kg	< 0.01	max. 0.6
Mn	mg/kg	< 0.01	max. 0.6
Ni	mg/kg	< 0.005	max. 0.02 ⁵⁾
Zn	mg/kg	< 0.10	max. 25 max. 5 ⁴⁾
Primary aromatic amines ⁶⁾	mg/kg	negative ⁷⁾	max. 0.01
Specific migration into 95% ethanol, (40±2) °C / 10 days			
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate, PM/Ref. No. 68320, CAS 2082-79-3	mg/kg	1.2±0.2	max. 6
Specific migration into isooctane, (20±2) °C / 2 days			
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate, PM/Ref. No. 68320, CAS 2082-79-3	mg/kg	1.2±0.2	max. 6

Notes to the table:

- ¹⁾ Expressed as mg of element per kg of simulant
- ²⁾ Symbol „<“ means less than LOD (limit of detection) of the analytical method. The test results are expressed including the reported expanded uncertainty based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%.
- ³⁾ Limit values according to Commission Regulation (EU) No 10/2011
- ⁴⁾ The limit value valid from September 14, 2018
- ⁵⁾ The limit value valid from May 19, 2019
- ⁶⁾ Expressed as mg of aniline per kg of food stimulant
- ⁷⁾ 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.



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Testing Laboratory – D2

Attest No. 472111113

Sample description and identification:

ITC's number	Sample identification by client	Description of submitted sample
11113/1	PE-LD foil and bags; material: Lotréne FD0274	Transparent colourless plastic foil

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 the 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* and Commission Regulation (EU) No. 10/2011 *on plastic materials and articles intended to come into contact with food*.

Opinions and interpretations:

The evaluated product **“PE-LD foil and bags; material: Lotréne FD0274”** is intended for a direct contact with foodstuffs. According to the client the contact with all foodstuff types is presumed.

The requirements on products intended into direct contact with foodstuffs are given by Commission Regulation EU No. 10/2011 (hereinafter Regulation 10/2011) and by European Parliament and Council Regulation No. 1935/2004 (hereinafter Regulation 1935).

General requirements - 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 2 of this attest). The constituent transferring is discussed further.

Requirements on plastic products - Regulation 10/2011

Only the monomers and other basic substances listed in the Annex I to Regulation 10/2011 can be used for the manufacturing of the plastic products intended into contact with foodstuffs, complying with defined limitation. The client did not supply documentation declared the conformity of the raw material with the requirements for plastic composition. The identification of low-molecular substances by TD-GC-MS method was performed to verify the compliance of the above requirement. The test results this identification are listed in the table on the page 2.

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 including the migration conditions are mentioned on the page 3 of this attest.

Migration of components from plastic materials and products shall not exceed specific the migration limits (SML) or other restrictions included in the list of substances. The specific migration of substance octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate, PM/Ref. No. 68320, CAS 2082-79-3 was performed on the submitted sample. The test results of this specific migration including the migration conditions are mentioned in the table on the page 4 of this attest. All measured values of the specific migration meet the required limit value.

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Testing Laboratory – D2

Attest No. 472111113

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 the specific migration limit of these substances was verified experimentally and is shown in the table on the page 4 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 at refrigerated and frozen conditions including heating up to $70\text{ °C} \leq T \leq 100\text{ °C}$ for up to the maximum contact time $t = 120/2^{((T-70)/10)}$ minutes and/or
- Contact with all foodstuff types for up to 30 days at room or lower temperatures.
- Ratio: 60 cm^2 of product area/100 g (ml) of food (or more)

The opinion expressed and interpretation made by:

Dipl. Ing. Šárka Kopečková, May 17, 2018

Conclusion:

The 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

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