ISRAEL PLASTICS & RUBBER CENTER.

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ISO 9001:2015

Test Report

Specific migrations of metals, Primary aromatic amines and Phthalates

According to Commission Regulation (EU) No 10/2011, Annex II and Israeli Standard 5113

IPRC Job No.	R/3868
Client:	**BioTip.**
Contact person:	Ilan Sela
Client's Address:	Sha'ar Ha'negev regional council, d.n. Hof Ashkelon,78100 ,ISRAEL
Item tested:	Freshness Indicator Sensor(PP printed film +sensor) Thickness of cotton layers is 0.8mm, thickness of top cover is 0.12mm. Total thickness of sensor is 0.92mm.
Item designation:	Type of food on which sensor will be placed (direct contact with food) are fresh meat ,fish and poultry
Use:	Long term storage at, refrigerated and frozen conditions , for disposable use only
Arrival in Lab:	15-May-2024
Testing Period:	26-may-2024 - 20-June-2024
Sample supplied by:	Client
Objectives of examination:	To test Specific Migration according to commission Regulation (EU) No. 10/2011 (Annex I & II) of 14th Jan 2011 on Plastic Materials and Articles Intended to come in contact with food as amended till (EU) 2020/1245 and Israeli Standard 5113

Test Conducted:

1. Specific migration of metals: Al, Ba, Co, Cu, Fe, Li, Mn, Ni, Sb, Zn, Eu, Gd, La, Tb, As, Cd, Cr, Pb, Hg, Mg, K, Na.
   Specific migration of metals which are covered by overall migration results (R/3868 report): Ammonium and Calcium (Ca).
2. Specific migration of Phthalates.
3. primary aromatic amines (PAAs)

Table 1: Summary of test results

Item tested	Test Conducted	Result
Freshness Indicator Sensor(PP printed film +sensor) Thickness of cotton layers is 0.8mm, thickness of top cover is 0.12mm. Total thickness of sensor is 0.92mm.	**Specific Migration –Metals**	**PASS**
	Specific Migration – Primary aromatic amines	**ASS**
	Specific migration of Phthalates	**PASS**

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Specific migration of metals

Test requested:

Determination of specific migration of metals into simulant B (3% acetic acid) at the migration conditions 40°C/10 days.

Testing method used:

Sample preparation is performed according to EN 13130**.**

Specific migration of metals into 3% acetic acid by ICP-MS according to in-house procedure.

Mercury test based on IZP A-10-97.

Test conditions:

Contact temperature and contact time: (40±2)°C/10 days.

Migration ration: 1 piece\ 100 ml of simulant.

Test results:

Table 2: Freshness Indicator Sensor(PP printed film +sensor).

Element	Unit[4]	Result[1][4] Caps and glass bottle330 ml	Limit[2]
Aluminium Al	mg/kg	<0.10	max. 1
Barium Ba	mg/kg	<0.05	max. 1
Cobalt Co	mg/kg	<0.005	max. 0.05
Copper Cu	mg/kg	<0.05	max. 5
Iron Fe	mg/kg	<0.10	max. 48
Lithium Li	mg/kg	<0.01	max. 0.6
Manganese Mn	mg/kg	<0.01	max. 0.6
Nickel Ni	mg/kg	<0.01	max. 0.02
Antimony Sb	mg/kg	<0.005	max. 0.04
Zinc Zn	mg/kg	<0.10	max. 5
Europium Eu	mg/kg	<0.001	max. 0.05
Gadolinium Gd	mg/kg	<0.001	max. 0.05
Lanthanum La	mg/kg	<0.001	max. 0.05
Terbium Tb	mg/kg	<0.001	max. 0.05
Sum of Lanthanides	mg/kg	<0.004	max. 0.05
Arsenic As	mg/kg	<0.001	N.D (0.01)
Cadmium Cd	mg/kg	<0.001	N.D (0.002)
Chromium Cr	mg/kg	<0.005	N.D (0.01)
Lead Pb	mg/kg	<0.005	N.D (0.01)
Mercury Hg	mg/kg	<0.002	N.D (0.01)
Magnesium Mg	mg/kg	<5.0	-[5]
Potassium K	mg/kg	<5.0	-[5]
Sodium Na	mg/kg	<10	-[5]
Calcium Ca	mg/kg	<60	-[5]
Ammonium[3]	mg/kg	< 60	-

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Notes and Abbreviations to table 2:

(1) Expressed as mg of the element per Kg of simulant for the migration ratio 1 piece\100 ml of simulant..

(2) Symbol "<" means less than LOD (Limit of Detection)/LOQ (Limit of Quantitation) of the analytical method.

(3) Limit values according to Commission Regulation (EU) 10/2011 as amended

N.D.= not detectable; for limit of detection see the value in brackets

(4) Specific migration of metals which are covered by overall migration results: Ammonium, Calcium Max. limit: 60 mg/kg food or food simulant. Find report no. R/3868-OM for overall migration results.

(5) The migration is subject to Article 11(3) and article 12 of commission Regulation (EU)10\2011 as amended, additives which are also authorized as food additives by Regulation (EC) No 1333/2008 or as flavorings by Regulation (EC) No 1334/2008

Specific migration of Phthalates

According to regulation (EU) No. 10/2011 (Annex V Chapter I) and Israeli Standard 5113.

Test requested:

Determination of specific migration of phthalates into food simulants A (10% ethanol) and D2- 95% ethanol for the migration conditions (40 ± 2)°C /10 days, Isooctane for the migration conditions (20 ± 2)°C /2 days.

Testing method used:

Determination of phthalates in food simulants by UFLC method, according to in-house procedure of the testing laboratory IZP A-14-108).

(1)The test was conducted by third party accredited laboratory, certified by ISO 17025:2018.

Test conditions:

Contact temperature and contact time: (40±2)°C/10 days.

Migration ration: 1 piece\ 100 ml of simulant.

Test results:

Table 4: Freshness Indicator Sensor(PP printed film +sensor).

Specific migration into 10% ethanol, (40±2)°C/10 days

Substance	Unit(1)	Test result(2) 1st migration	Uncertainty(3)	Limit(4)
Di-butyl phthalate- DBP CAS 84-74-2 ,FCM 157	mg/Kg	< 0.1	-	Max. 0.12
Benzylbutyl phthalate-BBP CAS 85-68-7, FCM 159	mg/Kg	< 1	-	max. 6
Di-(2-ethylhexyl) phthalate-DEHP CAS 117-81-7, FCM 283	mg/Kg	< 0.5	-	max. 0.6
Di-isononyl phthalate- DINP CAS 28553-12-0, FCM 728	mg/Kg	< 1	-	max. 1.8(5)
Di-isodecyl phthalate -DIDP CAS 26761-40-0,FCM 729	mg/Kg	< 1	-	
Diisobutyl phthalate- DIBP CAS 84-69-5, FCM 1085	mg/Kg	<0.1	-	max. 0.15(6)

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Test results:

Table 4: Freshness Indicator Sensor(PP printed film +sensor).

Specific migration into 95% ethanol, (40±2)°C/10 days

Substance	Unit[1]	Test result[2] 1st migration	Uncertainty[3]	Limit[4]
Di-butyl phthalate- DBP CAS 84-74-2 ,FCM 157	mg/Kg	< 0.1	-	Max. 0.12
Benzylbutyl phthalate-BBP CAS 85-68-7, FCM 159	mg/Kg	< 1	-	max. 6
Di-(2-ethylhexyl) phthalate-DEHP CAS 117-81-7, FCM 283	mg/Kg	< 0.5	-	max. 0.6
Di-isononyl phthalate- DINP CAS 28553-12-0, FCM 728	mg/Kg	< 1	-	max. 1.8[5]
Di-isodecyl phthalate -DIDP CAS 26761-40-0,FCM 729	mg/Kg	< 1	-	
Diisobutyl phthalate- DIBP CAS 84-69-5, FCM 1085	mg/Kg	<0.1	-	max. 0.15[6]

Test results:

Table 4: Freshness Indicator Sensor(PP printed film +sensor).

Specific migration into isooctane, (20±2)°C/2 days

Substance	Unit[1]	Test result[2] 1st migration	Uncertainty[3]	Limit[4]
Di-butyl phthalate- DBP CAS 84-74-2 ,FCM 157	mg/Kg	< 0.1	-	Max. 0.12
Benzylbutyl phthalate-BBP CAS 85-68-7, FCM 159	mg/Kg	< 1	-	max. 6
Di-(2-ethylhexyl) phthalate-DEHP CAS 117-81-7, FCM 283	mg/Kg	< 0.5	-	max. 0.6
Di-isononyl phthalate- DINP CAS 28553-12-0, FCM 728	mg/Kg	< 1	-	max. 1.8[5]
Di-isodecyl phthalate -DIDP CAS 26761-40-0,FCM 729	mg/Kg	< 1	-	
Diisobutyl phthalate- DIBP CAS 84-69-5, FCM 1085	mg/Kg	<0.1	-	max. 0.15[6]

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Notes and abbreviations to table 4:

(1) Expressed as mg substance/element per kg of food simulant.

(2) Symbol "<" means less than LOQ (limit of quantification) of the analytical method.

(3)The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor of K=2,providing a level of confidence of approximately 95%

(4) Limit values according to Commission Regulation (EU) 10/2011, as amended

(5) Expressed as the sum of these substances

(6)Group restriction No.36: the limit value for DIBP is calculated using the following equation:
DIBP*4+BBP*0.1+DEHP*1=0.6mg\Kg(expressed as DEHP equivalents).
Specific migration of Diisobutyl phthalate, CAS 84-69-5 in food simulants by UFLC method-outside the sco[e of accreditation.

- The submitted samples comply with the metals requirements of Regulation (EU) No. 10/2011 (Annex II) and Israeli Standard 5113, for the above mentioned conditions and simulants.
  According to Chapter 2 of Annex V of the Regulation, testing condition 10 days at 40°C shall cover all storage time at refrigerated and frozen condition and for up 30 days at room temperature, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T-70)/10) minutes.
- All tested phthalates are below the specific migration limits, for the tested conditions and simulants. Therefore, the tested samples comply with Regulation (EU) No. 10/2011 (Annex V chapter I) and Israeli Standard 5113, regarding specific migration limits of the above mentioned phthalates (table 4), for the above mentioned conditions and simulants.

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Specific migration of primary aromatic amines (PAAs)

Test Specifications:

Test Method: Determination of primary aromatic amines by LC-MS/MS method according to In-House test IZP A-95-28 procedure of the testing laboratory

LC-MS/MS method: quantification of PAAs listed in entry 43 to Appendix 8 of Annex XVII to REACH (Regulation (EC) No. 1907/2006 of European Parliament and of Council), PAAs for which the specific migration limit in Annex I of Commission Regulation (EU) 10/2011 is stated and the selected other PAAs; detection of presence of other 25 PAAs

Test conditions: Food simulant B- 3% Acetic acid (w/v), at the migration conditions 40°C/10 days, disposable use only.
Migration ration: 1 piece\ 100 ml of simulant.

(1)The test was conducted by third party accredited laboratory, certified by ISO 17025:2018.

Results:

Table 5: Test result of specific migration of primary aromatic amines (PAAs) – Annex II (10/2011), food simulant 3% acetic acid, (40±2)°C/10 days

Primary aromatic amine (PAA)	CAS No.	Unit(1)	Test result(2)	Uncertainty	Limit(3)
PAAs listed in entry 43 to Appendix 8 of Annex XVII to REACH					
4-Amino-bipenyle	92-67-1	mg/kg	<0.002	-	N.D.
Benzidine	92-87-5	mg/kg	<0.002	-	N.D.
4-Chlor-o-toluidine	95-69-2	mg/kg	<0.002	-	N.D.
2-Naphthylamine	91-59-8	mg/kg	<0.002	-	N.D.
o-Aminoazotoluene	97-56-3	mg/kg	<0.002	-	N.D.
2-Amino-4-nitro-toluene	99-55-8	mg/kg	<0.002	-	N.D.
p-Chlor-aniline	106-47-8	mg/kg	<0.002	-	N.D.
2,4-Diamino-anisole	615-05-4	mg/kg	<0.002	-	N.D.
4,4'-Diamino-diphenylmethane	101-77-9	mg/kg	<0.002	-	N.D.
3,3'-Dichlor-benzidine	91-94-1	mg/kg	<0.002	-	N.D.
3,3'-Dimethoxy-benzidine	119-90-4	mg/kg	<0.002	-	N.D.
3,3'-Dimethyl-benzidine	119-93-7	mg/kg	<0.002	-	N.D.
3,3'-Dimethyl-4,4'-diaminodiphenylmethane	838-88-0	mg/kg	<0.002	-	N.D.
p-Cresidine	120-71-8	mg/kg	<0.002	-	N.D.
4,4'-Methylen-bis(2-chloraniline)	101-14-4	mg/kg	<0.002	-	N.D.
4,4'-Oxy-dianiline	101-80-4	mg/kg	<0.002	-	N.D.
4,4'-Thio-dianiline	139-65-1	mg/kg	<0.002	-	N.D.
o-Toluidine	95-53-4	mg/kg	<0.002	-	N.D.
2,4-Toluenediamine	95-80-7	mg/kg	<0.002	-	N.D.
2,4,5-Trimethyl-aniline	137-17-7	mg/kg	<0.002	-	N.D.
o-Anisidine	90-04-0	mg/kg	<0.002	-	N.D.
P-Aminoazobenzene	60-09-3	mg/kg	<0.002	-	N.D.
Other PAAs (not listed in REACH)					
Screening for others	4)	-		No PAA detected(5)	
Sum of detected PAAs		mg/kg	-	-	max. 0.01

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Notes and Abbreviations:

(1) Expressed as mg of substance per kg of food simulant

(2) Symbol "<" means less than LOD (limit of detection) of the analytical method

(3) Limit values according to Commission Regulation (EU) 10/2011 as amended

(4) These PAAs were screened- CAS No.95-68-1,CAS No.87-62-7, CAS No.2243-61-1, CAS No.62-53-3, CAS No.95-51-2, CAS No.108-42-9, CAS No.106-50-3, CAS No.823.40-5, CAS No.121-69-7, CAS No.1208-52-2, CAS No.6358-64-1, CAS No.95-82-9, CAS No.94-70-2, CAS No.2835-68-9, CAS No.81-16-3,
CAS No. 88-44-8, CAS No.49564-57-0, CAS No.95-23-8, CAS No. 90-41-5

(5)LOD (limit of detection)of individual PAA is 0.005 mg/kg

REACH=Regulation (EC) No. 1907/2006 of European Parliament and Council

N.D.= not detectable; limit of detection 0.002 mg/kg

Results:

Table 6: Test result of specific migration of primary aromatic amines (PAAs) – Annex I (10/2011), food simulant 3% acetic acid, (40±2)°C/10 days:1 piece\ 100 ml of simulant.

Primary aromatic amine (PAA)	CAS No.	Unit(1)	Test result(2)	Limit(3)
Bis(4-aminophenyl)sulphone	80-08-8	mg/kg	<0.005	Max. 5
2-Aminobenzamide	88-68-6	mg/kg	<0.005	Max. 0.05
1,3-Phenylenediamine	108-45-2	mg/kg	<0.002	N.D
4,4-Methylenebis(3-chloro-2,6-diethylaniline)	106246-33-7	mg/kg	<0.005	Max. 0.05

Notes and Abbreviations:

(1) Expressed as mg of substance per kg of food simulant

(2) Symbol "<" means less than LOD (limit of detection) of the analytical method

(3) Limit values according to Commission Regulation (EU) 10/2011; as amended : Annex I

N.D. =not detectable; limit of detection 0.002 mg\kg.

Conclusions:

The submitted samples comply with the requirements of Regulation (EU) No. 10/2011 and its amendments, and Israeli Standard 5113 for the above mentioned primary aromatic amines. According to Chapter 2 of Annex V of the Regulation, specific migration testing conditions of 10 days at 40°C all storage time at refrigerated and frozen condition and for up 30 days at room temperature, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T-70)/10) minutes.

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The submitted sample is shown in the following figure No. 1:

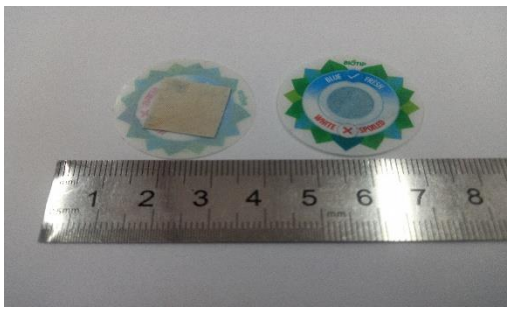

Fig. no. 1: Freshness Indicator Sensor(PP printed film +sensor) Total thickness of sensor is 0.92mm. Thickness of cotton layers is 0.8mm, thickness of top cover is 0.12mm , R/3868 samples.

Notes: The results reported herein, relate only to the sample tested and do not necessarily represent the lot from which they originate. Unless otherwise stated, the samples have been freely selected, indexed and provided by the client. Without written permission of IPRC this test report is not permitted to be duplicated. This test report does not entitle to carry any safety mark on this or similar products. It is the responsibility of the manufacturer of the finished plastic food contact article to verify that the finished articles are in compliance with the defined SML. The manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices and does not modify the organoleptic properties of the food. This test report does not entitle to carry any safety mark on this or similar products. This certificate is valid only with the rest of the test certificates for this product: report no. R/3868.

Tested by: **Approved by:**

Anya Bar
Chemist

Tested by IPRC

Hagit Ichye
Chemist

End of Report