

Lepe (Huelva), March 17, 2025.

POLISUR 2000, S.L.U. with registered office at Finca Las Majadillas, Ctra. Nac. 444-km. 2,95 - 21440 Lepe (Huelva) as a manufacturer of “POLARBOX Refrigerators and Tappers”,

DECLARES that its **POLARBOX** Coolers and Tappers are manufactured with 100% virgin Polypropylene (PP) and Polystyrene (Airpop) materials, which meet the manufacturing requirements for plastic materials intended to be in contact with food, complying with the requirements set by national and European legislation;

- **Commission Regulation (EU) No 10/2011** of 14 January 2011 and subsequent amendments; **Commission Regulation (EU) 2023/1442** of 11 June 2023, **Commission Regulation (EU) 2023/1627** of 10 August 2023, and **Commission Regulation (EU) 2025/351** of 21 February 2025.
- **Regulation (EC) No 1935/2004** of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.
- **Commission Regulation (EC) No 2023/2006** of 22 December 2006, as last amended by **Commission Regulation (EU) 2025/351** of 21 February 2025; we apply this Regulation on good manufacturing practices for materials and articles intended to come into contact with food, as amended, in our production process.
- **Regulation (EU) 2023/988** of 10 May 2023 on general product safety.
- **Royal Decree 847/2011**, of June 17, establishing the positive list of substances permitted for the manufacture of polymeric materials intended to come into contact with food.
- **Royal Decree 1055/2022** of December 27 on Packaging and Packaging Waste.
- **Royal Decree 773/2023**, of October 3, regulating the technological adjuvants used in the production and processing of raw materials and foods.

We confirm that the material used to manufacture our packaging does not intentionally contain prohibited aluminum, styrene, phenols, phthalates, or heavy metals, based on our suppliers' certifications.



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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 Comission on the 22nd of December 2006.**

Migration:

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

The following Global Migration and LME Verification (metals) tests have been carried out using the analysis procedures set out in the indicated standards; **Report 21-1271-22-0285** dated **03/23/2022** and **Report 22-3123-BI/1** dated **03/30/2023**, with the results being as indicated below:



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* Las actividades marcadas no están amparadas por la acreditación de ENAC.
* The marked activities are not covered by the ENAC accreditation.

CERTIFICADO DE ENSAYOS / TEST CERTIFICATE

Número / Number: 21-1271-22-0285
Fecha de ensayos / Date of tests: 10/03/2022
Fecha de certificado / Certificate issue: 22/03/2022

ENTIDAD / COMPANY

POLISUR 2000 S.L.

PETICIONARIO / PETITIONER

José Antonio Ramírez

DENOMINACIÓN DE PRODUCTO / PRODUCT NAME

NEVERA POLARBOX 12 LITROS
- Descripciónes/Descriptions: Recipiente color rosa/Pink container
- Códigos/Codes: 21-1271-1 y 22-0285-1

ENSAYOS REALIZADOS SEGÚN NORMAS O PROCEDIMIENTOS INTERNOS / TESTS PERFORMED ACCORDING TO STANDARDS OR INTERNAL PROCEDURES

Ensayos de migración global y específica, y funcionalidad para el cumplimiento de la legislación de plástico en contacto con alimentos.

Overall and specific migration tests, and functionality tests to verify the fulfilment of food contact plastic legislation.

RESULTADOS / RESULTS

Según consta en los informes / According to Reports:
21-1271-1-A-B-C-D-BI/1, 21-1271-1-N-BI/1, 22-0285-1-A-B-BI/1 y 22-0285-1-C-BI/1

Tabla / Table 1

Muestra/Sample: NEVERA POLARBOX 12 LITROS

Ensayo Test	Norma Standard	Legislación Legislation	Propiedad Properties	Valor Medio Mean Value	Requisito Requirement	Conclusión Conclusion
Migración global (Simulante A) Overall migration (Simulant A)	UNE-EN 1186-1:2002 UNE-EN 1186-3:2002	Reglamento/ Regulation 10/2011	M1 (mg/dm ²)	< 0,8	M2<M1	OK (1)
			M2 (mg/dm ²)	0,8 ± 0,4	M3<M2	OK
			M3 (mg/dm ²)	< 0,8	M3<10	OK
Migración global (Simulante B) Overall migration (Simulant B)	UNE-EN 1186-1:2002 UNE-EN 1186-3:2002	Reglamento/ Regulation 10/2011	M1 (mg/dm ²)	< 0,8	M2<M1	OK
			M2 (mg/dm ²)	< 0,8	M3<M2	OK
			M3 (mg/dm ²)	< 0,8	M3<10	OK
Migración global en simulante alternativo (iso-octano) Overall migration in alternative simulant (iso-octane)	UNE-EN 1186-1:2002 UNE-EN 1186-14:2002	Reglamento/ Regulation 10/2011	M1 (mg/dm ²)	1,7 ± 0,4	M2<M1	OK
			M2 (mg/dm ²)	< 0,8	M3<M2	OK
			M3 (mg/dm ²)	< 0,8	M3<10	OK
Migración global en simulante alternativo (etanol 95%) Overall migration in alternative simulant (ethanol 95%)	UNE-EN 1186-1:2002 UNE-EN 1186-14:2002	Reglamento/ Regulation 10/2011	M1 (mg/dm ²)	< 0,8	M2<M1	OK (1)
			M2 (mg/dm ²)	1,4 ± 0,4	M3<M2	OK
			M3 (mg/dm ²)	< 0,8	M3<10	OK



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**CERTIFICADO DE
ENSAYOS /
TEST CERTIFICATE**

Número / Number: 21-1271-22-0285

Fecha de ensayos / Date of tests: 10/03/2022

Fecha de certificado / Certificate issue: 22/03/2022

* Verificación de cumplimiento de LME de 19 metales del Anexo II * Verification of compliance of SML of 19 metals from Annex II	UNE-EN 13130-1:2005; Procedimiento interno Internal procedure	Reglamento/ Regulation 10/2011	M1, M2 y M3 (mg/kg)	Ver tablas 1, 2 y 3 de los informes/ See tables 1, 2 and 3 from reports 21-1271-1-N-BI/1 y 22-0285-1-A-B-BI/1	OK (2)
* Análisis sensorial basado en la norma UNE-ISO 13302:2008. Análisis sensorial. Métodos para la evaluación de las modificaciones producidas en las sensaciones olfativo-gustativas de los productos alimenticios debidas al envase/ * Sensory analysis based on standard UNE-ISO 13302:2008. Sensory analysis. Methods for assessing modifications to the flavour of food stuffs due to packaging	ISO 13302; UNE-EN ISO 4120	Reglamento/ Regulation 1935/2004	Diferencia entre muestra y blanco	NO Minimo 15 identificaciones correctas/ Minimum 15 correct identifications	OK
* Verificación de la ausencia de migración visible en simulantes A, B y D2/ * Visible migration absence verification in simulants A, B and D2	Resolución/ Resolution AP (89)	-	Migración visible	Ver figuras 1 y 2 del informe 22-0285-C-BI/1/ See figures 1 and 2 from report 22-0285-C-BI/1	OK

(1) As indicated in section 9.8.2 of EN 1186-1 standard, for aqueous simulants it is considered that there has been no increase in the mean of the results for the second test if its value is not higher than the mean of the result for the first extraction, in more than the allowed analytical tolerance. The value of this tolerance in the case of aqueous simulants is 2 mg/dm² (although EN 1186-1 standard indicates value of 1 mg/dm², in subsequent documents such as Directive 2002/72/EC, working documents for revision of UNE-EN 1186-3 standard or the draft of the document 'Technical guidelines for compliance testing' prepared by the JRC, this value is corrected by raising it to 2 mg/dm²). According to these instructions, it is considered that there has been no increase in the mean of the results of M2 respect to M1 and, therefore, sample meets the requirements established for repeated use contact with the simulant used in the tests.

(2) The specific migration test has been performed in the simulant considered as the most restrictive between A, B and D2, taken substance into account.

CONCLUSIONS

According to the results obtained from the overall and specific migration tests, reported in the reports 21-1271-1-A-B-C-D-BI/1, 21-1271-1-N-BI/1 and 22-0285-1-A-B-BI/1 the sample corresponding to the reference "NEVERA POLARBOX 12 LITROS" fulfils the overall and specific migration limits, for a use of repeated contact, established in Regulation 10/2011 and subsequent amendments, for contact with all types of food, for any long term storage at room temperature and below, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^Δ((T-70)/10) minutes.

The analysed sample, "NEVERA POLARBOX 12 LITROS" with a surface to volume ratio of 2.1 dm²/kg has been considered as representative of the total of samples of equal composition and equal or lower surface to volume ratio. Therefore, the product "NEVERA POLARBOX 20 LITROS" with a surface to volume ratio of 1.75 dm²/kg would also comply according to the results obtained in these tests.

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SUMMARY TABLES

22-3123-1

ENVASE TUPPER POLARBOX

	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	M1- Overall migration (mg/kg)	Mean Value: < 5.6 Uncertainty (k=2): -	-	-
				M1- Overall migration (mg/dm ²)	Mean Value: < 1.0 Uncertainty (k=2): -	M2 < M1	OK
				M2- Overall migration (mg/kg)	Mean Value: < 5.6 Uncertainty (k=2): -	-	-
				M2- Overall migration (mg/dm ²)	Mean Value: < 1.0 Uncertainty (k=2): -	M3 < M2	OK
				M3- Overall migration (mg/kg)	Mean Value: < 5.6 Uncertainty (k=2): -	-	-
				M3- Overall migration (mg/dm ²)	Mean Value: < 1.0 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	M1- Overall migration (mg/kg)	Mean Value: 11.9 Uncertainty (k=2): ±10.6	-	-
				M1- Overall migration (mg/dm ²)	Mean Value: 2.1 Uncertainty (k=2): ±1.0	M2 < M1	OK
				M2- Overall migration (mg/kg)	Mean Value: < 5.6 Uncertainty (k=2): -	-	-
				M2- Overall migration (mg/dm ²)	Mean Value: < 1.0 Uncertainty (k=2): -	M3 < M2	OK
				M3- Overall migration (mg/kg)	Mean Value: < 5.6 Uncertainty (k=2): -	-	-
				M3- Overall migration (mg/dm ²)	Mean Value: < 1.0 Uncertainty (k=2): -	M3 ≤ 10	OK



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Test	Standard	Regulation	Properties	Result	Requirement *	* Conclusions
C Overall migration in simulant D2	UNE-EN 1186-1:2002; UNE-EN 1186-2:2002	Regulation (EU) N° 10/2011	M1- Overall migration (mg/dm ²)	Mean Value: 4.6 Uncertainty (k=2): ±2.8	-	-
			M2- Overall migration (mg/dm ²)	Mean Value: 5.8 Uncertainty (k=2): ±2.8	-	-
			M3- Overall migration (mg/dm ²)	Mean Value: 11.0 Uncertainty (k=2): ±2.8	-	-
			M2-M1 (mg/dm ²)	Mean Value: 1.2	(M2-M1) < M1	OK
			M3-M2 (mg/dm ²)	Mean Value: 4.8	M3-M2 < (M2-M1) (M3-M2) ≤ 10	OK
D * Verification of compliance with SML of metals Annex II in simulant B	UNE-EN 13130-1:2005; Internal procedure	Regulation (EU) No 10/2011	Specific migration (mg/kg)	See Table	See table 4	OK
E * Verification of compliance with SML of Ref. 38507 in simulant A	UNE-EN 13130-1:2005; Internal procedure	Regulation (EU) No 10/2011	Specific migration RU (mg/kg), S/V test - M1	Mean value: < 0.6 Uncertainty (k=2): -	M2 < M1	OK
			Specific migration RU (mg/kg), S/V test - M2	Mean value: < 0.6 Uncertainty (k=2): -	M3 < M2	OK
			Specific migration RU (mg/kg), S/V test - M3	Mean value: < 0.6 Uncertainty (k=2): -	M3 ≤ 5	OK
F * Verification of compliance with SML of Ref. 38507 in simulant B	UNE-EN 13130-1:2005; Internal procedure	Regulation (EU) No 10/2011	Specific migration RU (mg/kg), S/V test - M1	Mean value: < 0.6 Uncertainty (k=2): -	M2 < M1	OK
			Specific migration RU (mg/kg), S/V test - M2	Mean value: < 0.6 Uncertainty (k=2): -	M3 < M2	OK
			Specific migration RU (mg/kg), S/V test - M3	Mean value: < 0.6 Uncertainty (k=2): -	M3 ≤ 5	OK
G * Verification of compliance with SML of Ref. 38507 in simulant D2	UNE-EN 13130-1:2005; Internal procedure	Regulation (EU) No 10/2011	Specific migration RU (mg/kg), S/V test - M1	Mean value: < 0.6 Uncertainty (k=2): -	M2 < M1	OK
			Specific migration RU (mg/kg), S/V test - M2	Mean value: < 0.6 Uncertainty (k=2): -	M3 < M2	OK
			Specific migration RU (mg/kg), S/V test - M3	Mean value: < 0.6 Uncertainty (k=2): -	M3 ≤ 5	OK



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22-3123-2							
TAPA TUPPER POLARBOX							
Test	Standard	Regulation	Properties	Result	Requirement *	* Conclusions	
A	Overall migration in simulant A	UNE-EN 1186-1:2002; UNE-EN 1186-3:2002	Regulation (EU) No 10/2011	M1- Overall migration (mg/dm ²)	Mean Value: 1.1 Uncertainty (k=2): ±1.9	M2 < M1	OK
				M2- Overall migration (mg/dm ²)	Mean Value: < 1.0 Uncertainty (k=2): -	M3 < M2	OK
				M3- Overall migration (mg/dm ²)	Mean Value: 1.1 Uncertainty (k=2): ±1.9	M3 ≤ 10	OK
B	Overall migration in simulant B	UNE-EN 1186-1:2002; UNE-EN 1186-3:2002	Regulation (EU) No 10/2011	M1- Overall migration (mg/dm ²)	Mean Value: 2.3 Uncertainty (k=2): ±1.9	M2 < M1	OK
				M2- Overall migration (mg/dm ²)	Mean Value: 1.1 Uncertainty (k=2): ±1.9	M3 < M2	OK
				M3- Overall migration (mg/dm ²)	Mean Value: 1.5 Uncertainty (k=2): ±1.9	M3 ≤ 10	OK
H	Overall migration in alternative simulant ethanol 95%	UNE-EN 1186-1:2002; UNE-EN 1186-14:2003	Regulation (EU) No 10/2011	M1- Overall migration (mg/dm ²)	Mean Value: < 1.0 Uncertainty (k=2): -	M2 < M1	OK
				M2- Overall migration (mg/dm ²)	Mean Value: < 1.0 Uncertainty (k=2): -	M3 < M2	OK
				M3- Overall migration (mg/dm ²)	Mean Value: < 1.0 Uncertainty (k=2): -	M3 ≤ 10	OK
I	Overall migration in alternative simulant isooctane	UNE-EN 1186-1:2002; UNE-EN 1186-14:2003	Regulation (EU) No 10/2011	M1- Overall migration (mg/dm ²)	Mean Value: 2.6 Uncertainty (k=2): ±1.9	M2 < M1	OK
				M2- Overall migration (mg/dm ²)	Mean Value: 1.7 Uncertainty (k=2): ±1.9	M3 < M2	OK
				M3- Overall migration (mg/dm ²)	Mean Value: 1.7 Uncertainty (k=2): ±1.9	M3 ≤ 10	OK
J	* Verification of compliance with SML of Ref. 68320 in simulant D2	UNE-EN 13130-1:2005; Internal procedure	Regulation (EU) No 10/2011	Specific migration RU (mg/kg), S/V=6 dm ² /kg - M1	Mean Value: 14.34 Uncertainty (k=2): ±2.28	M2 < M1	OK
				Specific migration RU (mg/kg), S/V=6 dm ² /kg - M2	Mean Value: < 2 Uncertainty (k=2): -	M3 < M2	OK
				Specific migration RU (mg/kg), S/V=6 dm ² /kg - M3	Mean value: < 2 Uncertainty (k=2): -	M3 ≤ 6	OK



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	Test	Standard	Regulation	Properties	Result	Requirement *	* Conclusions
K	* Verification of compliance with SML of metals Annex II in simulant B	UNE-EN 13130-1:2005; Internal procedure	Regulation (EU) No 10/2011	Specific migration (mg/kg)	See Table	see table 6	OK

CONCLUSIONS

The sample analyzed, "TAPPER CONTAINER" and "TAPPER LID" with a surface-volume ratio of 5.3 dm²/kg and 10 dm²/kg respectively, has been considered as representative of the total of samples of the same composition and equal or lower surface-volume ratio. "NEVERA POLARBOX 6L" products with an area-volume ratio of 2,3 dm²/kg, "NEVERA POLARBOX 12L" with an area-volume ratio of 2,1 dm²/kg and "NEVERA POLARBOX 20L" with an area-volume ratio of 1,75 dm²/kg, would also comply with the results of such tests.

Heavy Metals

Compliance with Article 12 of Royal Decree 1055/2022 and Article 11.1 of Directive 94/62/EC;

"The sum of the concentration levels of lead, cadmium, mercury, and hexavalent chromium present in packaging or its components shall not exceed 100 ppm by weight."

Test results:



Results

Start date: 2025/03/25

Finish date: 2025/04/11

Expressed in mg element/kg material (mg/kg)

Table 1			
Content (mg/Kg)			
Cd	Cr (VI)	Hg	Pb
<5	<5	<5	<5

SUMMARY TABLES

	Test	Standard	Legislation	Properties	Result	Requirement	Conclusions
A	Determination of Content in Cadmium, Chromium (VI), Mercury and Lead, according to Directive 94/62/CE	-	Directive 94/62/CE	Content (mg/kg)	See table 1	≤ 100	OK

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BPA and PFAS

The maximum migration of BPA (Bisphenols) and PFAS (Organic Fluoride) is certified, according to **report No. 24-2911-2 BI/2**, carried out in a laboratory accredited by ENAC (Aimplas, Plastics Technology Institute), in compliance with Regulation 10/2011, which states that the specific migration of BPA will not exceed 0.05 mg/kg.



Results

Start date: 2024/09/24
End date: 2024/09/26

Table 2		
	Residual content (mg/kg sample)	Maximum calculated specific migration (mg/kg simulant)
Mean value	0.38	0.023
Standard deviation	0.04	0.002
LOQ	0.05	0.003
Specific migration limit (mg/kg simulant)		0.05

Note maximum calculated specific migration
The maximum specific migration has been calculated from the residual content result assuming complete migration in a sample of 10.0 g/dm². The conversion has been made applying a surface to volume ratio of 6 dm² per kg of food.

The calculated maximum specific migration for BPA is in compliance with Regulation (EU) 10/2011, which states that the specific migration of BPA shall not exceed 0.05 mg/kg.

MOSH and MOAH

Specific migration of MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons).

According to tests performed on the final product, AIMPLAS **Report 25-1287-3-BI/1**, the manufactured products comply with the specific migration limits.

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



(1) (2) **FABRICA Y OFICINAS CENTRALES:** Finca las Majadillas. Ctra. N-444, Km 2,95. Apdo. de correos, 72. 21440 LEPE (Huelva) Tel. +34 959380224- Fax: 959380752 **PORTUGAL:** OLHÃO: Polígono Industrial c/21 Parc. 114 Tlf.: +351 289 703 777 Fax.: +351 289 703 795 e-mail: polisur@sapo.pt **DELEGACIONES:** Área Comercial: Móv.: 669861827 - 606414936 (2) ALGECIRAS: Pol. Ind. Palmes II - c/ Balandros, 58. 11207 Los Barrios. Tlf.: 639187821 (2) CÁDIZ: Muelle Levante s/n. Tlf. y Fax: 956 205 018 (2) Pto. de Sta Maria: Muelle Pesquero Almacén Metálico, 1. 11500 El Pto. de Sta. Maria.



Results

Start date: 2025/04/09
Finish date: 2025/05/12

Table 1

Specific migration (mg/kg)		
	Average	Unc. (k=2)
MOSH >=C10 a <=C16	0.155	±0.047
MOSH >C16 a <=C20	0.590	±0.18
MOSH >C20 a <=C25	1.940	±0.58
MOSH >C25 a <=C35	1.520	±0.46
MOSH >C35 a <=C40	0.501	±0.15
MOSH >C40 a <=C50	0.317	±0.10
MOAH >=C10 a <=C16	< 0.015	-
MOAH >C16 a <=C25	< 0.015	-
MOAH >C25 a <=C35	< 0.015	-
MOAH >C35 a <=C50	< 0.015	-

Notes:

-At the moment, in Annex I of Regulation (EU) No. 10/2011 there are 3 mineral oil hydrocarbons authorized as additives (FCM 93 with SML of 0.05 mg/kg and FCM 94. 95 without SML) and includes one hydrocarbon resin (FCM 97 without SML).

-The German Federal Institute for Risk Assessment (BfR) establishes reference values for MOSH in paper and board made from recycled fibers:

- 12 mg/kg of food for MOSH of chain length C10 to C16
- 4 mg/kg of food for MOSH of chain length >C16 to C20

-In May of 2022 the European Commission sets recommended limits on MOAH contamination in food, effective immediately; Limits are not legally binding. It is left up to the Member States to enforce the change. MOAH are now technically limited to:

- 0.5 mg/kg for dry foods with a low fat/oil content ($\leq 4\%$ fat/oil)
- 1 mg/kg for foods with a higher fat/oil content ($> 4\%$ fat/oil)
- 2 mg/kg for fats/ oils



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CONCLUSIONS

The tested material meets all the requirements established in Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles 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 fulfils the specific migration limits applied by them.

Specifications 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 dm²/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.

The information contained herein is based on information believed to be correct and up-to-date. Due to the constant evolution of national and international legislation, the legislative information for the aforementioned product may occasionally change. If you have any doubts regarding the validity of this declaration, please contact us for an update.

The application and conditions of use are beyond our control, and the product's performance and suitability for the customer's use depend on the specific conditions of use and the food being packaged. We recommend that customers ensure that each product meets all requirements before beginning the packaging process.

This declaration is valid for a period of two years from the date of this declaration and will be reviewed if there are changes in legislation, raw materials, the production process, or scientific data that may alter the product's compliance conditions.

Document verified and approved by:
Manager

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www.polisur.es

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