ISRAEL PLASTICS & RUBBER CENTER.

TEL AVIV BRANCH: SHENKAR COLLEGE, Mitchel Building,
12 Anna Frank St. - Ramat Gan, 5252626 - Israel
Phone: +972-3-6130111, Fax: +972-3-6130019

HAIFA BRANCH: TECHNION City, Haifa - 3200003 - Israel
Phone: +972-4-8225174, Fax: +972-4-8320157
www.isplrc.co.il, iprc@isplrc.co.il

Test Report

Overall migration

According to commission Regulation (EU) No. 10/2011 as amended till (EU) 2023/1442,
CFR - Code of Federal Regulations Title 21 - 175.300 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 drawn by:	Client
Objectives of examination:	To test Overall Migration according to Regulation (EU) No. 10/2011 of 14th Jan 2011 on Plastic Materials and Articles Intended to come in contact with food and Israeli Standard 5113

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,thicknes of top cover is 0.12mm. Total thickness of sensor is 0.92mm.	Overall Migration Test- EU10/2011	**PASS**
	Overall Migration Test FDA 21 CFR 175.300	**PASS**

ISRAEL PLASTICS & RUBBER CENTER.

TEL AVIV BRANCH: SHENKAR COLLEGE, Mitchel Building,
12 Anna Frank St. - Ramat Gan, 5252626 - Israel
Phone: +972-3-6130111, Fax: +972-3-6130019

HAIFA BRANCH: TECHNION City, Haifa - 3200003 - Israel
Phone: +972-4-8225174, Fax: +972-4-8320157
www.isplrc.co.il, iprc@isplrc.co.il

Overall Migration test:

Table 2: Applied test methods

- Overall migration of extractives from sensor, using solvents that are simulating types of foodstuffs for compliance with EU Regulation (EU) No. 10/2011 and its amendments: "Plastics materials and articles intended to come into contact with food", and overall migration according to Israeli standard 5113.
- To determine compliance with FDA- title 21 Code of Federal Regulations (CFR) section 175.300.

Table 2: Applied test methods

Test Method	Principle
EN 1186 - 3	Test methods for overall migration into aqueous food simulants by total immersion
EN 1186 - 13	Test methods for overall migration at high temperatures
EN 1186 - 14	Exposure into iso-octane and 95 % aqueous ethanol

Table 3: Standardized testing conditions

Test Number	Contact time in days [d] or hours [h] at Contact temperature in [°C]	Intended food contact conditions
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packed under hot-fill conditions, and/or heating up to a temperature T where 70 ˚C ≤ T ≤ 100 ˚C for a maximum of t = 120/2^((T-70)/10) minutes

ISRAEL PLASTICS & RUBBER CENTER.

TEL AVIV BRANCH: SHENKAR COLLEGE, Mitchel Building,
12 Anna Frank St. - Ramat Gan, 5252626 - Israel
Phone: +972-3-6130111, Fax: +972-3-6130019

HAIFA BRANCH: TECHNION City, Haifa - 3200003 - Israel
Phone: +972-4-8225174, Fax: +972-4-8320157
www.isplrc.co.il, iprc@isplrc.co.il

Table 4: Test Results EU 10/2011- (1 piece\100 ml of simulant)

Item	Units	Simulant	Test method	Test conditions	Overall Migration Results		Max. Per. Limit (*mg/article*)(*)
					Overall Migration Results (*mg/article*)(*)	Average	
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.	mg/dm²	A	EN 1186-3	10 d/40 °C	1.30 ; 1.40; 1.40	1.37	10
	mg/dm²	B	EN 1186-3	10 d/40 °C	1.10 ; 1.20 ; 0.9	1.10	10
	mg/dm²	D2	EN 1186-3	10 d/40 °C	2.13; 2.07; 2.07	2.09	10
	mg/dm²	E	EN 1186-13	10 d/40 °C	<1.0; <1.0; <1.0	< 1.0	10

Note: Simulant A: Ethanol 10% (v/v)
Simulant B: Acetic Acid 3% (w/v)
Simulant D2: Fatty simulant
Simulant E: poly(2,6-diphenyl-p-phenylene oxide)
mg/dm^2: milligram per square decimeter
ND = Not Detected; d=day; hr=hour; °C: degree Celsius

(*) According to chapter V, article 17, section 4 of the EU 10/2011 regulation; "For caps, gaskets, stoppers and similar sealing articles the overall migration value shall be expressed in (a) mg/dm2 applying the total contact surface of sealing article and sealed container if the intended use of the article is known;(b) mg/article if the intended use of the article is unknown.

(*) Due to technical challenges in the conditioning procedure of the samples; a change in mass between two consecutive weighing, of less than 5 mg/dm², could not be achieved. Therefore, alternative test method for the assessment was employed, as described in EN 1186-14: "Exposure into Iso-octane and 95 % ethanol". That is, the higher migration result is presented in the report as required in Commission Regulation 2016/1416 "Amending and correcting (EU) No 10/2011 on plastic materials and articles intended to come into contact with food". Therefore, in this case the highest results were received from migration in 95%Ethanol.

(*) For food categories where in sub-column D2 the cross is followed by (**) the testing in food simulant D2can be omitted if it can be demonstrated that there is no "fatty contact" with the plastic food contact material.

(*) According to EN 1186-1 paragraph 12.3 Validity of results for Aqueous food simulant analytical tolerances are allowed 6mg\kg or 1 mg\dm2 for all aqueous food simulants and for fatty food simulants 20mg\kg or 3 mg\dm2 for all fatty food simulants.

(*) Test simulant E (Tenax) for dry food contact was conducted in a closed system with a distance of approximately 1 cm to the Tenax.

ISRAEL PLASTICS & RUBBER CENTER.

TEL AVIV BRANCH: SHENKAR COLLEGE, Mitchel Building,
12 Anna Frank St. - Ramat Gan, 5252626 - Israel
Phone: +972-3-6130111, Fax: +972-3-6130019

HAIFA BRANCH: TECHNION City, Haifa - 3200003 - Israel
Phone: +972-4-8225174, Fax: +972-4-8320157
www.isplrc.co.il, iprc@isplrc.co.il

Table 5: Test Results FDA 21 CFR

Item	Simulant	Test Method Reference to	Test conditions	OML Res. (mg/in^2)		Max. 3) Per. (mg/in^2)
				Value obtained 1)	Uncertainty 2)	
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.**	Water	21 CFR 175.300	48h at 70°F(21.1°C))	0.11 (4)	0.06	0.5

Note: OML Res.: Overall Migration Results °F: degree Fahrenheit
Max. Per.: Max. Permissible Limit mg/in^2: milligram per square inch

1) Symbol < means less than LOD (limit of detection) of the analytical method.
2) The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage of k=2, providing a level of confidence of approximately 95%.
3) Limit according to FDA 21 CFR 175.300, paragraph c) (1) for a coating intended for or employed as a component Of a container not to exceed 1 gallon and intended for one-time use.
4) Method for determining the amount of chloroform-soluble extractives residue was used.

(*) "If when calculated by the equations in paragraph (e)(5)(i)(*a*) and (*b*) of this section, the concentration of extractives residue (*Ex*) exceeds 50 parts per million or the extractives in milligrams per square inch exceed the limitations prescribed in paragraph (c) of this section for the particular container size, proceed to to paragraph (e)(5)(ii) of this section (method for determining the amount of chloroform-soluble extractives residue)."

Conclusions:

- The submitted samples comply with the overall migration requirements of Regulation (EU) 10/2011 as amended; according to table 3 of Annex III of the Regulation, for Overall Migration, testing the **combination of simulants :A, B, D2(all types of food) and E allows to conclude on compliance for contact with chicken ,meat and fish, chilled or frozen** . According to Chapter 3 of Annex V of the Regulation, Overall Migration test condition OM2 covers any long term storage at room temperature or below, including when packed under hot-fill conditions, and/or heating up to a temperature T where 70 ˚C ≤ T ≤ 100 ˚C for a maximum of t = 120/2^((T-70)/10) minutes.
- The submitted samples complies with title 21 Code of Federal Regulations section 175.300 at use conditions ,F- Refrigerated storage (no thermal treatment in the container) as defined in table 2, for type of foods defined in Table 1; III. Aqueous ,acid or nonacid product containing free oil or fat: may contain salt and including water-in-oil emulsions of low- or high-fat content.
- Note: This certificate is valid only with the rest of the test certificates for this product.
- combination of simulants :A, B, D2(all types of food) and E allows to conclude on compliance for contact with chicken ,meat and fish, chilled or frozen in direct contact.

ISRAEL PLASTICS & RUBBER CENTER.

TEL AVIV BRANCH: SHENKAR COLLEGE, Mitchel Building,
12 Anna Frank St. - Ramat Gan, 5252626 - Israel
Phone: +972-3-6130111, Fax: +972-3-6130019

HAIFA BRANCH: TECHNION City, Haifa - 3200003 - Israel
Phone: +972-4-8225174, Fax: +972-4-8320157
www.isplrc.co.il, iprc@isplrc.co.il

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

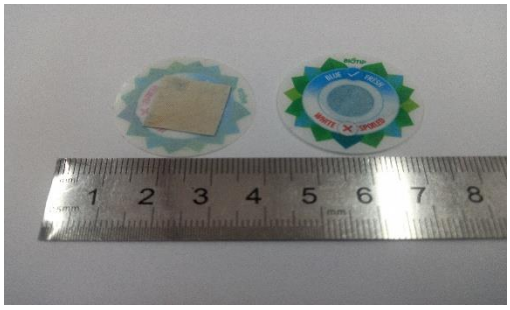

Fig. no. 1: Freshness Indicator Sensor(PP printed film +sensor), R-3868.
Thickness of cotton layers is 0.8mm, thickness of top cover is 0.12mm Total thickness of sensor is 0.8mm, thickness of top cover is 0.12mm.

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. The use of ISRAC symbol relates to tests which are included in the organization scope of accreditation and preformed according to the accreditation rules as detailed in the accreditation certificate. 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. ISRAC is not responsible for the results of the tests performed by the organization/research facility and accreditation/recognition does not constitute a certificate of approval of any item, system or process tested. The test report does not contain the uncertainty values. The tested sample is not cleared for contact with baby foods for infants and young children.

The test report does not contain the uncertainty values. This certificate is valid only with the rest of the test certificates for this product: specific migration test of metals, report no.: R/3868- (SML)

Tested by: **Approved by:**

Anya Bar
Chemist

Israel Plastics and Rubber Center Tested by IPRC

Hagit Ichye
Chemist

End of Report