

Lepe (Huelva), March 23, 2022

As defined in the 13<sup>th</sup> Article (Declaration for commerce) and detailed in the Annex VII R.D. 866/2008 on 23<sup>rd</sup> of May (B.O.E 131 on Friday the 30<sup>th</sup> of May 2008) and taking into account the modifications of R.D. 103/2009 on February (B.O.E 41 the 17<sup>th</sup>, Tuesday 2009):

**POLISUR 2000, S.L.U.** domiciled Finca Las Majadillas, Ctra. Nac. 444-km. 2,95 - 21440 Lepe (Huelva) and as producer of "POLARBOX portable coolers", is willing to declare the following:

**POLARBOX** are manufactured with Propilene (PP) and Poliestirene (Airpop) both 100% virgin, which fulfill the manufacture requirements on plastic materials and items intended to come into contact with food as regards national and european legislation;

- **Royal Decree 866/2008** (modified by R.D. 103/2009) and in the Regulation (EC) No. 1935/2004 of the European Parliament and Council, on 27 of October 2004, about materials and items intended to come into contact with food.

- **Regulation (EU) N. 10/2011** of the Comission on the 14th of February 2011 and its successive amendments (last amend Regulation (EU) 1245/2020 on the 2nd of September 2020).

- **Regulation (EU) No. 202/2014** on 3rd of March 2014, about materials and plastic objects intended to come into contact which derogates the Directive 2002/72/EC and Regulation (EU) 2015/174 of the Comission the 5th of February 2015.

- **Royal Decree 846/2011 and Royal Decree 847/2011**, the 17th of June, which stablishes the positive list of permitted substances for the manufacturing of polimetric materials intended to come into contact with food.

- **Regulation 2016/1416** ammends the Regulation 10/2011 of the European Union and stablishes changes the norms for plastic materials and objects intended to come into contact with food.

- **Regulation 2017/752** of the Comission on 28th of April 2017 ammends the Regulation 10/2011 of the European Union and stablishes changes in norms for those plastic materials and objects intended to come into contact with food.

POLISUR 2000, S. L. Inscrita en el Registro Mercantil de Huelva, Tomo 441; Libro 0 de la Sección 8ª, Folio 20, Hoja H-6205. Inscripción 1ª - C.I.F.: B-21255419



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**DELEGACIONES:**  
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- **Regulation (EU) 2019/37** of the Commission on 10th of January 2019 which amends the Regulation 10/2011 of the European Union establishes changes in norms for those materials and objects intended to come into contact with food.

The components in the composition are listed in the aforementioned Regulations.

On the other hand, we can confirm that the manufactured material with which the recipient does not contain intentionally and therefore is manufactured free of alum, styrenes, phenoles and flates, which are not permitted, as whereas heavy metals in the Directive 2008/39/EC, and so its inclusion to the Spanish legal system though the R.D 103/2009, based on our the certifications of our suppliers.

We certify the absence of Bisphenol A (BPA) N. CAS 80-05-7 and Bisphenol S (BPS) N. CAS 80-09-1.

**Polisur 2000, S.L.U.** is inscribed in the **General Health Registry for Food with N. 39.005756/H** as established in the Real Decree 191/2011, on 18th of February, as General Health Registry for Food Companies and Foods.

**POLARBOX** portable coolers fulfil the good practices for manufacturing materials and objects intended to come into contact with food as established in the **Regulation (EC) N. 2023/2006 of the Commission on the 22nd of December 2006** and its successive amendments.



### Migration:

The migration essays are constantly updated in certified laboratories by the Spanish Accreditation Agency (ENAC).

The following essays have been taken place with the analysis procedures held by indicated norms regarding Migration of metals, and according to the **Report 21-1271-1-A-B-C-D-BI/1** and **Report 21-1271-1-N-BI/1**, the results are indicated below:

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**Report 21-1271-1-A-B-C-D-BI/1**

21-1271-1							
NEVERA POLARBOX 12 litros							
Test	Standard	Regulation	Properties	Result	Requirement *	* Conclusions	
A	Overall migration in simulant A	UNE-EN 1186-1:2002; UNE-EN 1186-9:2002	Regulation (EU) No 10/2011	Overall migration (M1) (mg/kg)	Mean Value: < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M2) (mg/kg)	Mean Value: < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M3) (mg/kg)	Mean Value: < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M1) (mg/dm <sup>2</sup> )	Mean Value: < 0.8 Uncertainty (k=2): -	M2 < M1	OK (1)
				Overall migration (M2) (mg/dm <sup>2</sup> )	Mean Value: 0.8 Uncertainty (k=2): ±0.4	M3 < M1	OK
				Overall migration (M3) (mg/dm <sup>2</sup> )	Mean Value: < 0.8 Uncertainty (k=2): -	M3 ≤ 10	OK
B	Overall migration in simulant B	UNE-EN 1186-1:2002; UNE-EN 1186-9:2002	Regulation (EU) No 10/2011	Overall migration (M1) (mg/kg)	Mean Value: < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M2) (mg/kg)	Mean Value: < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M3) (mg/kg)	Mean Value: < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M1) (mg/dm <sup>2</sup> )	Mean Value: < 0.8 Uncertainty (k=2): -	M2 < M1	OK
				Overall migration (M2) (mg/dm <sup>2</sup> )	Mean Value: < 0.8 Uncertainty (k=2): -	M3 < M1	OK
				Overall migration (M3) (mg/dm <sup>2</sup> )	Mean Value: < 0.8 Uncertainty (k=2): -	M3 ≤ 10	OK

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**Report 21-1271-1-A-B-C-D-BI/1**

	Test	Standard	Regulation	Properties	Result	Requirement *	* Conclusions
C	Overall migration in alternative simulant (iso-octane)	UNE-EN 1186-1:2002; UNE-EN 1186-9:2002	Regulation (EU) No 10/2011	Overall migration (M1) (mg/kg)	<b>Mean Value:</b> 8.3 Uncertainty (k=2): ±2.1	-	-
				Overall migration (M2) (mg/kg)	<b>Mean Value:</b> < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M3) (mg/kg)	<b>Mean Value:</b> < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M1) (mg/dm <sup>2</sup> )	<b>Mean Value:</b> 1.7 Uncertainty (k=2): ±0.4	M2 < M1	OK
				Overall migration (M2) (mg/dm <sup>2</sup> )	<b>Mean Value:</b> < 0.8 Uncertainty (k=2): -	M3 < M1	OK
				Overall migration (M3) (mg/dm <sup>2</sup> )	<b>Mean Value:</b> < 0.8 Uncertainty (k=2): -	M3 ≤ 10	OK
D	Overall migration in alternative simulant (ethanol 95%)	UNE-EN 1186-1:2002; UNE-EN 1186-9:2002	Regulation (EU) No 10/2011	Overall migration (M1) (mg/kg)	<b>Mean Value:</b> < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M2) (mg/kg)	<b>Mean Value:</b> 6.8 Uncertainty (k=2): ±2.1	-	-
				Overall migration (M3) (mg/kg)	<b>Mean Value:</b> < 4.2 Uncertainty (k=2): -	-	-
				Overall migration (M1) (mg/dm <sup>2</sup> )	<b>Mean Value:</b> < 0.8 Uncertainty (k=2): -	M2 < M1	OK (1)
				Overall migration (M2) (mg/dm <sup>2</sup> )	<b>Mean Value:</b> 1.4 Uncertainty (k=2): ±0.4	M3 < M1	OK
				Overall migration (M3) (mg/dm <sup>2</sup> )	<b>Mean Value:</b> < 0.8 Uncertainty (k=2): -	M3 ≤ 10	OK

**Observations**

(1) As indicated in section 9.8.2 of EN 1186-1 standard, for aqueoussimulants it is considered that there has been no increase in the mean of theresults for the second test if its value is not higher than the meanof the result for the first extraction, in more thar the allowed analyticaltolerance.

The value of this tolerance in the case of aqueous simulants is 2 mg/dm<sup>2</sup> (although EN 1186-1standard indicates value of 1 mg/dm<sup>2</sup>,in subsequent documents such as Directive 2002/72/EC , working documents forrevision of UNE-EN 1186-3 standard or the draft of the document 'Technicalguidelines for compliance testing' prepared by the JRC, this value iscorrected by raising it to 2 mg/dm<sup>2</sup>).

According to these instructions, it is considered that there has been noincrease in the mean of the results of M2 respect to M1 and,therefore, sample meets the requirements established for repeated use contactwith the simulant used in the tests.

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**Report 21-1271-1-N-BI/1 (LME)**

**21-1271-1**

**NEVERA POLARBOX 12 LITROS**

**Table 1**

Substance	Specific migration (mg/kg) (M1) S/V=6dm <sup>2</sup> /kg		Specific migration (mg/kg) (M2) S/V=6dm <sup>2</sup> /kg		Specific migration (mg/kg) (M3) S/V=6dm <sup>2</sup> /kg		LD	Specific migration limit (SML) (mg/kg)
	Mean value	Uncertainty (k=2)	Mean value	Uncertainty (k=2)	Mean value	Uncertainty (k=2)		
Aluminium	0.0136	±0.0074	< 0.0086	-	< 0.0086	-	-	1
Antimony	0.0087	±0.0022	n.d.	-	n.d.	-	0.0004	0.04
Arsenic	n.d.	-	n.d.	-	n.d.	-	0.0004	ND = 0.01
Barium	0.0013	±0.0006	n.d.	-	n.d.	-	0.0004	1
Cadmium	n.d.	-	n.d.	-	n.d.	-	0.0004	0.002
Cobalt	n.d.	-	n.d.	-	n.d.	-	0.0004	0.05
Chromium	n.d.	-	n.d.	-	n.d.	-	0.0004	ND = 0.01(1)
Europium	n.d.	-	n.d.	-	n.d.	-	0.0007	0.05(2)
Iron	0.0106	±0.0027	n.d.	-	n.d.	-	0.0004	48
Gadolinium	n.d.	-	n.d.	-	n.d.	-	0.0007	0.05(2)
Lanthanum	n.d.	-	n.d.	-	n.d.	-	0.0007	0.05(2)
Terbium	n.d.	-	n.d.	-	n.d.	-	0.0007	0.05(2)
Lithium	n.d.	-	n.d.	-	n.d.	-	0.0004	0.6
Manganese	n.d.	-	n.d.	-	n.d.	-	0.0004	0.6
Mercury	n.d.	-	n.d.	-	n.d.	-	0.0004	ND = 0.01
Nickel	< 0.0009	-	n.d.	-	n.d.	-	0.0004	0.02
Lead	< 0.0009	-	n.d.	-	n.d.	-	0.0004	ND = 0.01
Copper	0.0025	±0.0008	n.d.	-	n.d.	-	0.0004	5
Zinc	0.0215	±0.0053	n.d.	-	n.d.	-	0.0004	5
Sum of lanthanides	< 0.0017	-	< 0.0017	-	< 0.0017	-	-	0.05(2)

(1) Based on Reg. 1245/2020 at consideranda No. 20 and remarks No. 3 of Annex II, if based on pre-existing documentary evidence, it is shown that hexavalent chromium was not used in the material analysed or formed during the entire production process, the specific migration value obtained can be considered trivalent chromium. In this case, a limit for the total chromium of 3.6 mg/kg food shall apply.

(2) The sum of all lanthanides must not exceed the specific migration limit of 0.05mg/kg according to Reg. 1245/2020.

**Note Specific migration (mg/kg), S/V=6dm<sup>2</sup>/kg**

Conversion of the results to mg of substance per kg of food simulant applying the surface to volume ratio of 6 dm<sup>2</sup>/kg. This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 2006/141/EC and 2006/125/EC.

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	Test	Standard	Legislation	Properties	Result	Requirement	Conclusions
<b>N</b>	Specific migration of 19 metals from annex II in simulatant B	UNE-EN 13130-1:2005; internal procedure	Regulation 10/2011	Specific migration (mg/kg of food)	See table 1	See table 1	OK (1)

(1) For all cases, the specific migration of the material in the second test does not exceed the level observed in the first test, and the specific migration in the third test does not exceed the level observed in the second test.

**CONCLUSIONS**

According to the results obtained by the migration essays, the sample with reference "POLARBOX portable cooler 12 L." with a relation to surface-volume 2,1 dm<sup>2</sup>/kg is considered as representation of the samples of similar composition with the same or less relation surface-volume; and relation surface-volume POLARBOX portable cooler 20 Liters – 1,75dm<sup>2</sup>/kg.

The tested material fullfil all global migration limits stablished in the Regulation (EU) N. 10/2011 of the Comission on the 14th of January 2011 about plastic materials and objects intended to come into contact with food.

**POLISUR 2000, S.L.U.**, considering the additives that the recipients may include according to the conformity declarations contributed by its suppliers, declares that fullfils the specific migration limits applied by them.

**Specifictions about the product utility**

1. Food type suitable to be in contact with: all type of food except alcoholic and no acid milk products with a pH >4,5 and fatty and dried food.
2. Contact with food: frozen or refrigerated.
3. The relation between the surface and the volume used for determining the product conformity:
  - Global migration is 4,8 dm<sup>2</sup>/kg.
4. Terms of use: the material must be stored in a dry storage area, where there are no significative temperature changes and relative humidity. The direct sun exposure can cause changes in the characteristics and the colour of the product, as well as deformations.

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This declaration is valid for a period of 2 years from now, and it will be revised if there are any legislation or raw material changes as well as changes in manufacturing or on the scientific data and that may alter the conformity terms of the product.

Verified and approved by:  
Managing Director



GA - 2007/0177  
(1) SEDES  
CERTIFICADAS



ER - 1794/2002  
(1) (2) SEDES  
CERTIFICADAS

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