INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.

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

TESTING LABORATORY - TESTING DIVISION

issues

ATTEST

No. 472113538-01

On sample:

Material HDPE – Formolene E924

(film, bags, t-shirt bags, disposable aprons)

Client:

PolyPak, s.r.o.

Osada Dukla 253, Újezdeček, 415 01, Czech Republic, IČ: 04030630

Evaluation of the measured parameters:

The evaluated parameters mentioned on the pages 2 - 6 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:

- Contact with all foodstuff types
- Long-time contact above 6 months at room or lower temperatures, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for up to the maximum contact time t = 120/2^((T-70)/10) minutes
- Ratio: 60 cm^2 of product area/100 g (ml) 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: 2,4-Di-*tert*-butylphenol, CAS No. 96-76-4, SML = 45 mg/kg (substance identified by TD-GC-MS method); this substance is not listed in Annex I, it is a degradation product of Irgafos 168 – Arvin 4. In accordance with article 19 of Commission Regulation (EU) 10/2011 a risk assessment was done and self-derived specific migration limit was calculated on the base of tolerable daily intake TDI value for the substance of interest. TDI value was self-derived and published by European Light Stabilisers and Antioxidants Association (ELISANA) – *"Arvin substances – Safety evaluation"* (http://elisana.cefic.org/).
- According to the Annex I of Commission Regulation 10/2011: primary aromatic amines
- According to the Annex II of Commission Regulation 10/2011: metals and primary aromatic amines.

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 report Ref. No. 472113538-01 issued on October 15, 2020

Issued on: October 15, 2020
Valid till: October 31, 2023

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

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

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Values obtained:

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

Material HDPE – Formolene E924

Substance name	CAS No.	PM/Ref. No.	Limit
Fatty acids, C_{16}–C_{18}	-	-	Without restriction[1)]
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	31570-04-4	74240	Without restriction[1)]
2,4-di-tertbutylphenol	96-76-4	-	SML=45 mg/kg [2)]
PE oligomers	-	-	Without restriction[1)]

Notes to Table:

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

2) This substance is not listed in the positive list of authorised substances for production of materials intended to come into contact with food in Annex I of Commission Regulation (EU) No 10/2011. Specific migration limit was calculated on the base of tolerable daily intake TDI value for the substance of interest. TDI value was self-derived and published by European light stabilisers and antioxidants association (ELISANA) – "Arvin substances – Safety evaluation"

Assessment of organoleptic properties

Material HDPE – Formolene E924

Food contact conditions		Drinking water, (40±2) °C / 48 hrs	
Assessor No.	**Unit**	**Odour**	**Flavour**
1	level	0	0
2	level	0	0
3	level	0	0
4	level	0	0
5	level	0	0
6	level	1	1
Mean	**level**	**0**	**0**

Notes to Table:

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 = Slightly perceptible off-odour or off-taste
3 = Clearly perceptible off-odour or off-taste
4 = Strong off-odour or off-taste

According to Regulation (EC) No. 1935/2004 of the European Parliament and of the Council the articles shall not cause deterioration in the organoleptic characteristics of food.

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Overall migration determination

Material HDPE – Formolene E924

Food simulant	Unit	Value obtained [1]		Uncertainty [2]	Limit [3]
		Single results	Average		
10% ethanol, 40±2 °C/10 days	mg/dm²	1.6; 1.8; 2.1	**1.8**	0.4	max. 10
3% acetic acid, 40±2 °C/10 days	mg/dm²	2.2; 1.9; 2.0	**2.0**	0.3	max. 10
olive oil, 40±2 °C/10 days	mg/dm²	0.6; 0.6; 1.0; 1.4	**0.9**	0.4	max. 10

Notes to Table:

1) Symbol „<" means less than LOD (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

Test result of specific migration of primary aromatic amines (PAAs) - Annex I (10/2011);

Material HDPE – Formolene E924

Food simulant 3% acetic acid, 60°C / 10 days

Primary aromatic amine	CAS No.	Unit [1]	Test result [2]	Limit [3]
Bis(4-aminophenyl)sulphone	80-08-0	mg/kg	< 0.005	max. 5
2-Aminobenzamide	88-68-6	mg/kg	< 0.005	max. 0.05
1,3-Phenylenediamine	108-45-2	mg/kg	< 0.002	max. 0.002
1,3-Bis(aminomethyl)benzene	1477-55-0	mg/kg	< 0.005	max. 0.05
Evaluation		**Compliance**		

Notes to Table:

1) Expressed as mg of the substance per kg of food simulant
2) Symbol „<" means less than limit of detection of the analytical method
3) Limit values according to Commission Regulation EU 10/2011 as amended

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Specific migration of primary aromatic amines

Material HDPE – Formolene E924

Food simulant 3% acetic acid, 60°C / 10 days

Primary aromatic amine (PAA)	CAS No.	Unit [1]	Test result [2]	Limit [3]
PAAs listed in entry 43 to Appendix 8 of Annex XVII to REACH				
4-Amino-biphenyle	92-67-1	mg/kg	< 0.002	N.D.
Benzidine	92-87-5	mg/kg	< 0.002	N.D.
4-Chlor-o-toluidine	95-69-2	mg/kg	< 0.002	N.D.
2-Naphthylamine	91-59-8	mg/kg	< 0.002	N.D.
o-Aminoazotoluene	97-56-3	mg/kg	< 0.002	N.D.
2-Amino-4-nitro-toluene	99-55-8	mg/kg	< 0.002	N.D.
p-Chlor -aniline	106-47-8	mg/kg	< 0.002	N.D.
2,4-Diamino-anisole	615-05-4	mg/kg	< 0.002	N.D.
4,4'-Diamino-diphenylmethane	101-77-9	mg/kg	< 0.002	N.D.
3,3'-Dichlor-benzidine	91-94-1	mg/kg	< 0.002	N.D.
3,3'-Dimethoxy-benzidine	119-90-4	mg/kg	< 0.002	N.D.
3,3'-Dimethyl-benzidine	119-93-7	mg/kg	< 0.002	N.D.
3,3'-Dimethyl-4,4'- diaminodiphenylmethane	838-88-0	mg/kg	< 0.002	N.D.
p-Keresidine	120-71-8	mg/kg	< 0.002	N.D.
4,4'-Methylen-bis(2-chloraniline)	101-14-4	mg/kg	< 0.002	N.D.
4,4'-Oxy-dianiline	101-80-4	mg/kg	< 0.002	N.D.
4,4'-Thio-dianiline	139-65-1	mg/kg	< 0.002	N.D.
o-Toluidine	95-53-4	mg/kg	< 0.002	N.D.
2,4-Toluenediamine	95-80-7	mg/kg	< 0.002	N.D.
2,4,5-Trimethyl-aniline	137-17-7	mg/kg	< 0.002	N.D.
o-Anisidine	90-04-0	mg/kg	< 0.002	N.D.
o-Aminoazobenzene	60-09-3	mg/kg	< 0.002	N.D.
Other PAAs (not listed in REACH)				
2,4-dimethylaniline	95-68-1	mg/kg	< 0.005	-
2,6-dimethylaniline	87-62-7	mg/kg	< 0.005	-
1,5-diaminonaphthalene	2243-62-1	mg/kg	< 0.005	-
Aniline	62-53-3	mg/kg	< 0.005	-
Screening for others		-	No PAA detected	
Sum of detected PAAs		mg/kg	-	max. 0.01
Evaluation		**Compliance**		

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Notes to Table:

1) Expressed as mg of the substance per kg of food simulant
2) Symbol „<" means less than limit of detection of the analytical method
3) Limit values according to Commission Regulation EU 10/2011 as amended

REACH = Regulation (EC) No. 1907/2006 of European Parliament and of Council
N.D. = not detectable; limit of detection 0.002 mg/kg

Specific migration of metals

Material HDPE – Formolene E924

Element	Unit	Test results [1]	Limit [2]
3% acetic acid, (60±2) °C / 10 days			
Barium Ba	mg/kg	< 0.05	max. 1
Cobalt Co	mg/kg	< 0.005	max. 0.05
Copper Cu	mg/kg	< 0.05	max. 5
Iron Fe	mg/kg	< 0.10	max. 48
Lithium Li	mg/kg	< 0.01	max. 0.6
Manganese Mn	mg/kg	< 0.01	max. 0.6
Zinc Zn	mg/kg	< 0.10	max. 5
Aluminium Al	mg/kg	< 0.10	max. 1
Nickel Ni	mg/kg	< 0.01	max. 0.02
Antimony Sb	mg/kg	< 0.005	max. 0.04
Europium Eu	mg/kg	< 0.001	max. 0.05
Gadolinium Gd	mg/kg	< 0.001	max. 0.05
Lanthanum La	mg/kg	< 0.001	max. 0.05
Terbium Tb	mg/kg	< 0.001	max. 0.05
Sum of Lanthanides	mg/kg	< 0.004	max. 0.05
Arsenic As	mg/kg	< 0.001	N.D. (0.01)
Cadmium Cd	mg/kg	< 0.001	N.D. (0.002)
Chromium Cr	mg/kg	< 0.005	N.D. (0.01)
Lead Pb	mg/kg	< 0.005	N.D. (0.01)
Mercury Hg	mg/kg	< 0.002	N.D. (0.01)

Notes to Table :

1) Symbol „<" means less than limit of detection of the analytical method. Expressed as mg of the element per kg of food simulant
2) Limit values according to Commission Regulation (EU) 10/2011 as amended

N.D. = not detectable; for limit of detection see the value in brackets

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Test results of specific migrations

Material HDPE – Formolene E924

Parameter	Unit [1]	Test result [2]	Limit [3]
Specific migration into 90% ethanol, (60±2) °C / 10 days			
2,4-di-*tert*-butylphenol	mg/kg	< 0.1	max. 45

Notes to Table:

1) Expressed as mg of substance per kg of food simulant.
2) Symbol „<" means LOD (limit of detection) of the analytical method.
3) Self-derived specific migration limit was calculated on the base of tolerable daily intake TDI value for the substance of interest. TDI value was self-derived and published by European light stabilisers and antioxidants association (ELISANA) – "Arvin substances – Safety evaluation"

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Testing Laboratory – D2

Attest No. 472113538-01

Sample description and identification:

ITC's number	Sample identification by client	Description of submitted sample
13538/1	Material HDPE – Formolene E924	Transparent bag

According to the client's information submitted samples are s manufactured from material HDPE - Formolene E924: film, bags, t-shirt bags and disposable aprons.

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.*

Opinions and interpretations:

The evaluated products **"film, bags, t-shirt bags, disposable aprons** made from **material HDPE – Formolene E924"**are 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 2 of this attest). The constituent transferring is discussed further.

Requirements for plastic products – Decree 38/2001. Regulation 10/2011

Only the monomers and other basic substances listed in the supplement of Decree 38/2001 or 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 submit a document declaring the conformity of raw material used for manufacturing with the requirements for plastic composition.
TD-GC-MS method was carried out on the sample to identify low-molecular substances. The identified substances including their specific migration limits are listed in the table on the page 2 of this attest.
Besides the commonly used additives (Irgafos 168 and fatty acids) 2,4-Di-*tert.*-butylphenol was identified in the sample. This substance is a degradation product of Irgafos 168 and is not listed in the Union list of authorised substances (Annex I of Commission Regulation (EU) 10/2011). According to the article 19 *"Assessment of substances not included in the Union list"* the compliance of non-intentionally added substances (article 6, paragraph 4) with article 3 of Regulation (EU) 1935/2004 shall be assessed in accordance with internationally recognised scientific principles on risk assessment. Within this assessment the test of specific migration of 2,4-Di-*tert.*-butylphenol from the sample into the strictest food simulant 95% ethanol was carried out and the test result was compared to the self-derived specific migration limit calculated from tolerable daily intake (TDI). The value of self-derived TDI was taken from the document "*Arvin substances – Safety evaluation"* published by European Light Stabilisers and

Antioxidants Association – ELISANA on the internet (http://elisana.cefic.org/). Specific migration limit was calculated for a person of 60 kg body weight and a consumption of 1 kg of food packed in 6 dm^2 of the assessed material. The test result of migration is listed on the page 6 and meets the self-derived limit.

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.

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.

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

Materials and articles shall not release primary amines in foods or food simulants in quantities exceeding the specific migration limits set out in the Annex I and II to this Regulation. The results are mentioned in the tables on pages 3 and 4 of this attest.

Materials and articles shall not release metals in foods or food simulants in quantities exceeding the specific migration limits set out in the Annex II to this Regulation. The results are mentioned in the table on page 5 of this attest.

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

- **Contact with all foodstuff types**
- **Long-time contact above 6 months at room or lower temperatures, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for up to the maximum contact time t = 120/2^((T-70)/10) minutes**
- **Ratio: 60 cm^2 of product area/100 g (ml) of food (or more)**

The opinion expressed and interpretation made by:
Dipl. Ing. Ludmila Zálešáková, October 15, 2020

Conclusion:
The comparison of obtained results with limits of Decree No. 38/2001 Coll., as amended. of Commission Regulation (EU) No. 10/2011 and of the article 3 of the 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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