

TEST REPORT No 98314 A

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1. Customer, it's address **CITA SANTEHNIKA LTD, 7b Rencenu Street, Riga, Latvia.**

2. Sample identification according to the announcement No L-22858 from 19/09/2023:

Sample name: **Polypropylene bag 57x95 cm**
Intended use: **Intended for packaging of food products**
Sample amount: **3 pcs**

3. Sample description/photo

White polypropylene bag



4. Testing time	Received 19/09/2023	Started 09/10/2023	Finished 31/10/2023
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5. Test results and methods

5.3 Organoleptic assessment

Tested parameter	Test result	Test method
Organoleptic assessment of distilled water after the test:		T-138-31-1:2011 *
- smell intensity	grade 0	
- taste intensity	grade 0	

Organoleptic assessment was carried out by immersing sample material in distilled water and exposing for 10 days at a temperature of +40 °C. Surface/volume ratio by organoleptic assessment was 6:1.

Explanation: grade 0 - unchanged grade 2 - minor changes grade 4 - strong changes
grade 1 - just perceptible changes grade 3 - major changes

* The method is not included in the scope of accreditation

5.1 Overall migration

Tested parameter	Test result	Test method
Overall migration to food simulant E (TENAX)	< 3.0 mg/dm ² surface area of sample	PN-EN 1186-13:2007 (met. B) **

**** Overall migration test in food simulant E was performed in a subcontracting laboratory. Weight of food simulant/Food contact surface area: 4 g/l dm². Test conditions: exposing for 10 days at a temperature of +40°C.**

Requirements:

- The overall migration limit – 10 mg/dm² (Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food)

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5.2 Specific migration of substances to food simulant B (Acetic acid 3%)

Tested parameter	SML, mg/kg food simulant ^a	Test result, mg/kg food simulant	Test method
Aluminium	1	< 0.5	EN ISO 11885:2009
Barium	1	< 0.1	EN ISO 11885:2009
Cobalt	0.05	< 0.005	EN ISO 11885:2009
Copper	5	< 0.5	EN ISO 11885:2009
Iron	48	< 1.0	EN ISO 11885:2009
Lithium	0.6	< 0.05	EN ISO 11885:2009
Manganese	0.6	< 0.05	EN ISO 11885:2009
Nickel	0.02	< 0.01	EN ISO 11885:2009
Zinc	5	< 0.5	EN ISO 11885:2009
Antimony	0.04	< 0.01	EN ISO 11885:2009
Europium	0.05	< 0.05	EN ISO 11885:2009 modif *
Gadolinium	0.05	< 0.05	EN ISO 11885:2009 modif *
Lanthanum	0.05	< 0.05	EN ISO 11885:2009 modif *
Terbium	0.05	< 0.05	EN ISO 11885:2009 modif *
Arsenic	ND=0.01	< 0.01	EN ISO 11885:2009
Cadmium	ND=0.002	< 0.002	EN ISO 11885:2009
Chromium	ND=0.01	< 0.01	EN ISO 11885:2009
Lead	ND=0.01	< 0.01	EN ISO 11885:2009
Mercury	ND=0.01	< 0.01	EN ISO 11885:2009 modif *
Ammonium	***	< 0.01	EN ISO 14911:1999 modif *
Calcium	***	62	EN ISO 14911:1999 modif *
Magnesium	***	0.2	EN ISO 14911:1999 modif *
Potassium	***	< 0.01	EN ISO 14911:1999 modif *
Sodium	***	< 0.01	EN ISO 14911:1999 modif *

The specific migration test was carried out by immersing sample material in food simulant B (3% acetic acid) and exposing 10 days at a temperature of +60 °C. Surface/volume ratio in specific migration test was 6:1.

^a - Commission Regulation (EU) No 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

*** The migration shall be evaluated according to the Article 11 (3) and Article 12 of the Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

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5.4 Specific migration of primary aromatic amines to food simulant B (Acetic acid 3%)

Test method: T-138-48-1:2022 * (High performance liquid chromatography/mass spectrometry)

Tested primary aromatic amine	CAS Number	Test result
biphenyl-4-ylamine 4-aminobiphenyl xenylamine	92-67-1	< 0.002 mg/kg food simulant
benzidine	92-87-5	< 0.002 mg/kg food simulant
4-chloro-o-toluidine	95-69-2	< 0.002 mg/kg food simulant
2-naphthylamine	91-59-8	< 0.002 mg/kg food simulant
o-aminoazotoluene 4-amino-2',3 dimethylazobenzene 4-o-tolylazo-o-toluidine	97-56-3	< 0.002 mg/kg food simulant
5-nitro-o-toluidine	99-55-8	< 0.002 mg/kg food simulant
4-chloroaniline	106-47-8	< 0.002 mg/kg food simulant
4-methoxy-m-phenylenediamine	615-05-4	< 0.002 mg/kg food simulant
4,4'-methylenedianiline 4,4'-diaminodiphenylmethane	101-77-9	< 0.002 mg/kg food simulant
3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4' ylenediamine	91-94-1	< 0.002 mg/kg food simulant
3,3'-dimethoxybenzidine o-dianisidine	119-90-4	< 0.002 mg/kg food simulant
3,3'-dimethylbenzidine 4,4'-bi-o-toluidine	119-93-7	< 0.002 mg/kg food simulant
4,4'-methylenedi-o-toluidine	838-88-0	< 0.002 mg/kg food simulant
6-methoxy-m-toluidine p-cresidine	120-71-8	< 0.002 mg/kg food simulant
4,4'-methylene-bis-(2-chloro-aniline) 2,2'-dichloro-4,4'-methylene-dianiline	101-14-4	< 0.002 mg/kg food simulant
4,4'-oxydianiline	101-80-4	< 0.002 mg/kg food simulant
4,4'-thiodianiline	139-65-1	< 0.002 mg/kg food simulant
o-toluidine 2-aminotoluene	95-53-4	< 0.002 mg/kg food simulant
4-methyl-m-phenylenediamine	95-80-7	< 0.002 mg/kg food simulant
2,4,5-trimethylaniline	137-17-7	< 0.002 mg/kg food simulant
o-anisidine 2-methoxyaniline	90-04-0	< 0.002 mg/kg food simulant
4-amino azobenzene	60-09-3	< 0.002 mg/kg food simulant

The specific migration test was carried out by immersing sample material in food simulant B (3% acetic acid) and exposing 10 days at a temperature of +60 °C. Surface/volume ratio in specific migration test was 6:1.

Requirements:

- Primary aromatic amines shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant. They shall not be detectable using analytical equipment with a limit of detection of 0.002 mg/kg food or food simulant applied to each individual primary aromatic amine. (Commission Regulation (EU) No 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food).

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5.6 Content of Cadmium, Mercury, Lead, Chromium (VI)

Tested parameter	Test result	Test method
Cadmium	< 1 mg/kg	LVS EN 1122:2001 *
Mercury	< 0.2 mg/kg	LVS EN 1122:2001 modif *
Lead	< 2 mg/kg	LVS EN 1122:2001 modif *
Chromium (VI)	< 2 mg/kg	LVS EN 1122:2001 modif *
Sum of Cadmium, Mercury, Lead and Chromium (VI)	< 5 mg/kg	Calculation

Requirements:

- Sum of concentration of Lead, Cadmium, Mercury and Hexavalent Chromium shall not exceed 100 ppm (100 mg/kg) (European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste);
- Concentration of Cadmium (expressed as Cd metal) shall not be equal to or greater than 0.01 % by weight of the plastic material (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Annex XVII, Entry 23).

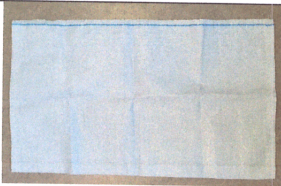
* The method is not included in the scope of accreditation

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DECLARATION OF COMPLIANCE

for articles from plastic intended to come into contact with food

1.	The identity and address of the business operator issuing the declaration of compliance:	Cita Santehnika, SIA 7b Rencenu Str., Riga, Latvia, LV-1073
2.	The identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles:	<p>Manufacturer: YAKSH POLYPACK, LILAPAR ROAD, MORBI-36364, INDIA</p> <p>Importer: Cita Santehnika, SIA, 7b Rencenu Str., Riga, Latvia</p>
3.	The identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles:	<p>Product: Polypropylene bags mech 10x10 and 11x11, 60-180 gms (woven material) 57x95</p> 
4.	The date of the declaration:	12/ 12/2023
5.	Confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) No 1935/2004:	<p>We hereby confirm, that product specified in point 3 complies with the relevant requirements of following acts, in their version valid on the date of issue of this document:</p> <ul style="list-style-type: none"> - Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food , - Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (Article 3, 11(5), 15 and 17)
6.	<p>Adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.</p> <p>At intermediate stages, this information shall include the identification and amount of substances in the intermediate material,</p> <p>— that are subject to restrictions in Annex II, or</p> <p>— for which genotoxicity has not been ruled out, and which</p>	<p>Monomers and substances in the composition of described product are listed in Annex I to Regulation 10/2011- Union list of authorized monomers and other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids, taking into account the information provided by raw material specifications.</p> <p>Monomers, substances used for manufacturing of this product, and identified products of degradation are not regulated with specific migration limits according to the Annex I of Regulation 10/2011 considering to the the information provided by raw material specifications.</p> <p>Specific migration limits of aluminium, ammonium, antimony, arsenic, barium, cadmium, calcium, chromium, cobalt, copper, europium, gadolinium, iron, lanthanum, lead, lithium, magnesium, manganese, mercury, nickel, potassium, sodium, terbium, zinc and primary aromatic amines* from</p>

6.	originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant;	product conform to the requirements of Regulation (EU) No 10/2011 Annex II. *Primary aromatic amines ("PAAs") listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council		
7.	Adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food:	Above mentioned product does not contains chemical Above mentioned product contains chemical substances that are classified as "dual-use" additives according to Regulation (EU) No 1333/2008 and/or Regulation (EU) No 1334/2008 considering to the the information provided by raw material specifications: <table><tr><td>Ingredient</td></tr><tr><td>Calcium carbonates E170</td></tr></table>	Ingredient	Calcium carbonates E170
Ingredient				
Calcium carbonates E170				
8.	Specifications on the use of the material or article, such as: (i) type or types of food with which it is intended to be put in contact; (ii) time and temperature of treatment and storage in contact with the food; (iii) the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 of Regulation 10/2011 or equivalent information;	(i) product is intended to direct contact with prepacked food, dry food, (ii) product is intended with the following conditions of contact with foodstuff : long - term (up to 1 year), temperature from 0 °C to +40°C ; (iii) ratio of food contact surface area to volume differs depending from the specific usage of article and can be calculated.		
9.	When a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of Regulation 10/2011:	Does not concern		

This declaration is based on the information about production processes, documentation provided by raw material suppliers, internal production control and the results of products tests proceeded by independent testing laboratory - Latvian Certification Centre, Ltd. test report No 98314A 01/11/2023.

Test results prove that:

- the our products conforms to Commission Regulation (EC) No 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (regarding to possible influence of the articles to the foodstuffs organoleptic characteristics)
- overall migration from products does not exceed established maximum limit 10 mg/dm²

Food simulant	Test conditions	Results
Food simulant E <i>TENAX</i>	10 days, temp. +40°C	<3,0 mg/dm ²

- specific migration limits of primary aromatic amines from products does not exceed limit specified in Regulation 10/2011 Annex II:

Primary aromatic amines ('PAAs') listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006	Food simulant	Test conditions	Results, mg/kg food simulant	Limit
biphenyl-4-ylamine	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.002	shall not be detectable, Detection limit : < 0.002 mg/kg food simulant
4-aminobiphenyl xenylamine			< 0.002	
benzidine			< 0.002	
4-chloro-o-toluidine			< 0.002	
2-naphthylamine			< 0.002	
o-aminoazotoluene			< 0.002	
4-amino-2',3'-dimethylazobenzene			< 0.002	
4-o-tolylazo-o-toluidine			< 0.002	
5-nitro-o-toluidine			< 0.002	
4-chloroaniline			< 0.002	
4-methoxy-m-phenylenediamine			< 0.002	
4,4'-methylenedianiline			< 0.002	
4,4'-diaminodiphenylmethane			< 0.002	
3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamin			< 0.002	
3,3'-dimethoxy-benzidine o-dianisidine			< 0.002	
3,3'-dimethylbenzidine			< 0.002	
4,4'-bi-o-toluidine			< 0.002	
4,4'-methylenedi-o-toluidine			< 0.002	
6-methoxy-m-toluidine p-cresidine			< 0.002	

4,4'-methylene-bis-(2-chloro-aniline)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.002	shall not be detectable, Detection limit : < 0.002 mg/kg food simulant
2,2'-dichloro-4,4'-methylene-dianiline			< 0.002	
4,4'-oxydianiline			< 0.002	
4,4'-thiodianiline			< 0.002	
o-toluidine			< 0.002	
2-aminotoluene			< 0.002	
4-methyl-m-phenylenediamine			< 0.002	
2,4,5-trimethylaniline			< 0.002	
o-anisidine			< 0.002	
2-methoxyaniline			< 0.002	
4-amino azobenzene			< 0.002	

– specific migration limits of following substances from products does not exceed limit specified in Regulation 10/2011 Annex II:

Substance	Food simulant	Test conditions	Results	Limit
Barium (Ba)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.1 mg/kg food simulant	1 mg/kg food simulant
Cobalt (Co)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.005 mg/kg food simulant	0.05 mg/kg food simulant
Copper (Cu)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.5 mg/kg food simulant	5 mg/kg food simulant
Iron (Fe)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 1.0 mg/kg food simulant	48 mg/kg food simulant
Lithium (Li)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.05 mg/kg food simulant	0.6 mg/kg food simulant
Manganese (Mn)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.05 mg/kg food simulant	0.6 mg/kg food simulant
Zinc (Zn)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.5 mg/kg food simulant	5 mg/kg food simulant
Aluminium (Al)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.5 mg/kg food simulant	1 mg/kg food simulant
Nickel (Ni)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.01 mg/kg food simulant	0.02 mg/kg food simulant
Antimony (Sb)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.01 mg/kg food simulant	0.02 mg/kg food simulant
Arsenic (As)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.01 mg/kg food simulant	shall not be detectable, detection limit : < 0.01 mg/kg food simulant
Cadmium (Cd)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.002 mg/kg food simulant	shall not be detectable, detection limit : < 0.002 mg/kg food simulant
Chromium (Cr)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.01 mg/kg food simulant	shall not be detectable, detection limit : < 0.01 mg/kg food simulant
Lead (Pb)	Food simulant B <i>Acetic acid</i> 3 % (v/v)	10 days, temp. +40°C	< 0.01 mg/kg food simulant	shall not be detectable, detection limit : < 0.01 mg/kg food simulant

Mercury (Hg)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	< 0.01 mg/kg food simulant	shall not be detectable, detection limit : < 0.01 mg/kg food simulant
Europium (Eu)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	< 0.05 mg/kg food simulant	0.05 mg/kg food simulant
Gadolinium (Gd)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	< 0.05 mg/kg food simulant	0.05 mg/kg food simulant
Lanthanum (La)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	< 0.05 mg/kg food simulant	0.05 mg/kg food simulant
Terbium (Tb)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	< 0.05 mg/kg food simulant	0.05 mg/kg food simulant
Sodium (Na)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	< 0.01 mg/kg food simulant	*
Ammonium (NH ₄)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	< 0.01 mg/kg food simulant	*
Potassium (K)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	< 0.01 mg/kg food simulant	*
Magnesium (Mg)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	0.2 mg/kg food simulant	*
Calcium (Ca)	Food simulant B <i>Acetic acid 3 % (v/v)</i>	10 days, temp. +40°C	62 mg/kg food simulant	*

*The migration shall be evaluated according to the Article 11(3) and Article 12 of the Commission Regulation (EU) No 10/2011

- sum of concentration of lead, cadmium, mercury and hexavalent chromium) in product does not exceed 100 mg/kg and conform to the requirements stated in article 7 of EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/62/EC of 20 December 1994 on packaging and packaging waste;
- concentration level of cadmium in product material does not be equal or exceed 0,01% by weight and conforms to the requirement stated in Entry 23, Annex XVII of Regulation (EC) No 1907/2006.

Restricted elements	Results
Cadmium	< 1 mg/kg
Mercury	< 0,2 mg/kg
Lead	< 2 mg/kg
Chromium (VI)	< 2 mg/kg
Sum of Cadmium, Mercury, Lead and Chromium (VI)	< 5 mg/kg

Cita santehnika, SIA authorised person
for Declaration of Compliance issuing:

Dmitrijs Bondarenko

position, name, surname

[Signature]

signature