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# Migration Report

15 August 2024

## 1 Sample Information

Sample name	Grade number 900353, Cup, cold drinks
Sample reception	19/06/2024
Sample no.	392-2024-00288701
Analysis period	21/06/2024 - 14/08/2024

## 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 # under the assumption that consumers **eat max. 0.25 kg per day of food packed in the tested material.**



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MSc. Chemistry

### 3 Applied Test Methods

#### 3.1 General Test References

Method	Parameters	Analysis principle	LOD	Um(%)
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 cell	-	-
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 cell	-	-
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 3% acetic acid by cell	-	-
Internal Method <sup>1</sup>	Metals	ICP-MS	0.0002 - 0.1 mg/kg	30%
Internal Method * <sup>1</sup>	Preparation for migration	Exposure to 95% ethanol by cell	-	-
Internal Method <sup>1</sup>	NIAS screening	GC-MS	0.01 mg/kg	50%

#### 3.2 Test Conditions

Simulant	Technique	Area exposed	Volume (Simulant)	Migration Conditions
		[dm <sup>2</sup> ]	[mL]	
10% ethanol (OM)	Cell	1.3	65	10 days at 40 °C
Olive oil (OM)	Cell	1.3	65	10 days at 40 °C
3% acetic acid (SM)	Cell	1	50	10 days at 60 °C
95% ethanol (SM)	Cell	1.3	65	10 days at 60 °C
Water (sensory)	Cell	1.3	400	2 days at 40 °C

OM: Overall migration, SM: Specific migration

<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

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## 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> ]		
10% ethanol	< 2	< 2	< 2	< 2	10
Olive oil	< 2	< 2	< 2	< 2	10

### 4.2 Specific Migration of Metals

Parameters	CAS No.	Food Simulant	Result	SML value
			(6 dm <sup>2</sup> / kg) <sup>#</sup> [mg/kg]	[mg/kg]
Aluminium (Al)	7429-90-5	3% acetic acid	0.024	1
Antimony (Sb)	7440-36-0	3% acetic acid	< 0.003	0.04
Arsenic (As)	7440-38-2	3% acetic acid	< 0.0003	0.01
Barium (Ba)	7440-39-3	3% acetic acid	< 0.003	1
Cadmium (Cd)	7440-43-9	3% acetic acid	< 0.0003	0.002
Chromium (Cr)	7440-47-3	3% acetic acid	0.009	0.01
Cobalt (Co)	7440-48-4	3% acetic acid	< 0.003	0.05
Copper (Cu)	7440-50-8	3% acetic acid	< 0.03	5
Europium (Eu)	7440-53-1	3% acetic acid	< 0.0024	0.05
Gadolinium (Gd)	7440-54-2	3% acetic acid	< 0.0024	0.05
Iron (Fe)	7439-89-6	3% acetic acid	0.078	48
Lanthanum (La)	7439-91-0	3% acetic acid	< 0.0024	0.05
Lead (Pb)	7439-92-1	3% acetic acid	0.0024	0.01
Lithium (Li)	7439-93-2	3% acetic acid	< 0.003	0.6
Manganese (Mn)	7439-96-5	3% acetic acid	0.033	0.6
Mercury (Hg)	7439-97-6	3% acetic acid	< 0.00006	0.01
Nickel (Ni)	7440-02-0	3% acetic acid	0.006	0.02
Terbium (Tb)	7440-27-9	3% acetic acid	< 0.0024	0.05
Zinc (Zn)	7440-66-6	3% acetic acid	< 0.03	5

# Recalculated test results based on the assumption that 1 kg of food is surrounded by 6 dm<sup>2</sup> (EU 10/2011/EC article 17 part 2c)

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### 4.3 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	6.677	118	Propanoic acid, 2-hydroxy-, ethyl ester	97-64-3	2.42
2	10.807	90	L-Lactic acid	79-33-4	0.48
3	10.881		d-Phenol (IS)		
4	11.684	90	1,4-Butanediol	110-63-4	1.11
5	14.143	144	1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3S-cis)-	4511-42-6	3.89
6	14.841	N/MW	Nitrogen compound	N/P	24.88
7	16.282	N/MW	Nitrogen compound	N/P	0.36
8	17.352	202	Diethyl adipate	141-28-6	0.15
9	19.261	N/MW	Aromatic Nitrogen compound	N/P	0.39
10	19.454	N/MW	Aromatic Nitrogen compound	N/P	2.74
11	19.536	200	Probably 1,6-Dioxacyclododecane-7,12-dione	777-95-7	0.87
12	20.123	230	Probably Methoxyacetic acid, decyl ester	259141-02-1	0.37
13	22.723	N/MW	Adipic acid derivative	N/P	0.80
14	22.916	N/MW	Aromatic Nitrogen compound	N/P	0.83
15	23.213	N/MW	Aromatic Nitrogen compound	N/P	3.95
16	23.867	256	n-Hexadecanoic acid	57-10-3	2.44
17	24.424	N/MW	Aromatic Nitrogen compound	N/P	0.28
18	25.813	284	Octadecanoic acid	57-11-4	2.59
19	25.977	N/MW	Nitrogen compound	N/P	0.21
20	26.066	N/MW	Aromatic Nitrogen compound	N/P	0.86
21	26.162	N/MW	Aromatic Nitrogen compound	N/P	0.45
22	26.311	N/MW	Aromatic Nitrogen compound	N/P	2.19
23	26.905	N/MW	Lactate derivative	N/P	0.81
24	27.202	N/MW	Adipic acid derivative	N/P	0.50
25	27.284	N/MW	Aromatic Nitrogen compound	N/P	0.22
27	27.901	N/MW	Aromatic Nitrogen compound	N/P	0.55
28	28.956		d-DEHP (IS)		
29	29.847	N/MW	Adipic acid derivative	N/P	0.44
30	29.914	N/MW	Aromatic Nitrogen compound	N/P	0.19

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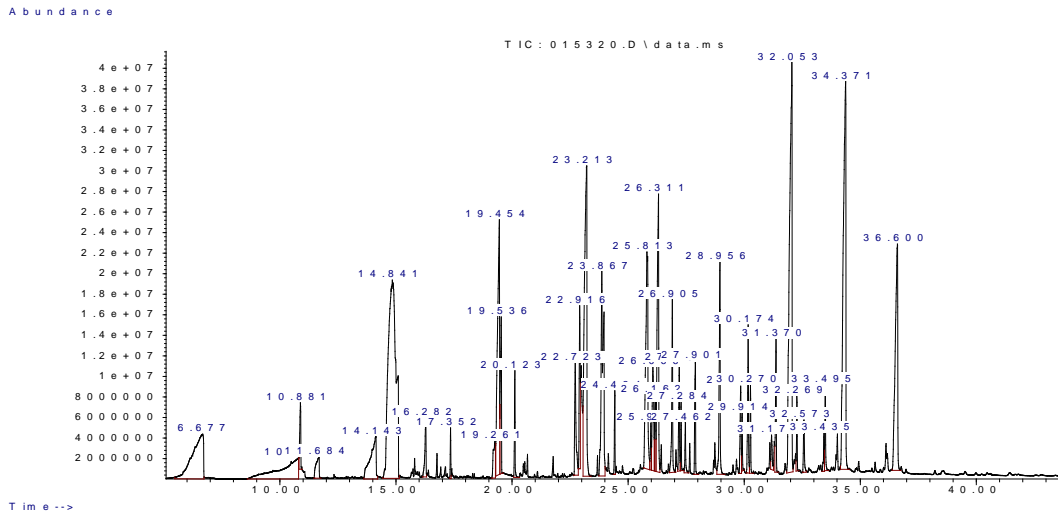
LOQ: Limit of quantification

Scan #	RT min.	MW	Identification	CAS #	mg/kg*
31	30.174	N/MW	Aromatic Nitrogen compound	N/P	0.65
32	30.270	N/MW	Aromatic Nitrogen compound	N/P	0.31
33	31.177	N/MW	Aromatic Nitrogen compound	N/P	0.20
34	31.370	N/MW	Aromatic Nitrogen compound	N/P	0.58
35	32.053	N/MW	Adipic acid derivative	N/P	5.36
36	32.269	N/MW	Aromatic Nitrogen compound	N/P	0.25
37	32.573	N/MW	Aromatic Nitrogen compound	N/P	0.29
38	33.435	N/MW	Aromatic Nitrogen compound	N/P	0.17
39	33.495	N/MW	Adipic acid derivative	N/P	0.34
40	34.371	N/MW	Aromatic Nitrogen compound	N/P	5.22
41	36.600	N/MW	Aromatic Nitrogen compound	N/P	2.95
Sum					<b>71.28</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

### Chromatogram



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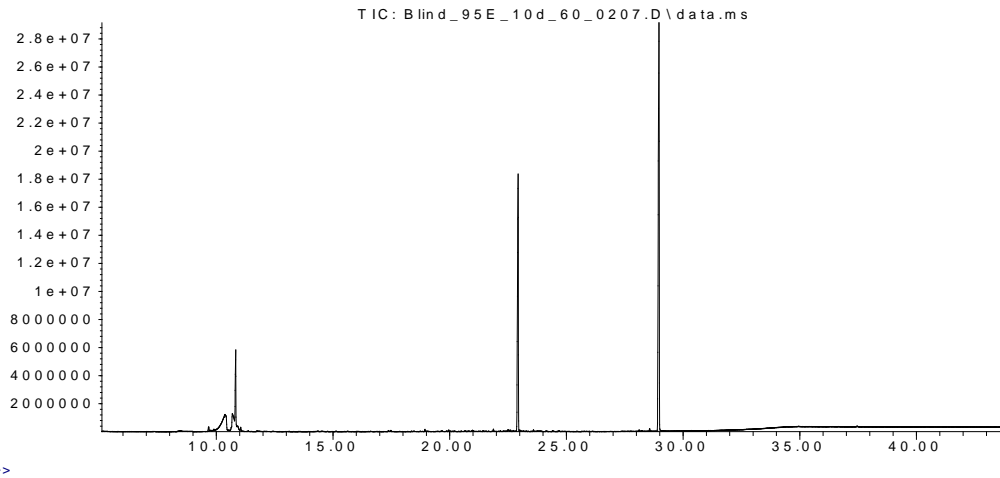
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Abundance



Time --&gt;

Not identified peaks: chromatography artefacts or peaks &lt; 0.01 mg/kg\*

### 4.3.1 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.

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

Scan #	CAS#	mg/kg*	Legislation	ID No.	Restriction [mg/kg food]	Compliant
1	97-64-3	2.42	(EU) No. 1334/2008	FI.No. 09.433	Food additive	Yes
2	79-33-4	0.48	EU 10/2011	FCM-No.: 99	none	Yes
4	110-63-4	1.11	EU 10/2011	FCM-No.: 254	5	Yes
5	4511-42-6	3.89	Not listed (NIAS)	-	5	Yes, see below
8	141-28-6	0.15	(EU) No. 1334/2008	FI.No. 09.348	Food additive	Yes
11	777-95-7	0.87	Not listed (NIAS)	-	1.8	Yes, see below
12	259141-02-1	0.37	Not listed (NIAS)	-	0.09	Yes, see below
16	57-10-3	2.44	EU 10/2011	FCM-No.: 105	none	Yes
18	57-11-4	2.59	EU 10/2011	FCM-No.: 106	none	Yes

# 5 Dilactid (CAS 4511-42-6) is the cyclic dimer of lactic acid, the monomer used for the manufacturing of polylactic acid (PLA). Dilactid was assessed by the European Chemical Agency (ECHA). A dossier for REACH registration is available

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on the ECHA website. According to these information the NOAEL (90d) was 100 mg/kg. According to EFSA Note For Guidance (doi: 10.2903/j.efsa.2008.21r) from 09.09.2020 a migration of more than 5 mg/kg requires also information on absorption, distribution, metabolism and excretion of the substance in human body. Such information were not available. Consequently the self derived SML was capped at 5 mg/kg although the toxicological data would have allowed a higher limit value.

- # 11 1,6-Dioxacyclododecane-7,12-dione (also called Adipic Acid Cyclic Butanediol Ester) is a cyclic dimer of Adipic Acid and Butanediol, raw materials used for polyurethane adhesives. For 1,6-Dioxacyclododecane-7,12-dione (CAS 777-95-7) the TTC-concept was applicable (no TTC-exclusion class). After completion of the decision tree it was classified as Cramer-class I. Consequently a maximum daily intake of 1.8 mg/Person can be considered as safe for consumers.
- # 12 For Methoxyacetic acid, decyl ester (CAS 259141-02-1) the TTC-concept was applicable (no TTC-exclusion class). After completion of the decision tree it was classified as Cramer-class III. Consequently a maximum daily intake of 0.09 mg/Person can be considered as safe for consumers. Assuming the default assumption of a body weight of 60 kg the consumption of **max. 0.25 kg of food per day** can be considered as safe.

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 assumption, that consumers eat max. 0.25 kg/person/day of food packed in the tested packaging, there are no indication for an objection.

#### 4.4 Sensory Analysis

Parameters	Food Simulant	Median Grade	Limit Value#
Odour	Water	1 (Just recognisable deviation)	2.5
Taste	Water	1.5 (Just recognisable to slight deviation, chemical)	2.5

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

### 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 result for specific migration **are below** the specific migration limit.

In the scope of the NIAS Screening performed there was **no indication for an objection** under the assumption that consumers eat **less than 0.25 kg of food per day** packed in the tested packaging.

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

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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/)

## 6 Picture of Sample



## 7 Version History

Report date	Report number	Modification
15/08/2024	392-2024-00288701_MP_EN	Current version

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