Informe de migración de SIMULANTES ALIMENTARIOS de acuerdo al REGLAMETO (UE) Nº 10/2011 relativo a materiales destinados a entrar en contacto con alimentos.

Número de informe	**EUP-SA102011-001**
Producto	PROTEK EPOXI 1312 SD
Fecha del informe	18/11/2024

El ANEXO III del REGLAMENTO (UE) Nº 10/2011 relativo a relativo a materiales destinados a entrar en contacto con alimentos determina los límites máximos de migración para los diferentes simulantes alimentarios.

En el cuadro 1 del ANEXO III de dicho reglamento se especifica:

- Etanol 10%: Simulante alimentario A
- Etanol 20%: Simulante alimentario C
- Etanol 50%: Simulante alimentario D1
- Aceite vegetal: Simulante alimentario D2

Según el REGLAMENTO (UE) Nº 10/2011 "Los simulantes alimentarios A, B y C se asignan a alimentos que tengan carácter hidrofílico y sean capaces de extraer sustancias hidrofílicas. El simulante alimentario C debe usarse para alimentos alcohólicos con un contenido de alcohol de hasta un 20 %, y para alimentos que contengan una cantidad importante de ingredientes orgánicos que lo hagan ser más lipofílico. Los simulantes D1 y D2 se asignan a alimentos que tengan carácter lipofílico y sean capaces de extraer sustancias lipofílicas. El simulante alimentario D1 se usará para alimentos alcohólicos con un grado alcohólico superior al 20 % y para aceite en emulsiones acuosas. El simulante D2 se usará para alimentos que contengan grasas libres en la superficie."

La migración global de los simulantes A, C, D1, D2 y agua se ha ensayado para el producto **PROTEK EPOXI 1312 SD con ensayo externo según informe 392-2024-00481601A_MP_EN de EUROFINS, cumpliendo con los límites de migración global para los simulantes alimentarios A,C, D1 y D2 tal como se muestra en el ANEXO I**. En este informe se certifica el cumplimiento con la migración global del simulante alimentario A (10% Ethanol), simulantes C y D1 (95 % Ethanol) , simulante D2 (Isooctante) y agua.

Por lo tanto, queda demostrada la conformidad de PROTEK EPOXI 1312 SD con el límite de migración global para:

- Los alimentos acuosos y alcohólicos (Hasta un 95% de alcohol)
- Los productos lácteos

EUPINCA, S.A.
C.I.F. - A - 12283388
Londres, 13 - Pol. Ind. Cabezo Beaza
30353 - CARTAGENA

Fdo: Dr. Rocío Misiego
Eupinca · Grupo tkrom
I+D+i

CLÁUSULA DE RESPONSABILILDAD: Los resultados obtenidos sólo se refieren al material sometido a ensayo. Este informe tiene carácter exclusivamente comercial y no podrá ser utilizado en cualquier procedimiento judicial o administrativo, ni como dictamen pericial ni como prueba documental.

ANEXO I: Informe de migración 392-2024-00481601A_MP_EN de EUROFINS

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EUPINCA S.A. TKROM
C/ Londres, 13
30353 CARTAGENA (Murcia)
SPAIN

Eurofins Product Testing Denmark A/S
Smedeskovvej 38
8464 Galten
Denmark

DK-CustomerSupport@cpt.eurofinseu.com
www.eurofins.com

Migration Report

05 November 2024

1 Sample Information

Sample name	TKROM PROTEK EPOXI 1312 SD
Sample reception	16/10/2024
Sample no.	392-2024-00481601
Analysis period	17/10/2024 - 31/10/2024

2 Brief Evaluation of the Results

Type of analysis	Conclusion	Regulation or protocol
Overall Migration (10% ethanol)	Pass	(EU) No 10/2011
Overall Migration (95% ethanol)	Pass	(EU) No 10/2011
Overall Migration (Isooctane)	Pass	(EU) No 10/2011
Overall Migration (Water)	Pass	(EU) No 10/2011

Full details based on the testing and direct comparison with limit values are available in the following pages

Louise Skov Iversen
Analytical Chemist

Brian Jensen
MSc. Chemistry

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3 Applied Test Methods

3.1 General Test References

Method	Parameters	Analysis principle	LOD	Um(%)
DIN EN 1186-3:2022-10 mod. [1]	Preparation for migration	Exposure to demineralised water by immersion	-	-
DIN EN 1186-3:2022-10 mod. [1]	Overall migration into demineralised water	Gravimetry	2 mg/dm²	20%
DIN EN 1186-3:2022-10 mod. [1]	Preparation for migration	Exposure to 10% ethanol by immersion	-	-
DIN EN 1186-3:2022-10 mod. [1]	Overall migration into 10% ethanol	Gravimetry	2 mg/dm²	20%
DIN EN 1186-3:2022-10 mod. [1]	Preparation for migration	Exposure to 95% ethanol by immersion	-	-
DIN EN 1186-3:2022-10 mod. [1]	Overall migration into 95% ethanol	Gravimetry	2 mg/dm²	25%
DIN EN 1186-3:2022-10 mod. [1]	Preparation for migration	Exposure to isooctane by immersion	-	-
DIN EN 1186-3:2022-10 mod. [1]	Overall migration into isooctane	Gravimetry	2 mg/dm²	20%

3.2 Test Conditions

Simulant	Technique	Area exposed [dm²]	Volume (Simulant) [mL]	Migration Conditions
10% ethanol	Immersion	0.6	30	30 min at 40 °C
95% ethanol	Immersion	0.6	30	30 min at 40 °C
Isooctane	Immersion	0.6	30	6 min at 20 °C
Demineralised water	Immersion	0.6	30	30 min at 40 °C

[1] Eurofins Consumer Product Testing GmbH : DIN EN ISO/IEC 17025:2018 DAKKS D-PL-14435-01-00

*: Not accredited
<: Less than
>: Greater than
LOD: Limit of detection
#: Internal test method
n.d: Not detected
n.m: Not measurable
LOQ: Limit of quantification

Um(%): The expanded uncertainty Um(%) equals 2 x RSD%. For further information please visit www.eurofins.dk/uncertainty
The results are only valid for the tested sample(s).

EUPINCA, S.A
C.I.F – A- 12283388

Pol. Industrial Cabezo Beaza
C/Londres, 13
30353 Cartagena, Murcia
T: +34 968 089000 / +34 968 0890

tkrom.com
info@grupotkrom.com

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4 Results

4.1 Overall Migration

Simulant	Single determinations			Average	OML value
	[mg/dm²]	[mg/dm²]	[mg/dm²]	[mg/dm²]	[mg/dm²]
10% ethanol	< 2	< 2	< 2	< 2	10
95% ethanol	2.2	2.3	2.5	2.3	10
Demineralised water	< 2	< 2	< 2	< 2	10
Isooctane	< 2	< 2	< 2	< 2	10

5 Summary and Evaluation of the Results

The results for overall migration are below the threshold value of 10 mg/dm².

Consequently, the product tested complies with the requirements in Commission Regulation (EU) No 10/2011 with amendments up to and including Commission Regulation (EU) 2023/1627 on plastic materials and articles intended to come into contact with food for the above mentioned test conditions.

5.1 Decision Rules

Eurofins Product Testing A/S, declare statement of conformity based on the "Binary Statement for Simple Acceptance Rule" described in ILAC's "Guidelines on decision Rules and Statements of Conformity" ILAC-G8:09/2019.

This means that results above the detection limit are always reported with two significant digits. Results are evaluated with the same number of significant digits as the corresponding limit values, and conformity is based on results being less than or equal to limit values.

For further information please visit www.eurofins.dk/product-testing/om-os/beslutningsregler/

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EUPINCA, S.A
C.I.F – A- 12283388

Pol. Industrial Cabezo Beaza
C/Londres, 13
30353 Cartagena, Murcia
T: +34 968 089000 / +34 968 0890

tkrom.com
info@grupotkrom.com

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6 Picture of Sample

7 Version History

Report date	Report number	Modification
05/11/2024	392-2024-00481601A_MP_EN	Current version

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C.I.F – A- 12283388

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30353 Cartagena, Murcia
T: +34 968 089000 / +34 968 0890

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info@grupotkrom.com