



University of Chemistry and Technology, Prague
Independent packaging laboratory of UCT Prague

Technická 3, 166 28 Praha 6
Testing laboratory No. 1316 accredited by Czech Accreditation Institute
according to ČSN EN ISO/IEC 17025:2018

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Place of laboratory activities: Independent packaging laboratory of UCT Prague, Technická 3, 166 28 Praha 6

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TESTING PROTOCOL

No.: **060-en/22-01**

Customer: FARUSA Emballage a/s
Bygmarken 14,
DK-3520 Farum
Denmark
VAT DK27425518

Customer contact information: Martin Mikkelsen
telephone: + 45 4434 0999, email: martin@farusa.dk

Product: The sample of the plastic box.
The sample labelling in the laboratory – Customer designation*):
060/22/1 – the plastic box; material: HDPE,
dimensions 54 cm × 34 cm × 14 cm.

Producer: See the customer.

Objective: See the testing methods (page 2).

Processed by: Lenka Votavová, MSc, PhD

Appendix: Appendix No.1 – Certificate of Analysis PR2286384, PR2291385 and PR2294405. ALS Czech Republic, s.r.o. Na Harfe 336/9, 190 00 Prague 9, Czech Republic.
Appendix No.2 – Accredited laboratory test report ref. No. 472115644-01, 472115678-01 and 472115715-01. ITC a.s., třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic.



Approved:

Prague, October 3, 2022

Lukáš Vápenka, MSc, PhD
IPL manager

**) Customer-supplied data. The laboratory disclaims liability if the information provided by the customer may affect the validity of the results.*

*The results presented in this test report refer only to the samples tested as received.
Without the IPL authorization, this protocol may not be reproduced unless in whole.*

1. Basic information

Sample collection	Samples collected by		Customer
	Date of the collection		None
	Date of the transfer to IPL		August 16, 2022
Used testing methods IPL	ZM-01	Determination of overall migration from packaging materials into evaporable food simulants (<i>gravimetry, ČSN EN 1186; U.S. FDA, Code of Federal Regulations 21, chapter 175.300, p. d), e)</i>).	
	ZM-42 ^{N)}	Determination of overall migration from plastics into vegetable oil (<i>gravimetry, gas chromatography, ČSN EN 1186-10</i>).	
Sub-supplier of the tests within the scope of accreditation	Name, address		ALS Czech Republic, s.r.o., Na Harfě 9/336, CZ-190 00 Prague 9, Czech Republic.
	Tests realized		Determination of specific migration of the substances (24 metals and elements) into 3% acetic acid and content of heavy metals (8 metals) into 0.1M HCl ^{S)} .
	Name, address		ITC, a. s. třída Tomáše Bati 299, Louky, CZ-763 02 Zlín, Czech Republic.
	Tests realized		Determination of specific migration of primary aromatic amines (PAA) into 3% acetic acid ^{S)} .
Sub-supplier of the tests out of the scope of accreditation *)	Name, address		none
	Tests realized		none
Data of testing	August 19 – October 3, 2022		
Used devices	<ul style="list-style-type: none"> • analytical balance AND HR-200 (A&D Instruments Ltd, Japan) • laboratory thermostat Q-Cell (Q-Cell 240/60) • water bath (GFL 1031/1032) • dryer (WTB – Binder, type 15053300002020) • gas chromatograph Hewlett Packard 6890; detector Hewlett Packard 5973 ((Agilent Technologies, USA) 		

^{N)} Method out of the scope of accreditation.

^{S)} Provided by sub-supplier.

^{*)} Choice of the sub-supplier and the testing method on the base of the explicit ask of the customer.

2. Procedure of preparation of the samples for testing

Four pieces of the plastic box sample were obtained. The sample was tested in its original state after cutting into smaller parts of approximately 5 cm × 5 cm in size. According to the customer, the sample is intended for repeated use, therefore

it was tested as repeated use article; that is, the migration tests were performed three times a single sample using another portion of food simulant on each occasion.

The migration tests were performed according to the Regulation (EC) No. 1935/2004 of the European Parliament and of the Council and the Commission Regulation (EU) No. 10/2011 as amended. The leachates into food simulants were done in agreement with the procedure described in the Commission Regulation (EU) No. 10/2011, Chapter 2, section 2.1.6 and Chapter 3, section 3.3.2.

The conditions of the migration tests were as follows: full immersion of the parts of the plastic box sample (5 cm × 5 cm) into the food simulant, the food simulants: simulant A (10% ethanol), simulant B (3% acetic acid), simulant D2 (vegetable oil); contact temperature: 40 °C (for overall migration) and 60 °C (for specific migration); contact time: 240 hrs (10 days for 1st, 2nd and 3rd migration into simulants A, B and for 1st migration into simulant D2), 480 hrs (20 days, for 2nd migration into simulant D2) and 720 hrs (30 days, for 3rd migration into simulant D2), migration ratio: 1.00 dm²/100 ml of food simulant.

The leachate for the determination of the specific migration of substances (24 metals and elements) was prepared according to the following conditions: full immersion of the parts of the plastic box sample into the food simulant B (3% acetic acid); contact temperature: 60 °C; contact time: 240 hours (10 days for 1st, 2nd and 3rd migration); migration ratio: 1.00 dm²/100 ml of food simulant. The prepared leachate was sent to sub-supplier. The test methods used and the results of the determination are given in Appendix No. 1 of this testing protocol. The results of specific migrations of substances (24 metals and elements) expressed in milligrams of substance per liter of food simulant (mg / l) were recalculated and expressed in milligrams of substance released into one kilogram of food simulant (mg / kg) applying the surface to volume ratio 6 dm² / kg.

The leachate for determining the heavy metal content of the plastic box sample was prepared according to the following conditions: 10 g sample, 150 ml 0.1 M HCl, 23 °C, 1 hour. The leachate was sent to the sub-supplier. The test methods used and the results

of the determination are given in Appendix No. 1 of this testing protocol. The results of the heavy metal content expressed in milligrams per liter of 0.1M HCl, were recalculated and expressed in milligrams of heavy metal per kilogram of the plastic box sample.

The leachate for the determination of the specific migration of primary aromatic amines (PAA) into food simulant B (3% acetic acid) was prepared under the same conditions as the leachate for the determination of the specific migration of substances (24 metals and elements). The leachate was sent to sub-supplier. The testing methods used, the test conditions and the test results are given in Appendix No. 2 of this testing protocol.

The results of migration parameters were expressed according to the Commission Regulation (EU) No. 10/2011 (Chapter II, Article 11 and 12, Chapter V, Article 17) in milligrams of all substances released per square decimetre of the sample surface (mg / dm^2) for overall migration and in milligrams substance released per kilogram of food simulant (mg / kg) applying the surface to volume ratio $6 \text{ dm}^2 / \text{kg}$ for specific migration.



Figure 1 – Tested sample

3. Results

Table I: Overall migration.

Tested parameter	Conditions	Unit	Sample	Measurement uncertainty ^{*)}	Limit ^{**)}	Evaluation
			060/22/1			
Overall migration (ZM-01)	10% ethanol/ 40 °C/240 hrs 1 st migration	mg/dm ²	6.0	± 1.0	–	Within limit ***)
	10% ethanol/ 40 °C/240 hrs 2 nd migration		< 2.5 ⁺⁾	–	–	
	10% ethanol/ 40 °C/240 hrs 3 rd migration		< 2.5 ⁺⁾	–	10.0	
	3% acetic acid/ 40 °C/240 hrs 1 st migration		7.6	± 1.0	–	
	3% acetic acid/ 40 °C/240 hrs 2 nd migration		< 2.5 ⁺⁾	–	–	
	3% acetic acid/ 40 °C/240 hrs 3 rd migration		< 2.5 ⁺⁾	–	10.0	
Overall migration (ZM-42)^{N)}	vegetable oil/ 40 °C/240 hrs 1 st migration	mg/dm ²	8.0	± 3.0	–	Within limit ***)
	vegetable oil/ 40 °C/480 hrs 2 nd migration		4.9 ⁺⁺⁾	± 3.0	–	
	vegetable oil/ 40 °C/720 hrs 3 rd migration		3.1 ⁺⁺⁺⁾	± 3.0	10.0	

Notes to Table I:

⁺⁾ Symbol „<“ means less than the limit of quantification of the analytical method used.

⁺⁺⁾ Difference between result of the 2nd (480 hrs) and the 1st (240 hrs) migration test; see the Commission Regulation (EC) No. 10/2011 as amended. Chapter 3, section 3.3.2.

⁺⁺⁺⁾ Difference between result of the 3rd (720 hrs) and the 2nd (480 hrs) migration test; see the Commission Regulation (EC) No. 10/2011 as amended. Chapter 3, section 3.3.2.

Annotations to Table I:

^{*)} Stated uncertainty is expressed as expanded combined uncertainty based on standard deviation multiplied by coverage factor ($k = 2$), defines an interval having a level of confidence of approximately 95 %.

^{**)} Limit according to the Commission Regulation (EC) No. 10/2011 as amended.

^{***)} According to European Standard EN 1186-1, Chapter 12.3 Validity of results.

Table II: Specific migration of substances (24 metals and elements) according to of the Commission Regulation (EU) No. 10/2011 as amended, Annex II.

Tested parameter	Conditions	Unit	Sample	Measurement uncertainty	Limit ^{**)}	Evaluation	
			060/22/1				
Migration of substances ^{S)} (24 metals and elements)	3% acetic acid 60 °C/ 240 hrs 1 st migration	mg/kg ^{+))}	0.0303	*)	1	Within limit ^{***)}	
			Ba		0.0184		1
			Co		< 0.0010		0.05
			Cu		< 0.0085		5
			Fe		0.0300		48
			Li		< 0.00508		0.6
			Mn		< 0.000508		0.6
			Ni		< 0.0013		0.02
			Zn		0.0214		5
			Sb		< 0.00508		0.04
			Eu		< 0.00025		0.05
			Gd		< 0.00025		0.05
			La		< 0.0025		0.05
			Tb		< 0.0025		0.05
			As		< 0.0025		ND = 0.01
			Cd		< 0.00020		ND = 0.002
			Cr		< 0.0020		ND = 0.01
			Pb		< 0.0025		ND = 0.01
			Hg		< 0.0000051		ND = 0.01
			Ca		0.488		–
			Mg		0.103		–
			K		< 0.254		–
			Na		2.69		–
			NH ₄ ⁺		< 0.0814		–

Notes to Table II:

Symbol „<“ means less than limit of reporting (LOR) (see Appendix No. 1 of this testing protocol).

^{+))} The results of the sub-supplier given in mg/l (see Appendix No. 1 of this testing protocol) were recalculated to mg/kg of food simulatant applying the surface to volume ratio 6 dm² / kg.

Annotations to Table II:

^{*)} Measurement uncertainty see Appendix No. 1 of this testing protocol.

^{**)} Limit according to the Commission Regulation (EU) No. 10/2011 as amended, Annex II.

^{***)} The result with addition of measurement uncertainty is lower or equal to the specified limit.

The term "ND = numerical value, e.g., 0.01" means undetectable (the substance must not migrate in a detectable amount) with a detection limit of the value given after the sign =.

^{S)} Provided by sub-supplier.

Table III: Specific migration of substances (24 metals and elements) according to of the Commission Regulation (EU) No. 10/2011 as amended, Annex II.

Tested parameter	Conditions	Unit	Sample	Measurement uncertainty	Limit ^{**)}	Evaluation	
			060/22/1				
Migration of substances ^{S)} (24 metals and elements)	3% acetic acid 60 °C/ 240 hrs 2 nd migration	mg/kg ^{+))}	0.0172	*)	1	Within limit ^{***)}	
			Ba		0.00849		1
			Co		< 0.0010		0.05
			Cu		< 0.00508		5
			Fe		0.0166		48
			Li		< 0.00508		0.6
			Mn		< 0.000508		0.6
			Ni		< 0.0010		0.02
			Zn		< 0.0102		5
			Sb		< 0.00508		0.04
			Eu		< 0.00025		0.05
			Gd		< 0.00025		0.05
			La		< 0.0025		0.05
			Tb		< 0.0025		0.05
			As		< 0.0025		ND = 0.01
			Cd		< 0.00020		ND = 0.002
			Cr		< 0.0010		ND = 0.01
			Pb		< 0.0025		ND = 0.01
			Hg		< 0.0000051		ND = 0.01
			Ca		< 0.254		–
			Mg		0.0554		–
			K		< 0.254		–
			Na		2.06		–
			NH ₄ ⁺		< 0.025		–

Notes to Table III:

Symbol „<“ means less than limit of reporting (LOR) (see Appendix No. 1 of this testing protocol).

^{+))} The results of the sub-supplier given in mg/l (see Appendix No. 1 of this testing protocol) were recalculated to mg/kg of food simulatant applying the surface to volume ratio 6 dm² / kg.

Annotations to Table III:

^{*)} Measurement uncertainty see Appendix No. 1 of this testing protocol.

^{**)} Limit according to the Commission Regulation (EU) No. 10/2011 as amended, Annex II.

^{***)} The result with addition of measurement uncertainty is lower or equal to the specified limit.

The term "ND = numerical value, e.g., 0.01" means undetectable (the substance must not migrate in a detectable amount) with a detection limit of the value given after the sign =.

^{S)} Provided by sub-supplier.

Table IV: Specific migration of substances (24 metals and elements) according to of the Commission Regulation (EU) No. 10/2011 as amended, Annex II.

Tested parameter	Conditions	Unit	Sample	Measurement uncertainty	Limit ^{**)}	Evaluation	
			060/22/1				
Migration of substances ^{S)} (24 metals and elements)	3% acetic acid 60 °C/ 240 hrs 3 rd migration	mg/kg ^{+))}	0.0137	*)	1	Within limit ^{***)}	
			Ba		0.0107		1
			Co		< 0.0010		0.05
			Cu		< 0.00508		5
			Fe		0.0162		48
			Li		< 0.00508		0.6
			Mn		< 0.000508		0.6
			Ni		0.0012		0.02
			Zn		0.0131		5
			Sb		< 0.00508		0.04
			Eu		< 0.00025		0.05
			Gd		< 0.00025		0.05
			La		< 0.0025		0.05
			Tb		< 0.0025		0.05
			As		< 0.0025		ND = 0.01
			Cd		< 0.00020		ND = 0.002
			Cr		< 0.0010		ND = 0.01
			Pb		< 0.0025		ND = 0.01
			Hg		< 0.0000051		ND = 0.01
			Ca		0,255		–
			Mg		0,0451		–
			K		< 0,254		–
			Na		1,42		–
			NH ₄ ⁺		< 0.025		–

Notes to Table IV:

Symbol „<“ means less than limit of reporting (LOR) (see Appendix No. 1 of this testing protocol).

^{+))} The results of the sub-supplier given in mg/l (see Appendix No. 1 of this testing protocol) were recalculated to mg/kg of food simulatant applying the surface to volume ratio 6 dm² / kg.

Annotations to Table IV:

^{*)} Measurement uncertainty see Appendix No. 1 of this testing protocol.

^{**)} Limit according to the Commission Regulation (EU) No. 10/2011 as amended, Annex II.

^{***)} The result with addition of measurement uncertainty is lower or equal to the specified limit.

The term "ND = numerical value, e.g., 0.01" means undetectable (the substance must not migrate in a detectable amount) with a detection limit of the value given after the sign =.

^{S)} Provided by sub-supplier.

Table V: Content of heavy metals (8 metals) according to of the Decree of the Ministry of Health No. 38/2001 Coll as amended. Annex 1.

Tested parameter		Condition	Unit	Sample	Measurement uncertainty	Limit **)	Evaluation
				060/22/1			
Heavy metal content ^{S)}	As	0.1 M HCl 23 °C/1 hr	mg/kg ⁺)	< 0.075	*)	2.0	Within limit ***)
	Ba			0.241		2.0	
	Cd			< 0.0060		2.0	
	Cr			< 0.030		20.0	
	Hg			< 0.00015		1.0	
	Pb			< 0.075		2.0	
	Sb			< 0.151		10.0	
	Se			< 0.151		2.0	

Notes to Table V:

Symbol „ < “means less than limit of reporting (LOR) (see Appendix No. 1 of this testing protocol).

^{+) The results of the sub-supplier given in mg/l (see Appendix No. 1 of this testing protocol) were recalculated to mg/kg of the plastic box sample.}

Annotations to Table V:

^{*) Measurement uncertainty, see Appendix no. 1 of this testing protocol.}

^{***) Limit according to the Decree of the Ministry of Health No. 38/2001 Coll. – Annex 1, Chapter 1, Section 1.1.1.}

^{****) The result with addition of measurement uncertainty is lower or equal to the specified limit.}

^{S) Provided by sub-supplier.}

Table VI: The results of specific migration of primary aromatic amines (PAA) listed in REACH.

Tested parameter	Conditions	Unit	Sample	Measurement uncertainty	Limit ^{**)}	Evaluation
			060/22/1			
PAAs listed in entry 43 to Appendix 8 of Annex XVII to REACH						
4-Amino-biphenyl migration^{S)} (CAS No. 92-67-1)	3% acetic acid 60 °C/240 h 1 st , 2 nd , 3 rd migration ⁺)	mg/kg ⁺⁺⁾	< 0.002	*)	N.D.	Within limit ^{***)}
Benzidine migration^{S)} (CAS No. 92-87-5)			< 0.002			
4-Chloro-o-toluidine migration^{S)} (CAS No. 95-69-2)			< 0.002			
2-Naphthylamine migration^{S)} (CAS No. 91-59-8)			< 0.002			
o-Aminoazotoluene migration^{S)} (CAS No. 97-56-3)			< 0.002			
2-Amino-4-nitrotoluene migration^{S)} (CAS No. 99-55-8)			< 0.002			
p-Chloraniline migration^{S)} (CAS No. 106-47-8)			< 0.002			
2,4-Diaminoanisole migration^{S)} (CAS No. 615-05-4)			< 0.002			
4,4'-Methylenedianiline migration^{S)} (CAS No. 101-77-9)			< 0.002			
3,3'-Dichlorobenzidine migration^{S)} (CAS No. 91-94-1)			< 0.002			
3,3'-Dimethoxybenzidine migration^{S)} (CAS No. 119-90-4)			< 0.002			
3,3'-Dimethylbenzidine migration^{S)} (CAS No. 119-93-7)			< 0.002			
3,3'-Dimethyl-4,4'-diaminodiphenylmethane migration^{S)} (CAS No. 838-88-0)			< 0.002			
p-Cresidine migration^{S)} (CAS No. 120-71-8)			< 0.002			

4,4'-Methylenebis(2-chloroaniline) migration^{S)} (CAS No. 101-14-4)	3% acetic acid 60 °C/240 h 1 st , 2 nd , 3 rd migration ^{+))}	mg/kg ⁺⁺⁾	< 0.002	*	N.D.	Within limit ^{***)}
4,4'-Oxydianiline migration^{S)} (CAS No. 101-80-4)			< 0.002			
4,4'-Thiodianiline migration^{S)} (CAS No. 139-65-1)			< 0.002			
o-Toluidine migration^{S)} (CAS No. 95-53-4)			< 0.002			
2,4-Diaminotoluene migration^{S)} (CAS No. 95-80-7)			< 0.002			
2,4,5-Trimethylaniline migration^{S)} (CAS No. 137-17-7)			< 0.002			
o-Anisidine migration^{S)} (CAS No. 90-04-0)			< 0.002			
4-Aminoazobenzene migration^{S)} (CAS No. 60-09-3)			< 0.002			

Notes to Table VI:

Symbol „<“ means less than limit detection of the analytical method; see note 2) given in Tables No. II in Appendix No. 2 of this testing protocol.

^{+))} The results were the same for the 1st, 2nd and 3rd migration test.

⁺⁺⁾ mg /kg of food simulant; see note 1) given in Tables No. II in Appendix No. 2 of this testing protocol.

Annotations to Table VI:

* Measurement uncertainty see Tables No. II in Appendix No. 2 of this testing protocol.

** Limit according to Commission Regulation (EU) No. 10/2011 as amended, Annex II.

*** The result with addition of measurement uncertainty is lower or equal to the specified limit.

Abbreviation REACH = Regulation (EC) No. 1907/2006 of the European Parliament and of the Council.

Abbreviation N.D. = not detectable; limit of detection 0.002 mg / kg; see notes given in Tables No. II in Appendix No. 2 of this testing protocol.

^{S)} Provided by sub-supplier.

Table VII: The results of specific migration of primary aromatic amines (PAA) unlisted in REACH.

Tested parameter	Conditions	Unit	Sample	Measurement uncertainty	Limit **)	Evaluation
			060/22/1			
Other PAAs (not listed in REACH).						
Screening for others PAAs migration ^{+) S)}	3% acetic acid 60 °C/240 h 1 st , 2 nd , 3 rd migration ⁺⁺⁾	mg/kg ⁺⁺⁺⁾	No PAA detected ⁺⁺⁺⁾		–	Within limit ^{***)}
Sum of detected PAAs migration ^{S)}			–	*)	0.01	

Notes to Table VII:

⁺⁾ These PAAs were screened; see note 3) given in Tables No. III in Appendix No. 2 of this testing protocol.

⁺⁾ The results were the same for the 1st, 2nd and 3rd migration test.

⁺⁺⁺⁾ mg /kg of food simulant; see note 1) given in Tables No. III in Appendix No. 2 of this testing protocol.

⁺⁺⁺⁾ LOD (limit of detection) of individual PAA is 0.005 mg/kg; see note 4) given in Tables No. III in Appendix No. 2 of this testing protocol.

Annotations to Table VII:

^{*)} Measurement uncertainty see Tables No. III in Appendix No. 2 of this testing protocol.

^{**)} Limit according to Commission Regulation (EU) No. 10/2011 as amended, Annex II.

^{***)} The result with addition of measurement uncertainty is lower or equal to the specified limit.

Abbreviation REACH = Regulation (EC) No. 1907/2006 of the European Parliament and of the Council.

^{S)} Provided by sub-supplier.

Table VIII: Specific migration of primary aromatic amines (PAA) according to the Commission Regulation (EU) No. 10/2011 as amended, Annex I.

Tested parameter	Conditions	Unit	Sample	Measurement uncertainty	Limit *)	Evaluation
			060/22/1			
Bis(4-aminophenyl sulphone migration ^{S)} (CAS No. 80-08-0)	3% acetic acid 60 °C/240 h 1 st , 2 nd , 3 rd migration ⁺⁾	mg/kg ⁺⁺⁾	< 0.005	*)	5	Within limit ^{***)}
2-Aminobenzamide migration ^{S)} (CAS No. 88-68-6)			< 0.005		0.05	
1,3-Phenylenediamine migration ^{S)} (CAS No. 108-45-2)			< 0.002		0.002	
4,4'-Metylenebis (3-chloro-2,6-diethylaniline migration ^{S)} (CAS No. 106246-33-7)			< 0.005		0.05	

Notes to Table VIII:

Symbol „<“ means less than limit detection of the analytical method; see note 2) given in Tables No. IV in Appendix No. 2 of this testing protocol.

⁺⁾ The results were the same for the 1st, 2nd and 3rd migration test.

⁺⁺⁾ mg /kg of food simulant; see note 1) given in Tables No. IV in Appendix No. 2 of this testing protocol.

Annotations to Table VIII:

^{*)} Measurement uncertainty see Tables No. IV in Appendix No. 2 of this testing protocol.

^{**)} Limit according to Commission Regulation (EU) No. 10/2011 as amended, Annex I.

^{***)} The result with addition of measurement uncertainty is lower or equal to the specified limit.

^{S)} Provided by sub-supplier.

4. Deviations from recorded testing procedures, additional information

None

5. Conclusions

The migration tests were performed according to the Regulation (EC) No. 1935/2004 of the European Parliament and of the Council and the Commission Regulation (EU) No. 10/2011 as amended. The tested plastic box sample meets the required limits.

The end of the testing protocol.