

Gaia BioMaterials AB  
Bunkagårdsgatan 13  
253 68 Helsingborg  
SWEDEN

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

CustomerSupport@eurofins.com  
www.eurofins.com

## Migration Report

21 June 2024

### 1 Sample Information

Sample name	ULTRA THIN BAG
Sample reception	22/01/2024
Sample no.	392-2024-00031701
Analysis period	24/01/2024 - 27/02/2024 and 23/04/2024 – 21/06/2024

### 2 Brief Evaluation of the Results

Type of analysis	Conclusion	Regulation or protocol
Overall Migration	Pass	(EU) No 10/2011
Specific Migration	Pass	(EU) No 10/2011
NIAS Screening (GC/MS)	No objection	(EU) No 10/2011
Sensory Analysis	Pass	(EU) No 1935/2004, article 3, 1.c)

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



Catja Foged Wittrup  
Analytical Chemist



Brian Jensen  
MSc. Chemistry

### 3 Applied Test Methods

#### 3.1 General Test References

Method	Parameters	Analysis principle	LOD	Um(%)
DIN EN 1186-3:2022-10 mod. <sup>1</sup>	Preparation for migration	Exposure to 3% acetic acid by immersion	-	-
DIN EN 1186-3:2022-10 mod. <sup>1</sup>	Overall migration into 3% acetic acid	Gravimetry	2 mg/dm <sup>2</sup>	20%
Internal Method <sup>*1</sup>	Preparation for sensory test	Exposure to water	-	-
DIN 10955 <sup>2</sup>	Sensory analysis	Assessment of odour and taste by 6 judges	Grade scale 0-4	-
DIN EN 1186-3:2022-10 mod. <sup>1</sup>	Preparation for migration	Exposure to 10% ethanol by immersion	-	-
DIN EN 1186-3:2022-10 mod. <sup>1</sup>	Overall migration into 10% ethanol	Gravimetry	2 mg/dm <sup>2</sup>	20%
DIN EN 1186-3:2022-10 mod. <sup>1</sup>	Preparation for migration	Exposure to olive oil by immersion	-	-
DIN EN 1186-2:2022-10 mod. <sup>1</sup>	Overall migration into olive oil	Gravimetry	2 mg/dm <sup>2</sup>	45%
DIN EN 13130-1:2004-08 <sup>1</sup>	Preparation for migration	Exposure to olive oil by immersion	-	-
Internal Method <sup>*1</sup>	Tetrahydrofurane	HS-GC-MS	0.05 mg/kg	30%
DIN EN 13130-1:2004-08 <sup>1</sup>	Preparation for migration	Exposure to 3% acetic acid by immersion	-	-
LA-GC-301.02:2021-09 <sup>⊠1</sup>	1,4-butanediol	GC-MS	5 mg/kg	30%
Internal Method <sup>1</sup>	Isophthalic acid	LC-MS/MS	0.01 mg/kg	20%
Internal Method <sup>1</sup>	Terephthalic acid	LC-MS/MS	0.01 mg/kg	20%
Internal Method <sup>*1</sup>	Preparation for migration	Exposure to 95% ethanol by immersion	-	-
Internal Method <sup>1</sup>	NIAS screening	GC-MS	0.01 mg/kg	50%

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

<sup>2</sup> Eurofins Analytik GmbH : DIN EN ISO/IEC 17025:2018 DAKKS D-PL-14251-01-00

\*: Not accredited

⊠: Internal test method

<: Less than

n.d: Not detected

>: Greater than

n.m: Not measurable

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Um(%): The expanded uncertainty Um(%) equals 2 x RSD%. For further information please visit [www.eurofins.dk/uncertainty](http://www.eurofins.dk/uncertainty)

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### 3.2 Test Conditions

Simulant	Technique	Area exposed	Volume (Simulant)	Migration Conditions
		[dm <sup>2</sup> ]	[mL]	
3% acetic acid	Immersion	1	50	10 days at 40 °C
10% ethanol (OM)	Immersion	1	100	10 days at 40 °C
Olive oil (OM)	Immersion	1	100	10 days at 40 °C
95% ethanol (SM)	Immersion	1	100	10 days at 60 °C
3% acetic acid (SM)	Immersion	1	100	10 days at 60 °C
Olive oil (SM)	Immersion	1	100	10 days at 60 °C
Water (sensory)	Immersion	5	500	2 days at 40 °C

OM: Overall migration, SM: Specific migration

## 4 Results

### 4.1 Overall Migration

Simulant	Single determinations			Average	OML value
	[mg/dm <sup>2</sup> ]	[mg/dm <sup>2</sup> ]	[mg/dm <sup>2</sup> ]	[mg/dm <sup>2</sup> ]	[mg/dm <sup>2</sup> ]
<b>3% acetic acid</b>	11	9.9	9.0	10	10
<b>10% ethanol</b>	4.1	4.2	3.8	4.0	10
<b>Olive oil</b>	3.1	4.2	2.4	3.0	10

### 4.2 Specific Migration

Parameters	CAS No.	Food Simulant	Result [mg/kg]	SML value [mg/kg]
<b>Terephthalic acid</b>	100-21-0	3% acetic acid	0.11	7.5
<b>Isophthalic acid</b>	121-91-5	3% acetic acid	< 0.01	5
<b>1,4-butanediol</b>	110-63-4	3% acetic acid	< 5	5
<b>Tetrahydrofurane *</b>	109-99-9	Olive oil	< 0.05	0.6

### 4.3 Sensory Analysis

Parameters	Food Simulant	Median Grade	Limit Value#
<b>Odour</b>	Water	2 (Weak odour deviation, chemical, plastic)	2.5
<b>Taste</b>	Water	2 (Weak taste deviation, chemical, plastic)	2.5

# From 61. Statement of BfR, Bundesgesundheitsbl. 46, 2003, 362-5.

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#### 4.4 NIAS Screening

##### Determination of organic compounds in Ethanol (95%) migrate, single use

Organic compounds of the migrate (sample exposed to 95% ethanol) were detected and quantified as equivalent of internal standards.

##### Results

Migration in mg/kg (real filled foodstuff – here 95% ethanol) as equivalent of internal standards:

Scan #	RT min.	MW	Identification	CAS #	mg/kg*
1	9.819	90	Butanediol isomer	N/P	0.05
2	10.354		d-Phenol (IS)		
4	22.418		d-Nonadecane (IS)		
5	23.309	256	n-Hexadecanoic acid	57-10-3	0.04
7	25.189	284	Octadecanoic acid	57-11-4	0.08
8	26.110	402	Tributyl acetylcitrate	77-90-7	0.02
9	26.920	281	Oleamide	301-02-0	0.09
10	27.967	N/MW	probably Alkyl nitrile	N/P	0.01
11	28.428		d-DEHP (IS)		
12	28.569	N/MW	unsaturated Alkylamide	N/P	0.14
13	28.621	N/MW	unsaturated Alkylamide	N/P	0.05
14	28.740	N/MW	probably Alkylamide	N/P	0.02
15	30.188	337	Erucylamide	112-84-5	4.40
16	30.270	339	Behenic amide	3061-75-4	0.09
17	31.347	400	probably 1,6-Dioxacyclododecane-7,12-dione Dimer	N/P	0.47
18	31.518	N/MW	unsaturated Alkylamide	N/P	0.05
20	33.620	N/MW	possibly aromatic compound from an copolyester or Copolyether with terephthalic acid in the polymer chain	N/P	0.23
21	35.544	N/MW	possibly aromatic compound from an copolyester or Copolyether with terephthalic acid in the polymer chain	N/P	0.07
Sum					<b>5.81</b>

Key: N/MW Not possible to determine molecular weight  
 N/CAS No CAS Number Assigned to this compound  
 N/P Not possible to assign a CAS Number because only functionality is named  
 mg/kg\* for the EU-convention of 6 dm<sup>2</sup> packaging for 1 kg food

probably : ~80 % fit with spectra library  
 possibly : ~60 % fit with spectra library

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☒: Internal test method

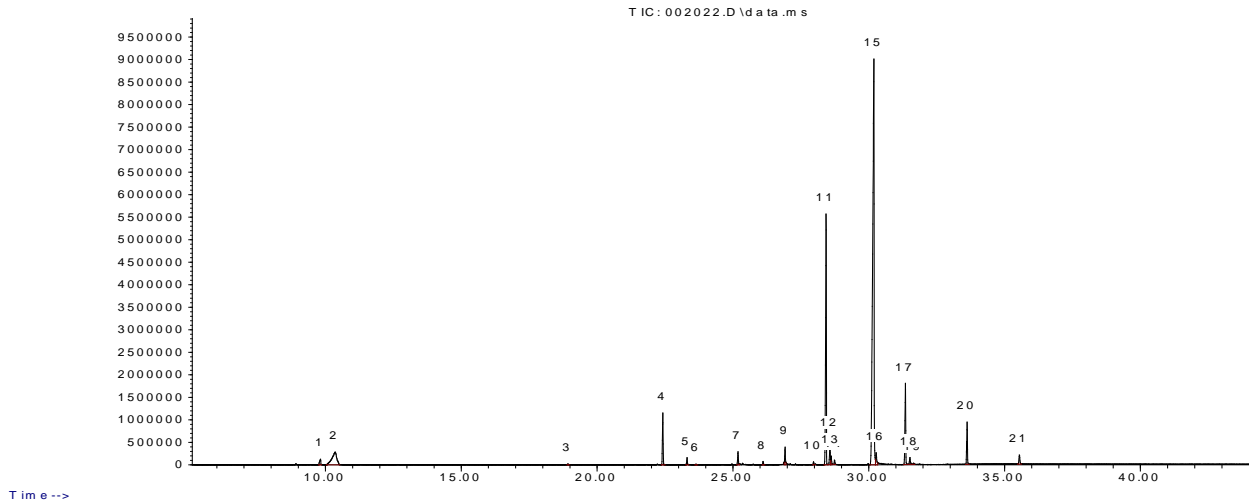
n.d: Not detected

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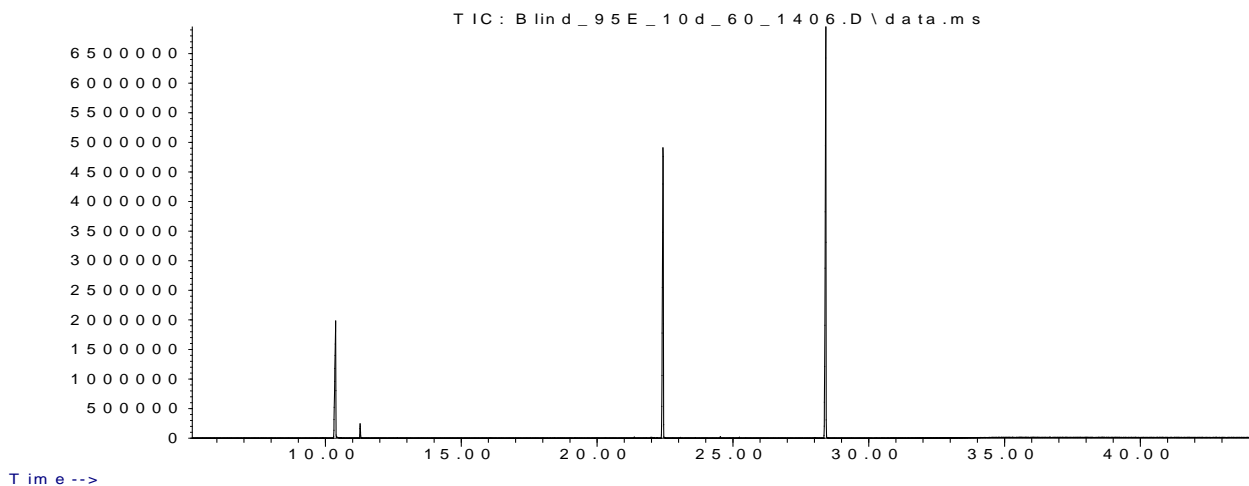
LOQ: Limit of quantification

## Chromatogram

Abundance



Abundance



Not identified peaks: chromatography artefacts or peaks < 0.01 mg/kg\*

### 4.4.1 NIAS Screening - Conclusion

According to the European Framework-Regulation (EC) No. 1935/2004 food contact materials may not release substances in food or its surface in quantities that could

1. Endanger human health
2. Bring about an unacceptable deterioration of the composition or the organoleptic properties (smell, taste) or the appearance of food (e.g. colour)

During the manufacturing process reaction- and degradation-products of formulation components may be formed (so-called NIAS, non-intentionally added substances). If yes, the manufacturer has to prove their harmlessness according to intentionally accepted scientific standards for risk assessment.

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In the NIAS-screening substances were detected above the detection limit of 10 ppb.

Scan #	CAS#	mg/kg*	Legislation	FCM No.	Restriction [mg/kg food]	Compliant
5	57-10-3	0.04	(EU) No 10/2011	105	none	Yes
7	57-11-4	0.08	(EU) No 10/2011	106	none	Yes
8	77-90-7	0.02	(EU) No 10/2011	138	none	Yes
9	301-02-0	0.09	(EU) No 10/2011	335	none	Yes
15	112-84-5	4.40	(EU) No 10/2011	271	none	Yes
16	3061-75-4	0.09	(EU) No 10/2011	458	none	Yes

The additional substances can't be identified further or are toxicological harmless. Therefore they aren't considered in the evaluation.

Based on the information above and under the general assumption, that consumers eat max. 1 kg/person/day of food packed in the tested packaging, there are no indication for an objection.

## 5 Summary and Evaluation of the Results

The results for overall migration **are below** the threshold value of 10 mg/dm<sup>2</sup>.

The results for specific migration **are below** the specific migration limits.

In the scope of the NIAS Screening performed there was **no indication for an objection**.

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.

The results of the sensory analysis **comply** with the requirements in (EU) No 1935/2004, article 3, 1 c).

### 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/](http://www.eurofins.dk/product-testing/om-os/beslutningsregler/)

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## 6 Picture of Sample



## 7 Version History

Report date	Report number	Modification
28/02/2024	392-2024-00031701_MP_EN	No longer valid.
21/06/2024	392-2024-00031701_MP_EN_Rev1	Current version. Additional tests added

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