

Prüfbericht Nr. 214-1/21

Konformität mit der geltenden europäischen und nationalen Gesetzgebung [Verordnung (EU) Nr. 10/2011 und folgende Änderungen und Modifikationen und DM IT 21.3.73 und folgende Änderungen und Modifikationen] der Muster " Polibox® isothermischer Behälter, aus expandiertem Polypropylen (PPE) - blaue Farbe ".

SAMMLUNG

Es wurde eine ausreichende Anzahl von Proben verwendet, um die Prüfungen gemäß den angenommenen technischen Normen durchzuführen.

GETESTETE PROBEN

Polibox® Isotherm-Behälter aus expandiertem Polypropylen (EPP) – blaue Farbe.

DURCHGEFÜHRTE KONTROLLEN

ÜBERPRÜFUNG DER EIGNUNG FÜR DEN LEBENSMITTELKONTAKT GEMÄSS DM vom 21.3.73 S.O. EuGH Nr. 104 vom 20.04.73, VO (EG) Nr. 1935/2004, ABl. L 338 vom 13.11.04, VO (EU) Nr. 10/2011, ABl. L 12 vom 15.01.01, VO (EU) Nr. 1282/2011, ABl. L 328/22 vom 10.12.2011, VO (EU) Nr. 1183/2012, ABl. L 338/13 vom 12.12.2012; VO (EU) Nr. 202/2014, ABl. L 62 vom 4.3.2014; VO (EU) 2015/174, ABl. L 30/2 vom 05.02.2015, VO (EU) 2015/174. (EU) 2016/1416 ABl. L 230 vom 25.08.2016, Reg. (EU) 2017/752 ABl. L 113 vom 28.04.2017, Reg. (EU) 2018/79 ABl. L 14 vom 19.01.2018 und Reg. (EU) 2018/213 ABl. L 41 vom 14.02.2018, Reg. (EU) 2018/831 ABl. EU L 140 vom 06.06.2018, VO (EU) 2019/37 ABl. EU L 9 vom 10.01.2019, VO (EU) 2019/1338 ABl. EU L 209 vom 09.08.2019 und VO (EU) 2020/1245 ABl. EU L 288 vom 03.09.2020.

1. Globale Migration bei der Simulation von 3%iger wässriger Essigsäurelösung und Ethanol-Tauchlösungen (LOQ: 1 mg/dm²)

Methode: Verordnung (EU) Nr. 10/2011 ABl. L 12 vom 15.01.2011 (Alle V) + Verordnung (EU) 2016/1416 ABl. L 230 vom 22.08.2016 + Verordnung (EU) 2017/752 ABl. L 113 vom 29.04.2017 + Verordnung (EU) 2019/37 ABl. L 9 vom 10.01.2019 + UNI EN 1186-1:2003 + UNI EN 1186-3:2003

Der Test wurde mit Flüssigkeiten aus dem ersten, zweiten und dritten Kontakt durchgeführt

KONTAKTFLÄCHE = 1 dm²; SIMULATIONSVOLUMEN = 250 ml

2. Globale Migration in alternativen Simulanzien zu D2 durch Eintauchen (LOQ: 1 mg/dm²)

Methode: Verordnung (EU) Nr. 10/2011 ABl. L 12 vom 15/01/2011 (Alle V) + Verordnung (EU) Nr. 10/2011 ABl. 2016/1416 ABl. EU L 230 vom 22/08/2016 + VO (EU) 2017/752 ABl. EU L 113 vom 29/04/2017 + UNI EN 1186-1:2003 + UNI EN 1186-14:2003

Der Test wurde mit Flüssigkeiten aus dem ersten, zweiten und dritten Kontakt durchgeführt

KONTAKTFLÄCHE = 1 dm²; SIMULATIONSVOLUMEN = 250 ml

Äquivalente Kontaktbedingungen bei 100°C für 4 Stunden in Pflanzenöl

3. Screening-Analyse - Head Space GC-MS (Auswertung flüchtiger Substanzen)

Die Analyse zielt darauf ab, kritische oder unerwünschte flüchtige organische Verbindungen, einschließlich nicht absichtlich hinzugefügter Stoffe (NIAS), in den Testproben mittels HS-GC-MS gemäß dem Verfahren der EN 13628-2:2004 nachzuweisen.

4. Screening-Analyse - Lösungsmittlextraktion und GC-MS-Analyse

Die Analyse zielt darauf ab, kritische oder unerwünschte halbflüchtige und nichtflüchtige organische Verbindungen, einschließlich nicht absichtlich hinzugefügter Stoffe (NIAS), in Testproben mittels GC-MS nachzuweisen.

5. PRIMÄRE AROMATISCHE AMINE = Summe

6. PRIMÄRE AROMATISCHE AMINE - LC-MS-Methode zur individuellen Quantifizierung

7. Spezifische Migration von Metallen aus Anhang II der Verordnung (EU) Nr. 10/2011 in der Fassung der Verordnung (EU) 2020/1245 - Simulanzmittel B

8. Restgehalt von Stoffen x5, die mit einer Vertraulichkeitsvereinbarung mitgeteilt wurden

9. Restgehalt des Stoffes x1, der mit einer Vertraulichkeitsvereinbarung mitgeteilt wird

SCHLUSSFOLGERUNGEN

Auf der Grundlage der durchgeführten Analysen entsprechen die Proben der "Polibox® isothermal container, made of expanded polypropylene (PPE) - blue colour" den geltenden nationalen und europäischen Rechtsvorschriften [DM 21.3.73 und nachfolgende Aktualisierungen und Änderungen sowie Verordnung (EU) Nr. 10/2011 und nachfolgende Aktualisierungen und Änderungen], beschränkt auf die kontrollierten Parameter.



RESPONSABILE UFFICIO QUALITA'

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IL LEGALE RAPPRESENTANTE

POLIBOX s.r.l.
Azienda con sistema di gestione qualità

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certificata
ISO 9001:2015
ISO 14001:2015
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Test report nr. 214-1/21

Date: March, 26th 2021

Subject: Compliance to the current European and National legislation [Reg. (EU) N.10/2011 and further updates and modifications and DM IT 21.3.73 and further updates and modifications] of your samples of "Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour".

The analyses were performed by Pack Co. staff, with its own instrumentation, in collaboration with LATA S.r.l. laboratory in Milan, under the agreements existing between the two entities.

Below, after the CONCLUSIONS section, the results of the performed tests are reported.

CONCLUSIONS

On the basis of the analyses reported in the RESULTS section, your sample of "Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour" are in compliance with the current European and National legislation [Reg. (EU) N.10/2011 and further updates and modifications, with respect to the checked parameters].

GENERAL DATA

- Samples arrival date:	March, 10 th 2021
- Reception date:	March, 10 th 2021
- Analyses start date:	March, 10 th 2021
- Analyses end date:	May, 26 th 2021
- Deviations from the agreed procedures:	NO

SAMPLING

The initial sampling was performed by the client.

All the tests were performed on an appropriate number of samples, as required by the adopted technical standards.

DECLARATION

This test report relates only to the tested items as received and it shall not be partially reproduced, if not under written approval by this laboratory.

The laboratory declines every responsibility relate to the information provided by the client, included in the present test report, and possibly influencing the validity of the results.

LOQ: Quantification Limit. It is the lowest analyte concentration that can be revealed with acceptable precision (repeatability) and accuracy in well specified conditions. A result expressed as "<LOQ" does not indicate the absence of the searched analyte in the examined sample.

U: Uncertainty. If not otherwise specified, the uncertainty is extended and has been calculated with a recovery factor $k=2$ corresponding to a probability interval of about 95%, or as confidence range calculated at a level of probability of about 95%.

If not otherwise specified, every eventual declaration of compliance reported in the CONCLUSION section arises from the comparison of the obtained results with the legislative limits considering the measure uncertainty.

SAMPLE DESCRIPTION

The following information are given by the client

- Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour

DETERMINATION AND TEST METHODS

COMPLIANCE FOR FOOD CONTACT MATERIALS ACCORDING TO THE DM of 21.3.73 S.O. GU n° 104 of 20/04/73, Reg. (EU) N. 10/2011 OJEU L 12 of 15/01/01, Reg. (EU) N. 1282/2011 OJEU L 328/22 of 10/12/2011, Reg. (EU) N. 1183/2012 OJEU L 338/13 of 12/12/2012; Reg. (EU) N. 202/2014 OJEU L 62 of 4/3/2014; Reg. (EU) 2015/174 OJEU L 30/2 of 05/02/2015, Reg. (EU) 2016/1416 OJEU L 230 of 25/08/2016, Reg. (EU) 2017/752 OJEU L 113 of 28/04/2017, Reg. (EU) 2018/79 OJEU L 14 of 19/01/2018, Reg. (EU) 2018/213 OJEU L 41 of 14/02/2018, Reg (EU) 2018/831 OJEU L 140 of 06/06/2018, Reg (EU) 2019/37 OJEU L 9 of 10/01/2019, Reg. (EU) 2019/1338 OJEU L 209 of 09/08/2019 and Reg. (EU) 2020/1245 OJEU L 288/1 of 3/09/2020.

1. Overall migration in aqueous solution of simulant 3 % acetic acid and of ethanol by immersion (LOQ: 1 mg/dm²)

Method: Reg. (EU) n. 10/2011 OJEU L 12 of 15/01/2011 (All V) + Reg. (EU) 2016/1416 OJEU L 230 of 22/08/2016 + Reg. (EU) 2017/752 OJEU L 113 of 29/04/2017 + Reg. (EU) 2019/37 OJEU L 9 of 10/01/2019 + UNI EN 1186-1:2003 + UNI EN 1186-3:2003.

Simulants	Contact conditions	Contact mode
Acetic acid 3% (w/v) – B	4 hours at 100 °C – repeated	Immersion
Ethyl alcohol 50% (v/v) – D1	4 hours at reflux temperature – repeated	Immersion

March, 26th 2021

The test was performed on the simulants coming from the first, second and third contact
CONTACT SURFACE = 1 dm²; SIMULANT VOLUME = 250 ml

2. Overall migration in simulants alternative to D2 by immersion (LOQ: 1 mg/dm²)

Method: Reg. (EU) n. 10/2011 OJEU L 12 of 15/01/2011 (All V) + Reg. (EU) 2016/1416 OJEU L 230 of 22/08/2016 + Reg. (EU) 2017/752 OJEU L 113 of 29/04/2017 + UNI EN 1186-1:2003 + UNI EN 1186-14:2003.

Simulant	Contact conditions	Contact mode
Isooctane – alternative to D2	3 hours at 60 °C – repeated ⁽¹⁾	Immersion

The test was performed on the simulants coming from the first, second and third contact
CONTACT SURFACE = 1 dm²; SIMULANT VOLUME = 250 ml

⁽¹⁾ : contact conditions equivalent to 100°C for 4 ore in vegetal oil

3. Screening analysis - Head Space GC-MS (evaluation of the volatile substances)

Analysis for the search and quantification, in the samples, of critic organic volatiles substances or undesired, including Non-Intentionally Added Substances (NIAS), via HS-GC-MS, on the basis of the procedure included in the normative UNI EN 13628-2:2004.

Three aliquots of sample of around 0.2 g, are transferred in hermetically closed 20 ml vials and conditioned for 30 minutes at 125°C. The sampling of the volatiles organic compounds is made by automatic HS-GC-MS instrumentation, operating as follow:

Agilent 7697A – Head Space autosampler

Oven: 125°C for 30 minutes

Transfer line: 140°C

Injection volume: 1500 µl

Agilent 7890B Gas-chromatograph

Column Restek RTX-5MS 30 m x 0.25 mm x 1.0 µm

Temperature program:

T_{start} 45 °C x 3 min

Ramp to T₁ 50°C in 10°C/min

Ramp to T₂ 150°C in 20°C/min

Ramp to T₃ 300°C in 30°C/min
T_{end} 300°C for 11.5 min
Total time: 25 minutes
Injector temperature: 200°C
Mode: split 10:1
Carrier: helium constant flux 1 ml/min

Agilent 5977B Mass spectrometer
Acquisition mode: SCAN
Acquisition range:
from 2.5 min with m/z from 33 to 250
from 10 min with m/z from 33 to 350
from 15 min with m/z from 33 to 500
Delay: 2.5 min

Semi-quantitative evaluation based on the response of a mixture to different known concentrations of specific volatile substances.

LOQ: 0.1 mg/kg of material

4. Screening analysis –Solvent extraction and GC-MS analysis

Screening analysis for the search and quantification on the material of critical or undesired semi- and non-volatile organic compounds, including the Non-Intentionally Added Substances (NIAS) and eventual restricted substances (SML or QM) via GC-MS.

Three aliquots of sample of around 0.2 g, are extracted with 6 ml of a solution of ethyl acetate/n-hexane doped with Methyl Heptadecanoate as internal standard, in ultrasonic bath at 60°C for 16 hours followed by analysis with the following operative conditions:

GERSTEL MPS liquid autosampler
Injection volume: 1.5 µl
Agilent 7890A Gas chromatograph
Agilent DB-5HT 15 m x 0.25 mm x 0.1 µm column
Temperature program:
T_{initial} 100°C x 2 min
Ramp to T₁ 130°C at 10°C/min
Ramp to T₂ 190°C at 15 °C/min
Ramp to T₃ 320°C at 20°C/min
T_{final} at 320°C for 7.5 min
Total time: 25 minutes

Injector: mode Splitless
Injector temperature: 290°C
Valve opening after 0.3 min
Carrier: constant flow helium at 1 ml/min

Agilent 5975C Mass spectrometer
Acquisition mode: SCAN
Acquisition range:
from 3 min with m/z from 33 to 300
from 10 min with m/z from 33 to 550
from 15 min with m/z from 33 to 700
Solvent delay: 3 min

Semiquantitative evaluation on the basis of the response of the detector to the internal standard.

LOQ: 1 mg/kg of material

5. PRIMARY AROMATIC AMINES = sum

Determination of the specific migration of Primary Aromatic Amines by spectrophotometry, in simulant B coming from the three contacts described in point 1.

Preparation of the contact by Pack Co., quantification of the specific migration by L.A.T.A. S.r.l. laboratory in Milan, under the agreement existing between the two entities.

The quantification of the primary aromatic amines is performed by a spectrophotometric method based on the formation of a chromophore complex of the amines through diazotization and copulation, followed by the concentration on solid phase column and elution of the coloured complex having the highest absorbance at 550 nm. For the quantification a calibration curve at 550 nm was prepared from a stock solution of Aniline Hydrochloride diluted so to obtain 0, 5, 10, 15, 20, 30, 40 and 60 ppb solutions of aniline hydrochloride in 100 ml of 3% acetic acid.

LOQ: 0.005 mg/kg of simulant (as sum of primary aromatic amines)

6. PRIMARY AROMATIC AMINES - LC-MS method for individual quantification

The evaluation of the specific migration of Primary Aromatic Amines (AAP) is carried out in the simulant B coming from the three contacts described in point 1.

The amines listed in the Annex XVII, appendix 8, entry 43 of the Regulation (EC) No. 1907/2006.

The quantification of the specific migration is made following the Protocol A published in the document "EUR 24815 EN" of the Joint Research Centre Institute for Health and

Consumer Protection.

LOQ: 0.002 mg/kg of Simulant

7. Specific Migrations of the Metals of the Annex II Reg. (EU) N. 10/2011 modified by Reg. (EU) 2020/1245 – simulant B

Research of metals in Annex II of Reg. (EU) No. 10/2011 and subsequent adj. and mod. in simulant B coming from the three contacts described in point 1.

Preparation of the contact by Pack Co., quantification of the specific migration by LATA S.r.l. laboratory in Milan, under the agreement existing between the two entities.

LOQ: 0.005 mg/kg of simulant for all the elements, except for the Cadmium, whose LOQ is 0.001 mg/kg.

8. Residual content of the substances X5, communicated under non-disclosure agreement

The extraction solution from the test on paragraph 4. is analysed by HPLC-MS instrumentation, working as follows:

HPLC Agilent 1260 Infinity

Raptor column C18 2.1 mm x 100 mm x 2.7 µm

Injection volume: 5 µl

Flow: 0.3 ml/min

Column temperature: 30 °C

Analysis total time: 13 minutes

Eluent:	0 min	7 min
Water + 0.1% Formic acid	70 %	30 %
Acetonitrile + 0.1% Formic acid	30 %	70 %

Massa spectrometer AGILENT 6120 SQ

Mode SIM+

Quantitative evaluation on the basis of a calibration line made from known concentration of the searched substance.

LOQ: 0.5 mg/kg of material

9. Residual content of the substance X1, communicated under non-disclosure agreement

The extraction solution from the test on paragraph 4. is analysed by HPLC-MS instrumentation, working as follows:

HPLC Agilent 1260 Infinity
 Zorbax column SB-C18 2.1 mm x 100 mm x 2.7 µm
 Injection volume: 1 µl
 Flow: 0.4 ml/min
 Column temperature: 30 °C
 Analysis total time: 5 minutes

Eluent:
 Water + 0.1% Formic acid 99.5 %
 Acetonitrile + 0.1% Formic acid 0.5 %

Massa spectrometer AGILENT 6120 SQ
 Mode SIM+

Quantitative evaluation on the basis of a calibration line made from known concentration of the searched substance.

LOQ: 0.5 mg/kg of material

RESULTS

1. Overall migration in aqueous solution of simulant 3 % acetic acid and of ethanol by immersion (LOQ: 1 mg/dm²)

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: B – acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100°C - first contact			
Unit of measure: mg/dm ²			
Determined values	Average value	Expanded uncertainty (U)	Limit value [Reg. (EU) N. 10/2011]
5.9	4.6	1.2	10±2
3.9			
4.1			

Isothermal container Polibox ®. made of expanded polypropylene (EPP) – blue colour			
Simulant: B – acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100°C - second contact			
Unit of measure: mg/dm ²			
Determined values	Average value	Expanded uncertainty (U)	Limit value [Reg. (EU) N. 10/2011]
3.7	2.7	1.2	10±2
3.1			
1.5			

Isothermal container Polibox ®. made of expanded polypropylene (EPP) – blue colour			
Simulant: B – acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100°C - third contact			
Unit of measure: mg/dm ²			
Determined values	Average value	Expanded uncertainty (U)	Limit value [Reg. (EU) N. 10/2011]
<1	<1	---	10±2
<1			
<1			

Isothermal container Polibox ®. made of expanded polypropylene (EPP) – blue colour			
Simulant: D1 - ethyl alcohol 50% (v/v)			
Contact conditions: 4 hours at reflux temperature – first contact			
Unit of measure: mg/dm ²			
Determined values	Average value	Expanded uncertainty (U)	Limit value [Reg. (EU) N. 10/2011]
2.6	2.2	1.2	10±2
2.0			
2.1			

Isothermal container Polibox ®. made of expanded polypropylene (EPP) – blue colour			
Simulant: D1 - ethyl alcohol 50% (v/v)			
Contact conditions: 4 hours at reflux temperature – second contact			
Unit of measure: mg/dm ²			
Determined values	Average value	Expanded uncertainty (U)	Limit value [Reg. (EU) N. 10/2011]
1.2	1.5	1.2	10±2
2.0			
1.2			

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: D1 - ethyl alcohol 50% (v/v)			
Contact conditions: 4 hours at reflux temperature – third contact			
Unit of measure: mg/dm ²			
Determined values	Average value	Expanded uncertainty (U)	Limit value [Reg. (EU) N. 10/2011]
<1	<1	---	10±2
<1			
<1			

2. Overall migration in simulants alternative to D2 by immersion (LOQ: 1 mg/dm²)

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: Isooctane - alternative to D2			
Contact conditions: 3 hours at 60 °C – first contact			
Unit of measure: mg/dm ²			
Determined values	Average value	Expanded uncertainty (U)	Limit value Reg. (EU) N. 10/2011
5.7	7.1	1.2	10±2
7.3			
8.4			

Isothermal container Polibox ®. made of expanded polypropylene (EPP) – blue colour			
Simulant: Isooctane - alternative to D2			
Contact conditions: 3 hours at 60 °C – second contact			
Unit of measure: mg/dm ²			
Determined values	Average value	Expanded uncertainty (U)	Limit value Reg. (EU) N. 10/2011
1.1	1.5	1.2	10±2
1.4			
2.1			

Isothermal container Polibox ®. made of expanded polypropylene (EPP) – blue colour			
Simulant: Isooctane - alternative to D2			
Contact conditions: 3 hours at 60 °C – third contact			
Unit of measure: mg/dm ²			
Determined values	Average value	Expanded uncertainty (U)	Limit value Reg. (EU) N. 10/2011
3.4	4.2	1.2	10±2
3.8			
5.4			

The test by filling cannot be performed because the simulant is absorbed. Here it is supposed that the test by immersion of the semi-expanded polymer is more severe than the real application.

3. Screening analysis - Head Space GC-MS (evaluation of the volatile substances)

In the following table, the amounts of the substances revealed in the samples with the technique described above, are reported as average of the three determinations, in mg/kg of material, its standard deviation (s.d.) and percentage standard deviation (s.d.%):

Volatiles 125°C 30 min		Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour		
RT min	COMPOUND	mg/kg	s.d.	s.d. %
3.20	Acetic acid	0.88	0.45	51

11.10	Aldehyde C9-C10	0.58	0.075	13
12.3-14.7	Linear and branched hydrocarbons C14-C20	5.3	2.1	40

4. Screening analysis – extraction with solvent and GC-MS analysis

In the following table, the amounts of the substances revealed in the samples with the technique described above, are reported as average of the three determinations, in mg/kg of material, its standard deviation (s.d.) and percentage standard deviation (s.d.%):

	Non-Volatiles EA/C6	Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour		
RT min	COMPOUND	mg/kg	s.d.	s.d. %
11.5-18.5	Linear and branched hydrocarbons C16-C28	360	31	9
12.90	CAS 82304-66-3	110	16	15
13.80	Acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters	85	11	13
20.40	Irgafos 168	84	33	39
20.90	Oxidized Irgafos 168	390	24	6

5. PRIMARY AROMATIC AMINES = sum

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: B - acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100° C – first contact			
Unit of measure: mg/kg of Simulant			
Determined values	Average value	Uncertainty	Limit value
< 0.005	< 0.005	---	0.01
< 0.005			
< 0.005			

Isothermal container Polibox ®. made of expanded polypropylene (EPP) – blue colour			
Simulant: B - acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100° C – second contact			
Unit of measure: mg/kg of Simulant			
Determined values	Average value	Uncertainty	Limit value
< 0.005	< 0.005	---	0.01
< 0.005			
< 0.005			

Isothermal container Polibox ®. made of expanded polypropylene (EPP) – blue colour			
Simulant: B - acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100° C – third contact			
Unit of measure: mg/kg of Simulant			
Determined values	Average value	Uncertainty	Limit value
< 0.005	< 0.005	---	0.01
< 0.005			
< 0.005			

6. PRIMARY AROMATIC AMINES - LC-MS method for individual quantification

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: B - acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100° C – first contact			
Unit of measure: mg/kg of Simulant			
Compound	Average value	Expanded uncertainty	SML
o-Toluidine	< 0.002	---	0.002
4-methyl-m-phenylenediamine	< 0.002	---	0.002
o-Anisidine	< 0.002	---	0.002
4-chloroaniline	< 0.002	---	0.002

2,4,5-trimethylaniline	< 0.002	---	0.002
6-methoxy-m-toluidine	< 0.002	---	0.002
4-amino-azobenzene	< 0.002	---	0.002
4-methoxy-m-phenylenediamine	< 0.002	---	0.002
4-chloro-o-toluidine	< 0.002	---	0.002
2-naphthyl-amine	< 0.002	---	0.002
5-nitro-o-toluidine	< 0.002	---	0.002
4-amino-biphenyl	< 0.002	---	0.002
Benzidine	< 0.002	---	0.002
4,4'-diaminodiphenylmethane	< 0.002	---	0.002
4,4'-oxydianiline	< 0.002	---	0.002
3,3'-dimethylbenzidine	< 0.002	---	0.002
4,4'-thiodianiline	< 0.002	---	0.002
o-amino-azotoluene	< 0.002	---	0.002
4,4'-methylenedi-o-toluidine	< 0.002	---	0.002
3,3'-dimethoxybenzidine	< 0.002	---	0.002
3,3'-dichlorobenzidine	< 0.002	---	0.002
4,4'-methylene-bis-(2-chloroaniline)	< 0.002	---	0.002

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: B - acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100° C – second contact			
Unit of measure: mg/kg of Simulant			
Compound	Average value	Expanded uncertainty	SML
o-Toluidine	< 0.002	---	0.002
4-methyl-m-phenylenediamine	< 0.002	---	0.002
o-Anisidine	< 0.002	---	0.002
4-chloroaniline	< 0.002	---	0.002
2,4,5-trimethylaniline	< 0.002	---	0.002

6-methoxy-m-toluidine	< 0.002	---	0.002
4-amino-azobenzene	< 0.002	---	0.002
4-methoxy-m-phenylenediamine	< 0.002	---	0.002
4-chloro-o-toluidine	< 0.002	---	0.002
2-naphthyl-amine	< 0.002	---	0.002
5-nitro-o-toluidine	< 0.002	---	0.002
4-amino-biphenyl	< 0.002	---	0.002
Benzidine	< 0.002	---	0.002
4,4'-diaminodiphenylmethane	< 0.002	---	0.002
4,4'-oxydianiline	< 0.002	---	0.002
3,3'-dimethylbenzidine	< 0.002	---	0.002
4,4'-thiodianiline	< 0.002	---	0.002
o-amino-azotoluene	< 0.002	---	0.002
4,4'-methylenedi-o-toluidine	< 0.002	---	0.002
3,3'-dimethoxybenzidine	< 0.002	---	0.002
3,3'-dichlorobenzidine	< 0.002	---	0.002
4,4'-methylene-bis-(2-chloroaniline)	< 0.002	---	0.002

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: B - acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100° C – third contact			
Unit of measure: mg/kg of Simulant			
Compound	Average value	Expanded uncertainty	SML
o-Toluidine	< 0.002	---	0.002
4-methyl-m-phenylenediamine	< 0.002	---	0.002
o-Anisidine	< 0.002	---	0.002
4-chloroaniline	< 0.002	---	0.002
2,4,5-trimethylaniline	< 0.002	---	0.002

6-methoxy-m-toluidine	< 0.002	---	0.002	
4-amino-azobenzene	< 0.002	---	0.002	
4-methoxy-m-phenylenediamine	< 0.002	---	0.002	
4-chloro-o-toluidine	< 0.002	---	0.002	
2-naphthyl-amine	< 0.002	---	0.002	
5-nitro-o-toluidine	< 0.002	---	0.002	
4-amino-biphenyl	< 0.002	---	0.002	
Benzidine	< 0.002	---	0.002	
4,4'-diaminodiphenylmethane	< 0.002	---	0.002	
4,4'-oxydianiline	< 0.002	---	0.002	
3,3'-dimethylbenzidine	< 0.002	---	0.002	
4,4'-thiodianiline	< 0.002	---	0.002	
o-amino-azotoluene	< 0.002	---	0.002	
4,4'-methylenedi-o-toluidine	< 0.002	---	0.002	
3,3'-dimethoxybenzidine	< 0.002	---	0.002	
3,3'-dichlorobenzidine	< 0.002	---	0.002	
4,4'-methylene-bis-(2-chloroaniline)	< 0.002	---	0.002	

7. Specific Migrations of the Metals of the Annex II Reg. (EU) N. 10/2011 modified by Reg. (EU) 2020/1245 – simulant B

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: B – acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100° C – first contact			
Unit of measure: mg/kg of simulant			
Element	Average value	Expanded uncertainty	Limit value Reg. (EU) N. 10/2011 up to Reg. (EU) 2020/1245
Aluminium	0.093	0.006	1
Antimony	< 0.005	---	0.04
Arsenic	< 0.005	---	0.01
Barium	< 0.005	---	1

Cadmium	< 0.001	---	0.002
Cobalt	< 0.005	---	0.05
Chromium	< 0.005	---	0.01 ⁽¹⁾
Europium	< 0.005	---	0.05
Iron	0.029	0.022	48
Gadolinium	< 0.005	---	0.05
Lanthanum	< 0.005	---	0.05
Lithium	< 0.005	---	0.6
Manganese	< 0.005	---	0.6
Mercury	< 0.005	---	0.01
Nickel	< 0.005	---	0.02
Lead	< 0.005	---	0.01
Copper	0.019	0.002	5
Terbium	< 0.005	---	0.05
Zinc	0.102	0.082	5

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: B – acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100° C – first contact			
Unit of measure: mg/kg of simulant			
Element	Average value	Expanded uncertainty	Limit value Reg. (EU) N. 10/2011 up to Reg. (EU) 2020/1245
Aluminium	0.057	0.015	1
Antimony	< 0.005	---	0.04
Arsenic	< 0.005	---	0.01
Barium	< 0.005	---	1
Cadmium	< 0.001	---	0.002
Cobalt	< 0.005	---	0.05
Chromium	< 0.005	---	0.01 ⁽¹⁾
Europium	< 0.005	---	0.05
Iron	0.007	0.007	48
Gadolinium	< 0.005	---	0.05
Lanthanum	< 0.005	---	0.05
Lithium	< 0.005	---	0.6
Manganese	< 0.005	---	0.6

Mercury	< 0.005	---	0.01
Nickel	< 0.005	---	0.02
Lead	< 0.005	---	0.01
Copper	0.009	0.002	5
Terbium	< 0.005	---	0.05
Zinc	0.036	0.020	5

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour			
Simulant: B – acetic acid 3% (w/v)			
Contact conditions: 4 hours at 100° C – third contact			
Unit of measure: mg/kg of simulant			
Element	Average value	Expanded uncertainty	Limit value Reg. (EU) N. 10/2011 up to Reg. (EU) 2020/1245
Aluminium	0.027	0.007	1
Antimony	< 0.005	---	0.04
Arsenic	< 0.005	---	0.01
Barium	< 0.005	---	1
Cadmium	< 0.001	---	0.002
Cobalt	< 0.005	---	0.05
Chromium	< 0.005	---	0.01 ⁽¹⁾
Europium	< 0.005	---	0.05
Iron	< 0.005	---	48
Gadolinium	< 0.005	---	0.05
Lanthanum	< 0.005	---	0.05
Lithium	< 0.005	---	0.6
Manganese	< 0.005	---	0.6
Mercury	< 0.005	---	0.01
Nickel	< 0.005	---	0.02
Lead	< 0.005	---	0.01
Copper	< 0.005	---	5
Terbium	< 0.005	---	0.05
Zinc	0.022	0.012	5

- (1) The limit for Chromium is set to 0.01 unless it is possible to exclude the presence of Cr^{VI}, in this case the limit is raised to 3.6 mg/kg of food or simulant.

8. Residual content of the substances X5, communicated under non-disclosure agreement

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour		
Solvent: Ethyl-acetate/n-hexane		
Extraction conditions: 60 °C in ultrasonic bath for 16 hours		
Unit of measure: mg/kg		
Determined values	Average value	Uncertainty
< 0.5	< 0,5	---
< 0.5		
< 0.5		

The residual content of the X5 substances is low enough to make the theoretical specific migration lower than the specific migration limit.

9. Residual content of the substances X1, communicated under non-disclosure agreement

Isothermal container Polibox ®, made of expanded polypropylene (EPP) – blue colour		
Solvent: Ethyl-acetate/n-hexane		
Extraction conditions: 60 °C in ultrasonic bath for 16 hours		
Unit of measure: mg/kg		
Determined values	Average value	Uncertainty
< 0.1	< 0,1	---
< 0.1		
< 0.1		

The residual content of the X5 substances is low enough to make the theoretical specific migration lower than the specific migration limit.

END OF THE TEST REPORT



March, 26th 2021

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