



INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

TESTING LABORATORY - TESTING DIVISION

issues

ATTEST

No. 472115170-01

On sample

Plastic caps made of PE RIBLENE MR 10R FE S312
(white, yellow)

Client

STOPLAST s.r.o., Formanská 416, 735 62 Český Těšín 6
IČ: 26786354

Evaluation of the measured parameters:

The evaluated parameters of the sample mentioned on the pages 3 – 8 of the Attest **meet** hygienic requirements for the **products made of plastics** given by **Czech Health Ministry Decree No. 38/2001 Coll.**, relating to hygienic requirements for the articles intended to come into contact with foodstuffs, as amended and **Commission Regulation (EU) No. 10/2011 of 14th January 2011** on plastic materials and articles intended to come into contact with food, as amended.

Food contact conditions:

- Long-term contact with dry foodstuff types for storage times above 6 months at room temperature and all storage time at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.
- Ratio: 13 cm² of product surface / 105 ml (g) of food (or more).

The evaluated sample meets requirements for the limit values of the substances limited by their specific migration limits (SML):

- According to the Annex I of Commission Regulation 10/2011: see page 2 of this attest
- According to the Annex II of Commission Regulation 10/2011: metals (Ba, Co, Cu, Fe, Li, Mn, Zn, Al, Ni, Sb, Eu, Gd, La, Tb, As, Cd, Cr, Pb, Hg)
- According to the Annex I and II of Commission Regulation 10/2011: primary aromatic amines.

The evaluated sample does not unacceptably change organoleptic characteristics of food.

The evaluated sample meets requirements of the article 3 of **Regulation (EC) No. 1935/2004 of the European Parliament and of the Council** on materials and articles intended to come into contact with food.

This Attest was issued on the basis of the accredited test report Ref. No. 472115170-01 issued on May 16, 2022.

Issued on: May 16, 2022

Valid till: May 31, 2025

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Dipl. Ing. Jiří Samsoněk, Ph.D.
Head of the testing laboratory



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List of the substances limited by their specific migration limits (SML) according to the Annex I of Commission Regulation 10/2011:

Plastic caps made of PE RIBLENE MR 10R FE S312 (white)

- No substances restricted by specific migration limit

Plastic caps made of PE RIBLENE MR 10R FE S312 (yellow)

- oktadecyl-3-(3,5-di-*terc*-butyl-4-hydroxyphenyl)propanoate – Irganox 1076, CAS 2082-79-3, PM/Ref 68320, FCM 433, SML = 6 mg/kg

Substances not listed in Annex I (Union list) to Commission Reegulation 10/2011 – NIAS (non-intentionally added substances) assessment:

The submitted sample was screened for NIAS (non-intentionally added substances) in the sample mass. Substances classified as NIAS were not detected – see table on the page 8 of this attest

CAS = Chemical Abstract Service number; PM/Ref = the EEC packaging material reference number; SML = specific migration limit; NIAS = non-intentionally added substances

Delivered sample:



**Fig. 1 – delivered sample –
Plastic caps made of PE RIBLENE MR 10R FE S312 (white, yellow)**



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Values obtained:

Assessment of organoleptic properties:

Plastic caps made of PE RIBLENE MR 10R FE S312 (white)

Food, contact conditions		Biscuits without flavouring agent (crushed), 40°C / 48 h	
Assessor No.	Assessor No.	Odour	Flavour
1	level	0	0
2	level	0	0
3	level	0	0
4	level	0	0
5	level	0	0
6	level	0	0
Mean	level	0	0

Plastic caps made of PE RIBLENE MR 10R FE S312 (yellow)

Food, contact conditions		Biscuits without flavouring agent (crushed), 40°C / 48 h	
Assessor No.	Assessor No.	Odour	Flavour
1	level	0	0
2	level	0	0
3	level	0	0
4	level	0	0
5	level	0	0
6	level	0	0
Mean	level	0	0

Off-odour and off-taste scale:

- 0 = No perceptible off-odour or off-taste
- 1 = Just perceptible off-odour or off-taste (off-odour and off-taste determination is very difficult)
- 2 = Moderate off-odour or off-taste
- 3 = Strong off-odour or off-taste
- 4 = Very strong off-odour or off-taste

According to Regulation (EC) No. 1935/2004 of the European Parliament and of the Council the articles shall not unacceptably change organoleptic characteristics of food.

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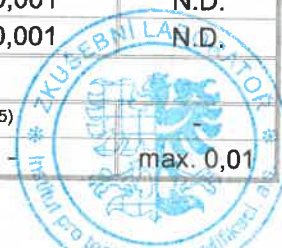
Test results of specific migration of primary aromatic amines:

Plastic caps made of PE RIBLENE MR 10R FE S312 (white, yellow)

Primary aromatic amine (PAA)	CAS No.	Unit ¹⁾	Test result ²⁾		Limit ³⁾
			white	yellow	
Food simulant B (3% acetic acid), 60 °C / 10 days					
PAAs listed in entry 43 to Appendix 8 of Annex XVII to REACH					
4-Amino-biphenyle	92-67-1	mg/kg	< 0,001	< 0,001	N.D.
Benzidine	92-87-5	mg/kg	< 0,001	< 0,001	N.D.
4-Chlor-o-toluidine	95-69-2	mg/kg	< 0,001	< 0,001	N.D.
2-Naphthylamine	91-59-8	mg/kg	< 0,001	< 0,001	N.D.
o-Aminoazotoluene	97-56-3	mg/kg	< 0,001	< 0,001	N.D.
2-Amino-4-nitro-toluene	99-55-8	mg/kg	< 0,001	< 0,001	N.D.
p-Chlor -aniline	106-47-8	mg/kg	< 0,001	< 0,001	N.D.
2,4-Diamino-anisole	615-05-4	mg/kg	< 0,001	< 0,001	N.D.
4,4'-Diamino-diphenylmethane	101-77-9	mg/kg	< 0,001	< 0,001	N.D.
3,3'-Dichlor-benzidine	91-94-1	mg/kg	< 0,001	< 0,001	N.D.
3,3'-Dimethoxy-benzidine	119-90-4	mg/kg	< 0,001	< 0,001	N.D.
3,3'-Dimethyl-benzidine	119-93-7	mg/kg	< 0,001	< 0,001	N.D.
3,3'-Dimethyl-4,4'-diaminodiphenylmethane	838-88-0	mg/kg	< 0,001	< 0,001	N.D.
p-Keresidine	120-71-8	mg/kg	< 0,001	< 0,001	N.D.
4,4'-Methylen-bis(2-	101-14-4	mg/kg	< 0,001	< 0,001	N.D.
4,4'-Oxy-dianiline	101-80-4	mg/kg	< 0,001	< 0,001	N.D.
4,4'-Thio-dianiline	139-65-1	mg/kg	< 0,001	< 0,001	N.D.
o-Toluidine	95-53-4	mg/kg	< 0,001	< 0,001	N.D.
2,4-Toluenediamine	95-80-7	mg/kg	< 0,001	< 0,001	N.D.
2,4,5-Trimethyl-aniline	137-17-7	mg/kg	< 0,001	< 0,001	N.D.
o-Anisidine	90-04-0	mg/kg	< 0,001	< 0,001	N.D.
o-Aminoazobenzene	60-09-3	mg/kg	< 0,001	< 0,001	N.D.
Other PAAs (not listed in REACH)					
Other detected PAAs	⁴⁾	-	PAA not detected ⁵⁾		
Sum of detected PAAs		mg/kg	-	-	max. 0,01

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Primary aromatic amine (PAA)	CAS No.	Unit ¹⁾	Test result ²⁾		Limit ³⁾
			white	white	
Food simulant B (3% acetic acid), 60 °C / 10 days					
Bis(4-aminophenyl)sulphone	80-08-0	mg/kg	< 0,001	< 0,001	max. 5
2-Aminobenzamide	88-68-6	mg/kg	< 0,001	< 0,001	max. 0,05
1,3-Phenylenediamine	108-45-2	mg/kg	< 0,001	< 0,001	N.D.
4,4'-Methylenebis(3-chloro-2,6-diethylaniline)	106246-33-7	mg/kg	< 0,001	< 0,001	max. 0,05

Notes to Tables:

- 1) Expressed as mg of PAA / kg of food simulant for migration ratio 13 cm² / 105 ml (g) of food
- 2) Symbol „<“ means 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. 2243-62-1, CAS No. 62-53-3, CAS No. 95-51-2, CAS No. 108-42-9, CAS No. 106-49-0, CAS No. 106-50-3, CAS No. 823-40-5, CAS No. 121-69-7, CAS No. 6582-52-1, 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. 132-32-1, CAS No. 95-54-5, CAS No. 67014-36-2, CAS No. 156-43-4, 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 of Council
N.D. = not detectable; limit of detection 0,002 mg/kg



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Plastic caps made of PE RIBLENE MR 10R FE S312
(white, yellow)

Test results of specific migration of elements according to Annex II, Commission Regulation (EU) No. 10/2011

Plastic caps made of PE RIBLENE MR 10R FE S312 (white, yellow)

Parameter	Unit ¹⁾	Test result ²⁾		Limit ³⁾
		white	yellow	
Food simulant B (3% acetic acid), 60 °C / 10 days				
Antimony	mg/kg	< 0,001	< 0,001	max. 0,04
Barium	mg/kg	< 0,01	< 0,01	max. 1
Aluminium	mg/kg	< 0,02	< 0,02	max. 1
Cobalt	mg/kg	< 0,001	< 0,001	max. 0,05
Lithium	mg/kg	< 0,002	< 0,002	max. 0,6
Manganese	mg/kg	< 0,002	< 0,002	max. 0,6
Cooper	mg/kg	< 0,01	< 0,01	max. 5
Nickel	mg/kg	< 0,002	< 0,002	max. 0,02
Zinc	mg/kg	< 0,02	< 0,02	max. 5
Iron	mg/kg	< 0,02	< 0,02	max. 48
Europium	mg/kg	< 0,001	< 0,001	max. 0,05
Gadolinium	mg/kg	< 0,001	< 0,001	max. 0,05
Lanthan	mg/kg	< 0,001	< 0,001	max. 0,05
Terbium	mg/kg	< 0,001	< 0,001	max. 0,05
Sum of lanthanides	mg/kg	< 0,004	< 0,004	max. 0,05
Arsenic	mg/kg	< 0,001	< 0,001	N.D. (0,01)
Cadmium	mg/kg	< 0,001	< 0,001	N.D. (0,002)
Chromium	mg/kg	< 0,001	< 0,001	N.D. (0,01)
Lead	mg/kg	< 0,001	< 0,001	N.D. (0,01)
Mercury	mg/kg	< 0,001	< 0,001	N.D. (0,01)

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Plastic caps made of PE RIBLENE MR 10R FE S312
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Notes to table:

- 1) Expressed as mg of the substance per kg of food simulant for migration ratio 13 cm² / 105 ml (g) of food
 - 2) Symbol „<“ means less than limit of detection of the analytical method.
 - 3) Limit values according to Decree of Health Ministry No. 38/2001 as amended and Commission Regulation EU 10/2011 as amended
- N.D. = not detectable; for limit of detection see value in bracket

Test results of specific migration of monomers and additives

Plastic caps made of PE RIBLENE MR 10R FE S312 (yellow)

Substance	Unit ¹⁾	Výsledek měření ²⁾	Uncertainty	Limit ³⁾
Specific migration into E (MPPO), 60°C / 10 days				
Irganox 1076, CAS 2082-79-3, Ref 68320, FCM 433	mg/kg	< 0,2	-	max. 6

Notes to table:

- 1) Expressed as mg of the substance per kg of food simulant for migration ratio 13 cm² / 105 ml (g) of food
- 2) Symbol „<“ znamená méně než detekční limit metody
- 3) Limit values according to Decree of Health Ministry No. 38/2001 as amended and Commission Regulation EU 10/2011 as amended

Test results of colour migration barvy

Plastic caps made of PE RIBLENE MR 10R FE S312 (yellow)

Sample	Unit	Výsledek zkoušky měření		Requirement
		B: 3% acetic acid	D2: Olive oil	
Plastic caps made of PE RIBLENE MR 10R FE S312 (yellow)	popis	No migration	No migration	¹⁾

Notes to table:

- 1) According to Resolution AP (89) 1, BfR IX. and Decree of Health Ministry No. 38/2001 Coll., as amended, colourants and pigments shall be fixedly embedded in product so as to preclude any visible migration into foodstuffs

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Plastic caps made of PE RIBLENE MR 10R FE S312
(white, yellow)

Test results of low molecular substances identification by TD-GC-MS
Plastic caps made of PE RIBLENE MR 10R FE S312 (white)

Substance name ¹⁾	CAS	FCM	Comment
Branched aliphatic oil ³⁾	-	-	Better identification could not be done
Alifatic amide / fatty acid amide ³⁾	-	-	Substances listed in Annex I with general migration limit ²⁾
Hexadecanoic acid	57-10-3	105	Substance listed in Annex I with general migration limit ²⁾
PE oligomers ³⁾	9002-88-4	549	Substances listed in Annex I with general migration limit ²⁾

Plastic caps made of PE RIBLENE MR 10R FE S312 (yellow)

Substance name ¹⁾	CAS	FCM	Comment
Branched aliphatic oil ³⁾	-	-	Better identification could not be done
Alifatic amide / fatty acid amide ³⁾	-	-	Substances listed in Annex I with general migration limit ²⁾
Hexadecanoic acid	57-10-3	105	Substance listed in Annex I with general migration limit ²⁾
PE oligomers ³⁾	9002-88-4	549	Substances listed in Annex I with general migration limit ²⁾

Notes to table:

- ¹⁾ Identified substances can be either original ones, presented in the sample, or it can be degradation products. Match of the MS spectra of found substances with standard MS spectra from D-base are in the range of 70-95 %.
- ²⁾ General limit = 60 mg/kg of food valid for the substances with no SML specified in Annex I; covered by overall migration test in case of non-volatile compounds
- ³⁾ Better identification could not be done



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Sample description and identification:

ITC's identification number	Sample identification by client	Description of submitted sample
472115170/01	Plastic caps made of PE RIBLENE MR 10R FE 312 (white)	White cap – see Fig. No. I
472115170/02	Plastic caps made of PE RIBLENE MR 10R FE 312 (yellow)	Yellow cap – see Fig. No. I

The client provided following data:

- Surface of the lid coming into contact with food: 13 cm²
- The container 75 ml – volume 105 cm³

Together with the sample a set of documents was supplied. The documentation includes following items:

- Declaration of conformity for colour WEISS K 70 PE with the Commission Regulation (EU) No. 10/2011, Decree of Health Ministry No. 38/2001 Coll. and Resolution EU AP.(89)1, issued by LIFOCOLOR s.r.o. on January 20, 2021.
- Declaration of conformity for colour LIFOCOLOR-YELLOW 10-1851 F/PE with the Commission Regulation (EU) No. 10/2011, Decree of Health Ministry No. 38/2001 Coll. and Resolution EU AP (89)1, issued by LIFOCOLOR s.r.o. on February 16, 2021.

Request

Evaluation of hygienic properties of the sample according to Decree of Health Ministry No. 38/2001 Coll. *for articles intended into a contact with foodstuffs*, as amended, in compliance with Law of Czech Republic No. 258/2000 Coll. *about protection of the public health*, as amended.

The evaluation of hygienic properties of the sample is based on European legislation in the sense of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council *on materials and articles intended to come into contact with food*, according to Commission Regulation EU No. 10/2011 *on plastic materials and articles intended to come into contact with food*.

Opinions and interpretations

The evaluated “**Plastic caps made of PE RIBLENE MR 10R FE 312 (white, yellow)** “ are intended to direct contact with foodstuffs.

The requirements for products intended to come into direct contact with foodstuffs are given by Decree of the Health Ministry No. 38/2001 Coll., as amended (hereinafter referred to as Decree 38/2001), by Commission Regulation EU No. 10/2011 (hereinafter referred to as Regulation 10/2011) and by European Parliament and Council Regulation No. 1935/2004 (hereinafter referred to as Regulation 1935).

General requirements - Decree 38/2001, Regulation 10/2011 and Regulation 1935

The products intended to contact with foodstuffs shall be manufactured so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: endanger human health or bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof. The performed tests verified that the evaluated sample does not influence the organoleptic properties of the food (see the table on the page 3 of this attest). The constituent transferring is discussed further.

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Requirements for the colour pigments - Decree 38/2001

Colorants and pigments shall be fixedly embedded in product and have to comply the requirements of the annex 1 to Decree 38/2001 or of Resolution AP (89)1. The client submitted the document (see D2-D4) confirming fulfilment of the pigment purity requirements as above mentioned. Determination of specific migration of primary aromatic amines to simulant of type B (3% acetic acid) and determination of colour migration into food simulants were performed on the supplied sample. Primary aromatic amines were not detected at the detection limit of 0.002 and 0.005 mg/kg for individual substances. The test results of colour migration are listed on the page 7 of this attest.

Requirements on plastic products - Decree 38/2001, Regulation 10/2011

Only the monomers and other basic substances listed in the supplement of Decree 38/2001 or Regulation 10/2011 can be used for the manufacturing of the plastic products intended into contact with foodstuffs, complying with defined limitation. The client submitted the documents (see D1 – D4) declaring the conformity of raw materials used for manufacturing with the requirements for plastic composition.

Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm²) (limit of overall migration). The tests of overall migration for articles intended to direct contact with dry kind of food is not required.

Migration of components from plastic materials and products shall not exceed specific migration limits (SML) or other restrictions included in the list of substances. The test results of the specific migration of substances Irganox 1076, CAS 2082-79-3, FCM 433 (yellow cap) including migration conditions are mentioned in the table on the page 7 of this attest. All measured values of specific migration meet the required limit values.

Within the evaluation of non-intentionally added substances (NIAS) TD-GC-MS analysis for determination of low-molecular substances (potential degradation products from polymer additives) in mass was done. No substances restricted by its specific migration limit were detected – see tables on the page 8 of this attest.

General restrictions on plastic materials and articles according to the Commission Regulation No. 10/2011/EC:

Materials and articles shall not release metals and primary aromatic amines in foods or food simulants in quantities exceeding the specific migration limits set out in the Annex II to this Regulation. Compliance with specific migration limit of these substances was verified experimentally and is shown in the table on the page 4-6 of this attest.

Tests results of overall and specific migration meet the above mentioned requirements under following conditions:

- Long-term contact with dry foodstuff types for storage times above 6 months at room temperature and all storage time at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.
- Ratio: 6 dm² of product surface / 1 kg (litter) of food (or more).

The opinion expressed and interpretation made by

Dipl. Ing. Martina Vyoralová, May 16, 2022

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Testing Laboratory – D2

ATTEST No. 472115170-01

Conclusion

The comparison of obtained results with limits of the Decree No. 38/2001 Coll., as amended, of the Commission Regulation (EU) No. 10/2011 and of the article 3 of the European Parliament and Council Regulation No. 1935/2004 and evaluation of the conformity with these regulations are mentioned on the page 1 of this Attest.

Dipl. Ing. Daniel Vít
Head of the laboratory of analytical chemistry and microbiology

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