



**INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI. a. s.**

**trída Tomáše Bati 299. Louky. 763 02 Zlín. Czech Republic**

**TESTING LABORATORY - TESTING DIVISION**

issues

**ATTEST**

**No. 472115654-01**

On sample:

**LDPE food film FC03**

**transparent, white**

Client:

**Novplasta, s.r.o**

**Cerovská 152, 900 81 Šenkvice, Slovak Republic,**

**ID: 35776455**

**Evaluation of the measured parameters:**

The evaluated parameters mentioned on the pages 2 - 7 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 14<sup>th</sup> 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  $70\text{ °C} \leq T \leq 100\text{ °C}$  for up to the maximum contact time  $t = 120/2^{((T-70)/10)}$  minutes
- Ratio: 60 cm<sup>2</sup> 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: see page 2
- 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. 472115654-01 issued on October 18, 2022

**Issued on:** October 18, 2022

**Valid till:** October 31, 2025



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

**Conditions for use of the Attest and associated information:**

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**1. 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;

**2. NIAS assessment**

The submitted samples were screened for NIAS (non-intentionally added substances) in the sample mass and quantified in 95% ethanol after migration.

- 2,4-di-*tert*-butylphenol = Arvin 4, CAS 96-76-4

For the test results and evaluation see page 4  
SML= specific migration limit

Submitted sample –



**Fig. No. 1: LDPE food foil FC03 – white**



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Values obtained:  
**LDPE food foil FC03 – white**

Substance name <sup>1)</sup>	CAS	FCM	Comment
2,4-di- <i>tert</i> -butylphenol	96-76-4	-	NIAS, Arvin 4; degradation product of IAS
phosphorous acid, tris(2,4-di- <i>tert</i> -butylphenyl)ester	31570-04-4	671	Substance listed in Annex I without SML
oleamide	301-02-0	335	Substance listed in Annex I without SML
erucamide	112-84-5	271	Substance listed in Annex I without SML

### Notes to Table:

<sup>1)</sup> Identified substances can be either original ones, presented in the sample, or it can be degradation products. Match of the MS spectra of found substances with standard MS spectra from D-base are in the range of 70-95 %. The compounds which are also presented in the blank are not given in the table above.

FCM = Food Contact Material No.

CAS No. = unique numerical identifier assigned by the Chemical Abstracts Service

Annex I = Annex I of Commission Regulation (EU) 10/2011 – list of authorised substances

SML = specific migration limit

NIAS = non-intentionally added substance

IAS = intentionally added substance

### Assessment of organoleptic properties

**LDPE food foil FC03 – white**

Food, contact conditions		boiled and cooled drinking water, 40 °C/48 h	
Assessor No.	Unit	Odour	Flavour
1	level	2 (chemical)	2.5 (metallic)
2	level	2 (earthy)	2 (bitter)
3	level	1.5	2 (plastic)
4	level	2 (plastic)	2.5 (bitter)
5	level	2 (aromatic)	3 (aromatic)
6	level	1.5	2 (chemical)
Mean	level	2	2.5

### 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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Values obtained:  
**Overall migration determination**  
**LDPE food foil FC03 – white**

Migration conditions: OM2 (40°C/10 days), test by total immersion: 100 cm<sup>2</sup>/100 ml

Food simulant	Unit	Value obtained <sup>1)</sup>					Analytical tolerance <sup>2)</sup>	Limit <sup>3)</sup>
		1.	2.	3.	4.	Mean		
A: 10 % ethanol	mg/dm <sup>2</sup>	4.5	3.7	5.2	-	4.5	1	10
B: 3% acetic acid	mg/dm <sup>2</sup>	1.3	2.1	2.3	-	1.9	1	10
D2: olive oil	mg/dm <sup>2</sup>	5.8	5.1	6.1	7.0	6.0	3	10

## Notes to Table:

- 1) Symbol „<“ means LOQ (limit of quantification) of the analytical method
- 2) Analytical tolerance according to ČSN EN 1186-1, article 12.3
- 3) Limit values according to Commission Regulation EU 10/2011 as amended

## Test results of specific migrations LDPE food foil FC03 – white

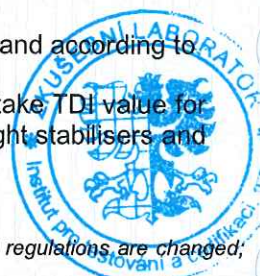
Parameter	Unit <sup>1)</sup>	Test result <sup>2)</sup>	Limit
<b>Specific migration into 10% ethanol, 60 °C/10 days</b>			
octadecyl 3-(3,5-di- <i>tert</i> -butyl-4-hydroxyphenyl)propionate, (Irganox 1076), PM/Ref. No. 68320, CAS 2082-79-3	mg/kg	< 1	max. 6 <sup>3)</sup>
<b>Specific migration into 3% acetic acid, 60 °C/10 days</b>			
octadecyl 3-(3,5-di- <i>tert</i> -butyl-4-hydroxyphenyl)propionate, (Irganox 1076), PM/Ref. No. 68320, CAS 2082-79-3	mg/kg	< 1	max. 6 <sup>3)</sup>
<b>Specific migration into 95% ethanol, 60 °C/10 days</b>			
octadecyl 3-(3,5-di- <i>tert</i> -butyl-4-hydroxyphenyl)propionate, (Irganox 1076), PM/Ref. No. 68320, CAS 2082-79-3	mg/kg	< 1	max. 6 <sup>3)</sup>
2,4-di- <i>tert</i> -butylphenol = Arvin 4, CAS 96-76-4	mg/kg	< 0.5	max. 45 <sup>4)</sup>
<b>Specific migration into isooctane, 20 °C/10 days</b>			
octadecyl 3-(3,5-di- <i>tert</i> -butyl-4-hydroxyphenyl)propionate, (Irganox 1076), PM/Ref. No. 68320, CAS 2082-79-3	mg/kg	< 1	max. 6 <sup>3)</sup>

## Notes to Table:

- 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
- 4) 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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Values obtained:

**Specific migration of metals**

**LDPE food foil FC03 – white**

Parameter	Unit	Test result <sup>1)</sup>	Uncertainty	Limit <sup>2)</sup>
<b>Specific migration into 3% acetic acid, 60 °C/10 days</b>				
Aluminium	mg/kg	< 0.10	-	max. 1
Antimony	mg/kg	< 0.005	-	max. 0.04
Barium	mg/kg	< 0.05	-	max. 1
Cobalt	mg/kg	< 0.005	-	max. 0.05
Copper	mg/kg	< 0.05	-	max. 5
Iron	mg/kg	< 0.10	-	max. 48
Lithium	mg/kg	< 0.01	-	max. 0.6
Manganese	mg/kg	< 0.01	-	max. 0.6
Nickel	mg/kg	< 0.01	-	max. 0.02
Zinc	mg/kg	< 0.10	-	max. 5
Europium	mg/kg	< 0.001	-	max. 0.05
Gadolinium	mg/kg	< 0.001	-	max. 0.05
Lanthanum	mg/kg	< 0.001	-	max. 0.05
Terbium	mg/kg	< 0.001	-	max. 0.05
Sum of Lanthanides	mg/kg	< 0.004	-	max. 0.05
Arsenic	mg/kg	< 0.001	-	N.D. (0.01)
Cadmium	mg/kg	< 0.001	-	N.D. (0.002)
Chromium	mg/kg	< 0.005	-	N.D. (0.01)
Lead	mg/kg	< 0.005	-	N.D. (0.01)
Mercury	mg/kg	< 0.002	-	N.D. (0.01)

**Notes to Table:**

- 1) Expressed as mg of substance per kg of 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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# ATTEST No. 472115654-01

Values obtained:

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

**LDPE food foil FC03 – white**

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

Primary aromatic amine (PAA)	CAS	Unit <sup>1)</sup>	Test result <sup>2)</sup>	Uncertainty	Limit <sup>3)</sup>
<b>PAAs listed in entry 43 to Appendix 8 of Annex XVII to REACH</b>					
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.
<b>Other PAAs (not listed in REACH)</b>					
Screening for others	4)	-	No PAA detected <sup>5)</sup>		-
Sum of detected PAAs		mg/kg	-	-	max. 0.01

## Notes to Table:

- 1) Expressed as mg of substance per kg of 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
- 4) The screening was performed for these PAAs: CAS No. 95-68-1, CAS No. 87-62-7, CAS No. 2243-62-1, CAS No. 62-53-3, CAS No. 95-51-2, CAS No. 108-42-9, CAS No. 106-49-0, CAS No. 106-50-3, CAS No. 823-40-5, CAS No. 121-69-7, CAS No. 6582-52-1, CAS No. 1208-52-2, CAS No. 6358-64-1, CAS No. 95-82-9, CAS No. 94-70-2, CAS No. 2835-68-9, CAS No. 81-16-3, CAS No. 88-44-8, CAS No. 49564-57-0, CAS No. 95-23-8, CAS No. 132-32-1, CAS No. 95-54-5, CAS No. 67014-36-2, CAS No. 156-43-4, CAS No. 90-41-5

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5) LOD (detection limit) of individual PAAs is 0.005 mg/kg  
REACH = Regulation (EC) No. 1907/2006 of European Parliament and of Council  
N.D. = not detectable; limit of detection 0.002 mg/kg

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

**LDPE food foil FC03 – white**

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

Primary aromatic amine (PAAs)	CAS	Unit <sup>1)</sup>	Test result <sup>2)</sup>	Uncertainty	Limit <sup>3)</sup>
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
4.4'-Methylenebis(3-chloro-2.6-diethylaniline)	106246-33-7	mg/kg	< 0.005	-	max. 0.05

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- 3) Limit values according to Commission Regulation EU 10/2011 as amended



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

Attest No. 472115654-01

**Sample description and identification:**

ITC's number	Sample identification by client	Description of submitted sample
15654/1	LDPE food foil FC03 – white	White foil – see the figure No. 1 on the page 2

The foil is produced in a transparent variant. According to the customer's information foils are made of the same material. The colour sample is different only in the colour concentrate used.

Based on an agreement with the customer, the tests were performed on colour variant of product that pose a higher risk in terms of health safety assessment.

Together with the sample a set of documents was supplied. The documentation includes the conformity declarations of raw materials with Commission Regulation (EU) No. 10/2011 including the information about the substances restricted by their specific migration limits (SML). These documents were classified as confidential.

**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 foils “**LDPE food foil FC03 – transparent, white**” 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 3 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 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 supplied the set of documents confirming the conformity of raw materials with the requirements of the legislation.

The submitted samples were screened for NIAS (non-intentionally added substances) by TD-GC-MS method. The identified substances including their restrictions are listed in the table on the page 3 of this attest. The test results of these specific migrations including the migration conditions are mentioned in

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

**Testing Laboratory – D2**

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the table on the page 4 of this attest. All measured values of specific migration meet the required limit value.

Migration of components from plastic materials and products shall not exceed specific migration limits (SML) or other restrictions included in the list of substances. The specific migrations of the substances listed on the page 2 were verified on the submitted sample. The test results of the specific migration of monomers, additives including the migration conditions are mentioned in the table on the page 4 of this attest. All measured values of the specific migrations meet the required limit values.

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<sup>2</sup>) (limit of overall migration). The test results of overall migration including migration conditions are mentioned on the page 4 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 6 and 7 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  $70\text{ °C} \leq T \leq 100\text{ °C}$  for up to the maximum contact time  $t = 120/2^{(T-70)/10}$  minutes**
- **Ratio: 60 cm<sup>2</sup> of product area/100 g (ml) of food (or more)**

**The opinion expressed and interpretation made by:**

Dipl. Ing. Ludmila Zálešáková, October 18, 2022

**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. Daniel Vít

Head of the laboratory of analytical chemistry and microbiology

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