POLIBOX®

(R)evolutionary

02/01/2023

Informe de ensayo nº 214-1/21

Conformidad con la legislación europea y nacional vigente [Reg. (UE) Nº 10/2011 y modificaciones posteriores y DM IT 21.3.73 y modificaciones posteriores] de las muestras "Contenedor isotérmico Polibox®, fabricado en polipropileno expandido (PPE) - color azul".

MUESTRAS

Para la realización de las pruebas ha sido utilizado un número de muestras adecuado, tal como exigen las normas técnicas adoptadas.

MUESTRAS EXAMINADAS

Contenedor isotérmico Polibox®, fabricado en polipropileno exandido (PPE) - color azul.

CONTROLES REALIZADOS

VERIFICACIÓN DE LA IDONEIDAD PARA EL CONTACTO CON ALIMENTOS SEGÚN DM de 21.3.73 S.O. DO No. 104 de 20/04/73, Reg. (CE) No. 1935/2004 DOUE L 338 de 13/11/04, Reg. (UE) No. 10/2011 DOUE L 12 de 15/01/01, Reg. (UE) No. 1282/2011 DOUE L 328/22 de 10/12/2011, Reg. (UE) No. 1183/2012 DOUE L 338/13 de 12/12/2012; Reg. (UE) No. 202/2014 DOUE L62 de 4/3/2014; Reg. (UE) 2015/174 DOUE L30/2 de 05/02/2015, Reg. (UE) 2016/1416 DOUE L 230 de 25/08/2016, Reg. (UE) 2017/752 DOUE L 113 de 28/04/2017, Reg. (UE) 2018/79 DOUE L 14 de 19/01/2018 y Reg. (UE) 2018/213 DOUE L 41 de 14/02/2018, Reg. (UE) 2018/831 DOUE L 140 de 06/06/2018, Reg. (UE) 2019/37 DOUE L 9 de 10/01/2019, Reg. (UE) 2019/1338 DOUE L 209 de 09/08/2019 y Reg. (UE) 2020/1245 DOUE L 288 de 03/09/2020.

1. Migración global en solución acuosa simulante de ácido acético al 3% y soluciones de inmersión en etanol (LOQ: 1 mg/dm2)

Método: Reg. (UE) nº 10/2011 DOUE L 12 de 15/01/2011 (Todos los V) + Reg. (UE) 2016/1416 DOUE L 230 de 22/08/2016 + Reg. (UE) 2017/752 DOUE L 113 de 29/04/2017 + Reg. (UE) 2019/37 DOUE L9 de 10/01/2019 + UNI EN 1186-1:2003 + UNI EN 1186-3:2003

La prueba se realizó con líquidos provenientes del primer, segundo y tercer contacto
SUPERFICIE DE CONTACTO = 1 dm2; VOLUMEN DE SIMULACIÓN = 250 ml

2. Migración global en simulantes alternativos al D2 por inmersión (LOQ: 1 mg/dm2)

Método: Reg. (UE) nº 10/2011 DOUE L 12 de 15/01/2011 (Todos los V) + Reg. 2016/1416 DOUE L 230 de 22/08/2016 + Reg. (UE) 2017/752 DOUE L 113 de 29/04/2017 + UNI EN 1186-1:2003 + UNI EN 1186-14:2003

La prueba se realizó con líquidos provenientes del primer, segundo y tercer contacto.

SUPERFICIE DE CONTACTO = 1 dm2; VOLUMEN DE SIMULACIÓN = 250 ml

Condición de contacto equivalente a 100°C durante 4 horas en aceite vegetal

3. Análisis de cribado - Head Space GC-MS (evaluación de sustancias volátiles)

El objetivo del análisis es buscar en las muestras de ensayo compuestos orgánicos volátiles críticos o indeseables, incluidas las sustancias no añadidas intencionadamente (NIAS), mediante HS-GC-MS, de acuerdo con el procedimiento de UNI EN 13628-2:2004.

4. Análisis de cribado - extracción con disolventes y análisis GC-MS

El análisis tiene por objeto detectar compuestos orgánicos semivolátiles y no volátiles críticos o indeseables, incluidas las sustancias no añadidas intencionadamente (NIAS), en las muestras de ensayo mediante CG-EM.

5. AMINAS AROMATICAS PRIMARIAS = suma

6. AMINAS AROMÁTICAS PRIMARIAS - Método LC-MS para la cuantificación individual

7. Migración específica de metales del anexo II REG. (UE) nº 10/2011 modificado por el Reglamento (UE) 2020/1245 - simulante B

8. Contenido residual de las sustancias x5 comunicado con acuerdo de confidencialidad

9. Contenido de fondo x1 comunicado con acuerdo de confidencialidad

CONCLUSIONES

En base a los análisis realizados, las muestras de "Contenedor isotérmico Polibox®, fabricado en polipropileno expandido (PPE) - color azul", resultan conformes con la legislación nacional y europea vigente [DM 21.3.73 y posteriores actualizaciones y modificaciones y Reg. (UE) N. 10/2011 y posteriores actualizaciones y modificaciones], limitándose a los parámetros comprobados.

ORDINE TECNOLOGI ALIMENTARI REGIONE LOMBARDIA E LIGURIA
Dott. RAVAROTTO ROBERTO ENRICO N. 24

RESPONSABILE UFFICIO QUALITA'

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IL LEGALE RAPPRESENTANTE

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, 10th 2021
- Reception date:	March, 10th 2021
- Analyses start date:	March, 10th 2021
- Analyses end date:	May, 26th 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 L62 of 4/3/2014; Reg. (EU) 2015/174 OJEU L30/2 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 L9 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/dm^2)

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 L9 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

The test was performed on the simulants coming from the first, second and third contact

CONTACT SURFACE = 1 dm^2; SIMULANT VOLUME = 250 ml

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

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 dm^2; 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 T_1 50°C in 10°C/min
Ramp to T_2 150°C in 20°C/min

Ramp to T_3 300°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 T_1 130°C at 10°C/min
Ramp to T_2 190°C at 15 °C/min
Ramp to T_3 320°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/dm²			
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/dm²			
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/dm²			
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/dm²			
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/dm²			
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/dm²			
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/dm²			
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.

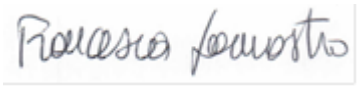
9. Residual content of the substances X1, communicated under non-disclosure agreement

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

Made by: **Francesca LOMASTRO – Pack Co. S.r.l.**
Area responsible



Approved by: **Gianluigi VESTRUCCI – Pack Co. S.r.l.**
Laboratory manager