

Declaration of Conformity

DECLARATION DE CONFORMITE • DECLARACION DE CONFORMIDAD • ERKLÄRUNG BEZÜGLICH EINHALTUNG
DER VORSCHRIFTEN DICHIARAZIONE DI CONFORMITÀ • CONFORMITEITSVERKLARING • DEKLARATION OM
ÖVERENSSTÄMMELSE EF-OVERENSSTEMMELSESERKLÆRING • VAATIMUSTENMUKAISUUSVAKUUTUS •
SAMSVARERKLÄRING DECLARAÇÃO DE CONFORMIDADE

MANUFACTURER:

"Alfa-Sintez" LCC

Heroes avenue 4, ap.96, Dnepr 49100, Ukraine

Alfasintez.com.ua

We hereby confirm that our product:

PET film

This declaration is valid for the whole range of products which made of this PET film

complies with:

- European Parliament and Council Regulation 1935/2004/EC on materials and subjects intended for contact with food and repealing of Directives 80/590/EEC and 89/109/EEC;
- Commission Regulation (EU) No.10/2011, on January 14,2011 on plastic materials and articles intended to come into contact with food;
- Commission Regulation (EU) No.2016/1416 of August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food;
- Yield of the Ministry of Agriculture and the Ministry of Health No.1799/2003-100 , § 16 section fifth section due to Requirements for materials and subjects of plastics and Annex No. 5 to 5th chapter II. part of Food Code Slovak Republic.

Test report no.: 17/01366 dated 27.06.2017, issued by Accredited testing laboratory Labeko, s.r.o., Krajinská cesta 2929, 921 01 Piešťany, Slovak Republic.

AUTHORIZED/APPROVED BY: ZHILYAEV M.S.
Director



DATE: 21/07/2017

**Labeko, s.r.o.**

Krajinská cesta 2929; 921 01 Piešťany
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Reg. No. 070/S-030

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Applicant/Customer "Alfa-Sintez" LCC
 Heroes avenue 4, ap.96, Dnepr 49100

The date of sample receiving 12.06.17

Number of samples 1

The measurement date from 12.06.17

to: 27.06.17

The taking of samples: The samples sending by customer

The date of the testing certificate produce: 27.06.17

The results of testing

Number of sample: 17-001755	Type of sample: The material in contact with food	Chemical analysis
The name of testing sample PET foil Manufacturer: "Alfa-Sintez" LCC, Heroes avenue 4, ap.96, Dnepr 49100		

Sample identification: Identification of sample, and the description is given in the table below. The tested surface of the sample is intended to come into contact with foodstuffs.

Registration number of sample	Identification of sample and its description
17-001755	PET foil

A/ The specific migration test results**Sample No. 17-001755 PET foil**

The results of the determination of the specific migration of chemical elements and the primary aromatic amines .

Food simulant : B (3% acetic acid)
 Test condition : 10 days at 40°C
 Surface/volume ratio : 300 cm² surface of the sample / 300 ml of food simulant

Parameter :	Units	Limit values ¹⁾	Measurement result ³⁾	Uncertainty of measurement ²⁾ (k=2)	Measurement method ⁴⁾	Evaluation	Type of testing
Zinc (Zn)	mg/kg	5.0	0.016	25 %	P-01,STN EN ISO 11885	meets the requirements	A
Barium (Ba)	mg/kg	1.0	< 0.005		P-01,STN EN ISO 11885	meets the requirements	A
Manganese (Mn)	mg/kg	0.6	< 0.005		P-01,STN EN ISO 11885	meets the requirements	A
Copper (Cu)	mg/kg	5.0	< 0.005		P-01,STN EN ISO 11885	meets the requirements	A
Cobalt (Co)	mg/kg	0.05	< 0.005		P-01,STN EN ISO 11885	meets the requirements	A
Lithium (Li)	mg/kg	0.6	< 0.005		P-01,STN EN ISO 11885	meets the requirements	A
Iron (Fe)	mg/kg	48.0	< 0.005		P-01,STN EN ISO 11885	meets the requirements	A
Aluminium (Al)	mg/kg	1.0	0.005	25 %	P-01,STN EN ISO 11885	meets the requirements	A
Primary aromatic amines	mg/kg	0.01	< 0.005		P-39	meets the requirements	A

Abbreviations : A – accredited test, N – unaccredited test

Notes

¹⁾ Limit values by Commission Regulation (EU) No. 10/2011 and (EU) No. 2016/1416

²⁾ The expansion of combined relative standard uncertainty with coverage factor k=2

³⁾ The symbol "<" means less than the detection limit of the analytical method for the determination

⁴⁾ Determination of chemical elements and the primary aromatic amines according to internal working regulation P-01 and P-39 and preparation of migration solutions according to STN EN 13130-1

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Sample No. 17-001755 PET foil

Results of the determination of terephthalic acid (FCM No.785), isophthalic acid (FMC No.291), ethylene glycol (FMC No.227) and diethylene glycol (FMC No.263)

Food simulant : B (3% acetic acid)
Test condition : 10 days at 40°C
Surface/volume ratio : 500 cm² surface of the sample / 500 ml of food simulant

Parameter :	Units	Limit values ¹⁾	Measurement result ³⁾	Uncertainty of measurement ²⁾ (k=2)	Measurement method ⁴⁾	Evaluation	Type of testing
Terephthalic acid (FCM No. 785)	mg/kg	7.5	< 1.0		P-04, STN EN 13130-2	meets the requirements	N
Isophthalic acid (FMC No. 291)	mg/kg	5.0	< 1.0		P-04, STN EN 13130-2	meets the requirements	N
Ethylene glycol (FMC No. 227)	mg/kg	30.0	< 1.0		P-10, STN EN 13130-7	meets the requirements	A
Diethylene glycol (FMC No. 263)	mg/kg	30.0	< 1.0		P-10, STN EN 13130-7	meets the requirements	A

Abbreviations : A – accredited test, N – unaccredited test

Notes

¹⁾ Limit values by Commission regulation (EU) No. 10/2011 and (EU) No. 2016/1416²⁾ The expansion of combined relative standard uncertainty with coverage factor k=2³⁾ The symbol "<" means less than the detection limit of the analytical method for the determination⁴⁾ Determination of terephthalic acid, isophthalic acid, ethylene glycol and diethylene glycol according to STN EN 13030-2 respectively STN EN 13030-7 and internal working regulation P-04 and P-10. Preparation of migration solutions according to STN EN 13130-1**B/ The overall migration test results****Sample No. 17-001755 PET foil**

Food simulant : Simulant B (3% acetic acid)
Test conditions : OM2 (10 days at 40°C)
Food simulant : Alternative fat simulant 96 % ethanol
Test conditions : OM2 (10 days at 40°C)
Food simulant : Alternative fat simulant isooctane
Test conditions : OM2 (10 days at 40°C)
Surface/volume ratio : 300 cm² surface of the sample / 300 ml of food simulant

Food simulant:	Units	The result of testing ³⁾				Uncertainty of measurements ²⁾ (k=2)	Limit values ¹⁾	Measurement method	Evaluation	Type of testing
		1.	2.	3.	Average					
B	mg/dm ²	1,0	1,2	1,2	1,1	20%	max. 10.0	STN EN 1186-1,3	meets the requirements	A
96%ethanol	mg/dm ²	1,2	1,5	1,4	1,4	20%	max. 10.0	STN EN 1186-1,14	meets the requirements	A
isooctane	mg/dm ²	1,8	1,7	2,1	1,9	20%	max. 10.0	STN EN 1186-1,14	meets the requirements	A

Abbreviations : A – accredited test, N – unaccredited test

Notes

¹⁾ Limit values by Commission regulation (EU) No. 10/2011 and (EU) No. 2016/1416²⁾ The expansion of combined relative standard uncertainty with coverage factor k=2³⁾ The symbol "<" means less than the detection limit of the analytical method for the determination

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C/ The results of sensory analysis**Sample No. 17-001755 PET foil**

Food simulants : Adjusted drinking water
Testing conditions : 10 days at 40 ± 2 °C
Surface/volume ratio : 100 cm² surface of the sample / 100 ml of food simulant
Evaluation : multicomparison paired test (according to DIN 10955 article 11.6.3. c)

Parameters	Test results ²⁾	Limit value	Used method	Evaluation	Test type
Odour ¹⁾	1	max. 2	DIN 10955	passed	N
Taste ¹⁾	1	max. 2	DIN 10955	passed	N

Notes¹⁾ Median of 6 values , number of assessors : 3²⁾ The intensity scale for assessment :

- 0 = no perceptible odour or taste
- 1 = just perceptible odour or taste
- 2 = weak difference in odour or taste
- 3 = marked difference in odour or taste
- 4 = strong difference in odour or taste

Abbreviations : A – accredited test, N – unaccredited test

Compliance / non-compliance with requirements :

Evaluation of the material PET foil was made in the terms of:

- European Parliament and Council Regulation 1935/2004/EC on materials and subjects intended for contact with food and repealing of Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EU) No.10/2011, on January 14, 2011 on plastic materials and articles intended to come into contact with food
- Commission Regulation (EU) No.2016/1416 of August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- Yield of the Ministry of Agriculture and the Ministry of Health No.1799/2003-100 , § 16 section fifth section due to Requirements for materials and subjects of plastics and Annex No. 5 to 5th chapter II. part of Food Code Slovak Republic

The material PET foil is not intended to repeated contact with food. Used simulant B (3 % acetic acid) is the strictest food simulant for specific migration tests (migration of the chemical elements) for materials and products made of plastic. Used substitute food simulants 96 % ethanol is the strictest food simulant for the specific migration tests (migration of the organic additives and monomers) for materials and products made of plastic. Used simulant B (3 % acetic acid) and alternative fat simulants (96% ethanol and isooctane) are the most suitable food simulants for overall migration tests for materials and products made of plastic. The tested product does not cause unacceptable changes in organoleptic properties of the food.

The tested material : PET foil under the conditions of migration tests meets the requirements of the above listed regulations. The tested material is suitable for long term storage of the foods up to 6 month at room temperature.

Based on the obtained hygienic evaluation results we can recommend the material PET foil produced by manufacturer : "Alfa-Sintez" LCC, Heroes avenue 4, ap.96, Dnepr 49100 for usage into contact with foodstuffs.

Note : The testing results and the conclusions drawn from this testing can be applied also in other products if composition and properties of these products completely correspond to the tested samples.

Anex No. 1 - Photograph of the tested product

Test equipment and measuring instruments utilized in the tests were calibrated and verified in accordance with applicable metrology regulations.

The test results refer exclusively to the subject of test and do not replace other documents (of administrative nature), which are the state supervision authorities under specific regulations required. The protocol can be reproduced only in complete form; partially, only after written approval of the testing laboratory.

The test report approved by : Dr. Jozef Hudec, head of Ecoanalytical laboratories

