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# Migration Report

10 January 2024

## 1 Sample Information

Sample name	900540 Carrier Bag
Sample reception	20/11/2023
Sample no.	392-2023-00538801
Analysis period	22/11/2023 - 10/01/2024

## 2 Brief Evaluation of the Results

Type of analysis	Conclusion	Regulation or protocol
Overall Migration (3% acetic acid)	Fail	(EU) No 10/2011
Overall Migration (olive oil)	Pass	(EU) No 10/2011
Overall Migration (10% ethanol)	Pass	(EU) No 10/2011
NIAS Screening (GC/MS)	No objection <sup>#</sup>	(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

<sup>#</sup> Under the assumption, that consumers eat **max. 0.447 kg/person/day of food** packed in the tested packaging, there are no indication for an objection.



Louise Skov Iversen  
Analytical Chemist



Brian Jensen  
MSc. Chemistry

### 3 Applied Test Methods

#### 3.1 General Test References

Method	Parameters	Analysis principle	LOD	Um(%)
Internal Method * <sup>2</sup>	Preparation for sensory test	Exposure to water by pouch	-	-
DIN 10955 <sup>1</sup>	Sensory analysis	Assessment of odour and taste by 6 judges	Grade scale 0-4	-
DIN EN 1186-3:2022-10 mod. <sup>2</sup>	Preparation for migration	Exposure to 10% ethanol by pouch	-	-
DIN EN 1186-3:2022-10 mod. <sup>2</sup>	Overall migration into 10% ethanol	Gravimetry	2 mg/dm <sup>2</sup>	20%
DIN EN 1186-3:2022-10 mod. <sup>2</sup>	Preparation for migration	Exposure to 3% acetic acid by pouch	-	-
DIN EN 1186-3:2022-10 mod. <sup>2</sup>	Overall migration into 3% acetic acid	Gravimetry	2 mg/dm <sup>2</sup>	20%
DIN EN 1186-3:2022-10 mod. <sup>2</sup>	Preparation for migration	Exposure to olive oil by immersion	-	-
DIN EN 1186-2:2022-10 <sup>2</sup>	Overall migration into olive oil	Gravimetry	2 mg/dm <sup>2</sup>	20%
Internal Method * <sup>2</sup>	Preparation for migration	Exposure to 95% ethanol by pouch	-	-
Internal Method * <sup>2</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	Pouch	2	100	10 days at 40 °C
3% acetic acid	Pouch	2	100	10 days at 40 °C
Olive oil	Immersion	2	100	10 days at 40 °C
95% ethanol	Pouch	2	100	10 days at 60 °C

<sup>2</sup> Eurofins Consumer Product Testing GmbH : DIN EN ISO/IEC 17025:2018 DAKKS D-PL-14435-01-00

<sup>1</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> ]		
3% acetic acid	43	42	41	42	10
10% ethanol	2.1	3.0	3.2	2.7	10
Olive oil	< 2	< 2	< 2	< 2	10

### 4.2 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	10.74	IS	d-Phenol (IS)	-	-
2	17.53	170	Diphenyl ether	101-84-8	0.47
3	18.154	158	Methoxynaphthalene isomer	N/P	0.14
4	18.51	206	probably $\alpha$ Isomethyl ionone	127-51-5	0.08
5	18.577	192	probably trans- $\beta$ -Ionone	79-77-6	0.05
6	18.733	213	probably 1-Dodecanamine, N,N-dimethyl-	112-18-5	0.07
7	18.86	206	2.4-Di-tert-Butylphenol	96-76-4	0.13
8	18.912	220	Butylated Hydroxytoluene	128-37-0	0.08
9	18.978	214	probably Methyl laurate	111-82-0	0.06
10	19.082	172	probably Ethoxynaphthalene isomer	N/P	0.05
11	19.179	N/MW	Alkylsalicylate	N/P	0.17
12	19.669	N/MW	Alkylsalicylate	N/P	0.29
13	20.509	202	probably Cinnamaldehyde, $\alpha$ -pentyl-	122-40-7	0.07
14	20.895	222	n-Hexyl salicylate	6259-76-3	1.07
15	21.289	242	probably Methyl myristate	124-10-7	0.08
16	21.541	N/MW	Alkylsalicylate	N/P	0.08
17	21.66	216	Octanal, 2-(phenylmethylene)-	101-86-0	0.83
18	21.772	228	Tetradecanoic acid	544-63-8	0.15
19	22.396	270	Isopropyl myristate	110-27-0	0.84

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Scan #	RT min.	MW	Identification	CAS #	mg/kg*
20	22.812	IS	d-Nonadecane (IS)	-	-
21	22.975	228	probably Benzyl salicylate	118-58-1	0.17
22	23.391	270	Methyl palmitate	112-39-0	0.46
23	23.428	276	7,9-Di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione	82304-66-3	0.20
24	23.978	256	n-Hexadecanoic acid	57-10-3	1.6
25	24.357	298	Isopropyl palmitate	142-91-6	0.52
26	25.211	N/MW	probably Alkylamine derivative	N/P	0.02
27	25.278	298	Methyl stearate	112-61-8	0.10
28	25.553	N/MW	unsaturated Alkylacid	N/P	1.2
29	25.798	284	Octadecanoic acid	57-11-4	1.1
30	26.511	402	Tributyl acetylacrylate	77-90-7	0.10
31	27.016	290	probably Octinoxate	5466-77-3	0.09
32	27.64	370	Bis(2-ethylhexyl) adipate	103-23-1	0.10
33	27.781	338	probably Piperonyl butoxide	51-03-6	0.05
34	28.844	IS	d-DEHP (IS)	-	-
35	28.94	315	Bumetizole	3896-11-5	0.28
36	29.794	361	Octocrylene	6197-30-4	0.04
37	30.277	390	probably Dioctyl isophthalate	137-89-3	0.20
38	30.508	337	Erucylamide	112-84-5	0.06
39	30.678	304	probably Quantacure BMS	83846-85-9	0.03
40	30.849	410	Squalene	7683-64-9	0.04
41	31.748	424	probably Dodecyl palmitate	42232-29-1	0.11
42	33.279	472	Tocopheryl acetate isomer	N/P	0.03
43	35.277	N/MW	possibly Antioxidant	N/P	0.01
44	36.101	530	Irganox 1076	2082-79-3	0.55
45	36.198	662	Irgafos 168 ox	95906-11-9	0.59
Sum					<b>35</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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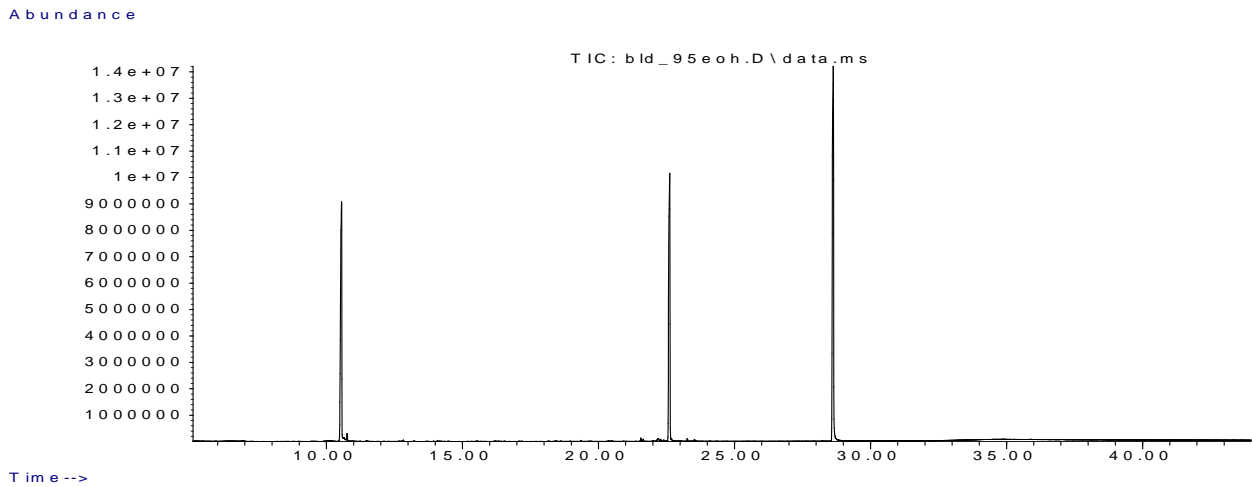
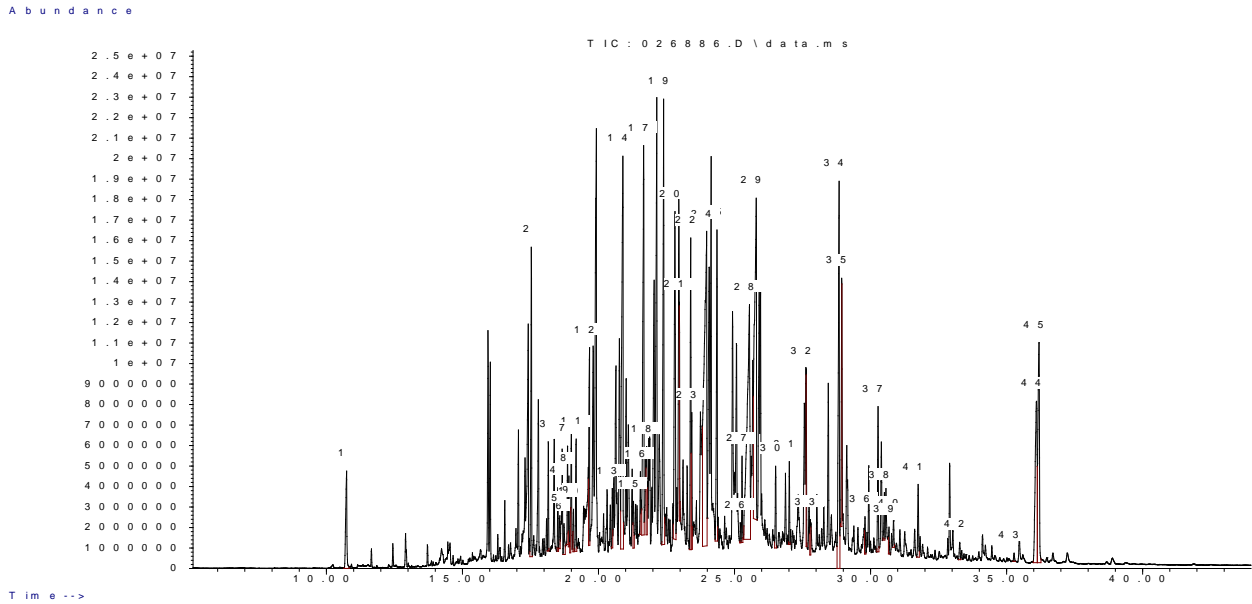
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**Chromatograms**


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

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#### 4.2.1 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]	Compliant
2	101-84-8	0.47	(EU) No. 1334/2008	Fl.No. 04.035	none	Yes
4	127-51-5	0.08	(EU) No. 1334/2008	Fl.No. 07.036	none	Yes
5	79-77-6	0.05	Not listed (NIAS)	-	43	Yes, see below
6	112-18-5	0.07	(EU) No 10/2011	FCM-No.: 15	30	Yes
7	96-76-4	0.13	Not listed (NIAS)	-	1	Yes, see below
8	128-37-0	0.08	(EU) No 10/2011	FCM-No.: 315	3	Yes
9	111-82-0	0.06	(EU) No 10/2011	FCM-No.: 879	none	Yes
13	122-40-7	0.07	(EU) No. 1334/2008	Fl.No. 05.040	none	Yes
14	6259-76-3	1.07	(EU) No. 1334/2008	Fl.No. 09.581	none	Yes
15	124-10-7	0.08	(EU) No. 1334/2008	Fl.No. 09.106	none	Yes
18	544-63-8	0.15	(EU) No 10/2011	FCM-No.: 348	none	Yes
19	110-27-0	0.84	(EU) No 10/2011	FCM-No.: 878	60	Yes
22	112-39-0	0.46	(EU) No 10/2011	FCM-No.: 879	none	Yes
23	82304-66-3	0.20	Not listed (NIAS)	-	0.09	Yes, see below
24	57-10-3	1.63	(EU) No 10/2011	FCM-No.: 105	none	Yes
25	142-91-6	0.52	(EU) No 10/2011	FCM-No.: 878	none	Yes
27	112-61-8	0.10	(EU) No 10/2011	FCM-No.: 879	none	Yes
29	57-11-4	1.08	(EU) No 10/2011	FCM-No.: 106	none	Yes
30	77-90-7	0.10	(EU) No 10/2011	FCM-No.: 138	none	Yes
31	5466-77-3	0.09	Not listed (NIAS)	-	1.8	Yes, see below
32	103-23-1	0.10	(EU) No 10/2011	FCM-No.: 207	18	Yes, see below
33	51-03-6	0.05	Not listed (NIAS)	-	9.6	Yes, see below
35	3896-11-5	0.28	(EU) No 10/2011	FCM-No.: 470	30	Yes

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Scan #	CAS#	mg/kg*	Legislation	ID No.	Restriction [mg/kg]	Compliant
36	6197-30-4	0.04	(EU) No 10/2011	FCM-No.: 492	0.05	Yes
37	137-89-3	0.20	Not listed (NIAS)	-	1.8	Yes, see below
38	112-84-5	0.06	(EU) No 10/2011	FCM-No.: 271	none	Yes
39	83846-85-9	0.03	Not listed (NIAS)	-	50	Yes, see below
40	7683-64-9	0.04	Not listed (NIAS)	-	132	Yes, see below
41	42232-29-1	0.11	(EU) No 10/2011	FCM-No.: 879	none	Yes
44	2082-79-3	0.55	(EU) No 10/2011	FCM-No.: 433	6	Yes
45	95906-11-9	0.59	Not listed (NIAS)	-	60	Yes, see below

- # 5 Trans- $\beta$ -Ionone was assessed by the European Chemical Agency (ECHA). A dossier for REACH registration is available on the ECHA website. According to these information the NOAEL (90d) was 72 mg/kg. Following the guideline for 'Risk Assessment of Non-Listed Substances (NLS) and Non-Intentionally Added Substances (NIAS) under Article 19 of the European Plastics-Regulation (EU) No 10/2011 by Plastics Europe a self-derived SML of 43 mg/person/day can be calculated using the above NOAEL (90d).
- # 7 The isomers of Di-tert-butylphenole are well known degradation products of a variety of commercially available antioxidants like Irganox® or Irgafos® stabilizers, 2,4-Di-tert-butylphenol is also known as Arvin 4 substance. The German Federal Institute on Risk Assessment (BfR) evaluated a series of these Arvin substances during its 18th meeting of food contact materials from 2017 April 26th. For Arvin 4 BfR used read-across approach to 2,4-Di-tert-amylphenol. This substance was assessed by the European Chemical Agency (ECHA). According to these information the NOAEL was 5 mg/kg bw/d. Based on this and taking under account correction factor of 3 for read-across adoption following the guideline for 'Risk Assessment of Non-Listed Substances (NLS) and Non-Intentionally Added Substances (NIAS) under Article 19 of the European Plastics-Regulation (EU) No 10/2011 by Plastics Europe a self-derived SML of 1 mg/kg can be calculated.
- # 23 7,9-Di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione (CAS 82304-66-3) is a well-known degradation product of a range of commercially relevant stabilizers and anti-oxidants like Irganox®1076 or Irganox®1010. It is also known as so called Arvin 8 substance. For this substance a structural alert for genotoxicity is derived by the TTC model. Oral information presented by ELISANA, the European industry organization of light stabilizer manufacturers, confirms that experimental toxicity studies showed no genotoxicity of Arvin 8. For 7,9-Di-tert-butyl-1-oxaspiro-4,5-deca-6,9-diene-2,8-dion (Arvin 8) 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. 0.447 kg of food per day** can be considered as safe.
- # 31 For 2-Ethylhexyl methoxycinnamate (CAS 5466-77-3) 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.
- # 32 Bis(2-ethylhexyl) adipate is listed in the European Plastic Regulation (EU) No. 10/2011 with a limit of 18 mg/kg. Consequently the migration was below both restrictions and the product complies.
- # 33 Piperonyl butoxide is used in the following products: biocides (e.g. disinfectants, pest control products) and plant protection products. Piperonyl butoxide was assessed by the European Chemical Agency (ECHA). A dossier for REACH registration is available on the ECHA website. According to these information the NOAEL was 16 mg/kg. Following the guideline for 'Risk Assessment of Non-Listed Substances (NLS) and Non-Intentionally Added Substances (NIAS) under Article 19 of the European Plastics-Regulation (EU) No 10/2011 by Plastics Europe a self-derived SML of 9.6 mg/person/day can be calculated using the above NOAEL.
- # 37 For Bis(2-ethylhexyl)isophthalate (CAS 137-89-3) 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.
- # 39 Quantacure BMS was assessed by the European Chemical Agency (ECHA). A dossier for REACH registration is available on the ECHA website. Following the guideline for 'Risk Assessment of Non-Listed Substances (NLS) and Non-Intentionally Added Substances (NIAS) under Article 19 of the European Plastics-Regulation (EU) No 10/2011 by Plastics Europe a self-derived SML of 50 mg/person/day can be calculated.

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- # 40 Squalen was assessed by the European Chemical Agency (ECHA). A dossier for REACH registration is available on the ECHA website. According to these information the NOAEL was 660 mg/kg. Following the guideline for 'Risk Assessment of Non-Listed Substances (NLS) and Non-Intentionally Added Substances (NIAS) under Article 19 of the European Plastics-Regulation (EU) No 10/2011 by Plastics Europe a self-derived SML of 132 mg/kg can be calculated using the above NOAEL.
- # 45 Tris(2,4-di-ter-buthylphenyl)phosphate is the oxidized form of the stabilizer Tris(2,4-di-ter-buthylphenyl)phosphit also known as Irgafos®168. This stabilizer is listed in (EU) No 10/2011 without restriction. Phosphates are usually considered as less toxic than the respective phosphites as they are of lower reactivity.

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. 0.447 kg/person/day of food packed in the tested packaging, there are no indication for an objection.

### 4.3 Sensory Analysis

Parameters	Food Simulant	Median Grade	Limit Value#
Odour	Water	1 (just recognizable deviation)	2.5
Taste	Water	1.5 (just recognizable to slight deviation, plastic, 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 in 3% acetic acid **exceeds** the threshold value of 10 mg/dm<sup>2</sup>.

In the scope of the NIAS Screening performed **there was no indication for an objection** with the assumption that consumers **eat max. 0.447 kg/person/day** of food packed in the tested packaging, there are no indication for an objection.

Consequently, the product tested **does not comply** 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 **acidic foodstuff** food for the above mentioned test conditions.

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 **non-acidic foodstuff** food for the above mentioned test conditions and limitation for daily intake.

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

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## 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/)

## 6 Picture of Sample



## 7 Version History

Report date	Report number	Modification
10/01/2024	392-2023-00538801_MP_EN	Current version

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