



INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.

třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
TESTING LABORATORY - TESTING DIVISION

Issues

ATTEST No. 472110570

on sample:

Spiral hose – type Rauspiraflex Liquitec

client:

**DLplast, s.r.o., Tovární 1633, 769 01 Holešov, Czech Republic,
Company ID. No.: CZ25592173**

issued for:

**REHAU AG + Co, Rheniumhaus, Otto-Hahn-Str. 2, 95111 Rehau, Germany
Company ID. No.: DE132944654**

Values obtained and the assessment of the technical parameters:

The evaluated parameters mentioned on the pages 4 - 9 of the Attest meet hygienic requirements for the **products made of plastics** given by **Czech Health Ministry Decree No. 38/2001 Coll.**, on plastic materials and articles intended to come into contact with food, 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:

- contact for up to 2 hours at a temperature of 40 °C
- contact with aqueous, acidic and alcoholic foods up to an alcohol content of 20 %, ratio: 60 cm² of product area/100 g (ml) of food (or more)

The evaluated sample meets requirements for the limit values of the substances limited by their specific migration limits (SML): - see page 2 of this attest

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. Complete assessment of raw materials as required under the article 5 and the Annex I to Commission Regulation 10/2011 is not a part of this attest.

This Attest was issued on the basis of the accredited test reports Ref. No. 472110570 from November 1, 2017, Ref. No. 472107562 from August 28, 2014 and attest No. 472107910 from December 22, 2014, all documents were issued by Institut pro testování a certifikaci, a.s. Zlín.

Issued on: November 01, 2017
Valid till: November 30, 2020



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

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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: the evaluated sample contains 5 substances with SML (confidential information), all substances, hereafter referred to as substance No. 1 – 5, meet the required migration limits
- according to the Annex II of Commission Regulation 10/2011: metals (Ba, Co, Cu, Fe, Li, Mn, Zn, Al, Ni) and primary aromatic amines.



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Picture 1: the supplied sample No. 472110570/1



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Sample: Spiral hose – type Rauspiraflex Liquitec

Assessment of the sensorial properties

(the test results were taken from Test report No. 472107562 from August 28, 2014)

Food, contact conditions		Overdone drinking water, (40±2)°C, 48 h	
assessor No.	odour	odour	flavour
1	level	0	0
2	level	0	0
3	level	0	0
4	level	0	1
5	level	0	0
6	level	0	0
Mean	level	0	0

Off-odour and off-taste scale:

0 = No perceptible odour or taste

1 = Just perceptible odour or taste (odour and taste determination is very difficult)

2 = Moderate odour or taste

3 = Strong odour or taste

4 = Very strong odour or taste

According to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) 10/2011 the articles shall not unacceptably change organoleptic characteristics of food.



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ATTEST

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Sample: Spiral hose – type Rauspiraflex Liquitec

Identification of additives by TD-GC-MS method

(the test results were taken from Test report No. 472110570 from November 1, 2017)

Substance name	Limit ¹⁾
transparent plasticized PVC	
Substance No. 1	SML = 60 mg/kg
Substance No. 2	SML = 6 mg/kg
red PVC spiral	
Substance No. 2	SML = 6 mg/kg

Notes to the table:

¹⁾ limit values according to Annex I of Commission Regulation (EU) No 10/2011

Determination of the toxic elements in the mass

(the test results were taken from Test report No. 472107562 from August 28, 2014)

Parameter	Unit ¹⁾	Test result ²⁾	Uncertainty ³⁾
Pb	mg/kg	< 10	-
Cd	mg/kg	< 10	-
Hg	mg/kg	< 10	-
Cr	mg/kg	< 50	-
Sb	mg/kg	< 10	-
As	mg/kg	< 10	-
Se	mg/kg	< 10	-

Notes to the table:

¹⁾ symbol „<“ means less than limit of detection of the analytical method

²⁾ pigments and fillers must not contain compounds based on these elements – Pb, Hg, Cd, Cr^{VI}, Sb, Se a As

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ATTEST

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Sample: Spiral hose – type Rauspiraflex Liquitec

Overall migrations into the food simulants

(the test results were taken from Test report No. 472107562 from August 28, 2014)

Food simulant, migration conditions	Unit	Value obtained ¹⁾		Uncertainty ²⁾	Limit ³⁾
		Single Values	Mean		
3% acetic acid, (40±2) °C, 10 days, 3. migration	mg/ dm ²	6,8; 8,2; 8,1	7,7	2,2	max. 10
20% ethanol, (40±2) °C, 10 days	mg/ dm ²	1,3; 0,6; 0,7	0,9	1,1	max. 10

Notes to the table:

- ¹⁾ the results are expressed in mg/dm² for migration ratio 1225 cm²/1225 ml
- ²⁾ 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%
- ³⁾ limit values according to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) No 10/2011

Overall migrations into the food simulants

(the test results were taken from Test report No. 472110570 from November 1, 2017)

Food simulant, migration conditions	Unit	Value obtained ¹⁾		Uncertainty ²⁾	Limit ³⁾
		Single Values	Mean		
3% acetic acid, (70±2) °C, 2 hours	mg/ dm ²	2,7; 3,0; 2,5	2,7	0,4	max. 10

Notes to the table:

- ²⁾ the results are expressed in mg/dm² for migration ratio 235,5 cm²/290 ml
- ²⁾ 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%
- ³⁾ limit values according to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) No 10/2011



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ATTEST

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Sample: Spiral hose – type Rauspiraflex Liquitec

Specific migration of metals and primary aromatic amines into food simulants

(the test results were taken from Test report No. 472107562 from August 28, 2014 and Test report No. 472110570 from November 1, 2017)

Parameter	Unit ¹⁾	Test result ²⁾	Uncertainty ³⁾	Limit ⁴⁾
specific migration into 3% acetic acid, (40±2) °C / 24 hours				
Ba	mg/kg	< 0,05	-	max. 1
Co	mg/kg	< 0,005	-	max. 0,05
Cu	mg/kg	< 0,05	-	max. 5
Fe	mg/kg	< 0,10	-	max. 48
Li	mg/kg	< 0,01	-	max. 0,6
Mn	mg/kg	< 0,01	-	max. 0,6
Zn	mg/kg	< 0,10	-	max. 25 max. 5 ⁶⁾
Al	mg/kg	0,11	0,02	max. 1 ⁶⁾
Ni	mg/kg	0,005	0,001	max. 0,02 ⁷⁾
primary aromatic amines	mg/kg ⁵⁾	< 0,01	-	max. 0,01
specific migration into 95% ethanol, (40±2) °C / 24 hours				
Ba	mg/kg	< 0,05	-	max. 1
Co	mg/kg	< 0,01	-	max. 0,05
Cu	mg/kg	< 0,05	-	max. 5
Fe	mg/kg	< 0,50	-	max. 48
Li	mg/kg	< 0,05	-	max. 0,6
Mn	mg/kg	< 0,05	-	max. 0,6
Zn	mg/kg	< 0,50	-	max. 25 max. 5 ⁶⁾

Notes to the table:

- ¹⁾ expressed as mg of substance/element per kg of food simulant
- ²⁾ symbol „<“ means LOD (limit of detection) of the analytical method;
the test results for specific migration of Al and Ni were taken from Test report No. 472110570,
the test results of other parameters were taken from Test report No. 4723107562
- 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⁾ the limit values according to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) No 10/2011
- ⁵⁾ expressed as mg of aniline per kg of stimulant
- ⁶⁾ limit is valid from 14. 9. 2018
- ⁷⁾ limit is valid from 19. 5. 2019

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Sample: Spiral hose – type Rauspiraflex Liquitec

Specific migration of substances No. 1 - 5

(the test results were taken from Test report No. 472107562 from August 28, 2014)

Food simulant, migration conditions	Unit ¹⁾	Test result ²⁾	Uncertainty	Limit ³⁾
Substance No. 1				
3% acetic acid, (40±2)°C / 24 hours	mg/kg	< 1	-	max. 60
20% ethanol, (40±2)°C / 24 hours	mg/kg	< 1	-	max. 60
Substance No. 2				
3% acetic acid, (40±2)°C / 24 hours	mg/kg	< 1	-	max. 6
20% ethanol, (40±2)°C / 24 hours	mg/kg	< 1	-	max. 6
Substance No. 3				
3% acetic acid, (40±2)°C / 24 hours	mg/kg	< 1	-	max. 1,5
20% ethanol, (40±2)°C / 24 hours	mg/kg	< 1	-	max. 1,5
Substance No. 4				
3% acetic acid, (40±2)°C / 24 hours	mg/kg	< 1	-	max. 9
20% ethanol, (40±2)°C / 24 hours	mg/kg	< 1	-	max. 9
Substance No. 5				
3% acetic acid, (40±2)°C / 24 hours	mg/kg	< 0,01	-	max. 0,01
20% ethanol, (40±2)°C / 24 hours	mg/kg	< 0,01	-	max. 0,01

Notes to the table:

¹⁾ expressed as mg of substance/element per kg of food simulant

²⁾ symbol „<“ means LOD (limit of detection) of the analytical method;

³⁾ the limit values according to Decree of Health Ministry No. 38/2001 Coll., as amended and according to Commission Regulation (EU) No 10/2011



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Sample: Spiral hose – type Rauspiraflex Liquitec

Determination of vinyl chloride ¹⁾ in the mass

(the test results were taken from Test report No. 472107562 from August 28, 2014)

Parameter	Unit	Test result ²⁾	Uncertainty data	Limit ³⁾
vinyl chloride in the mass	mg/kg ⁴⁾	< 0,08	-	max. 1
vinyl chloride in the leachate	mg/kg ⁵⁾	< 0,01 ⁶⁾	-	max. 0.01

Notes to the table:

- ¹⁾ vinyl chloride, Ref. No. 26050, Cas No. 75-01-4
- ²⁾ symbol „<“ means LOD (limit of detection) of the analytical method
- ³⁾ the limit values according to the Decree of Health Ministry No. 38/2001 Coll., as amended and according to the Commission Regulation (EU) No 10/2011
- ⁴⁾ expressed as mg of substance/element per kg of sample
- ⁵⁾ expressed as mg of substance/element per kg of food simulant
- ⁶⁾ SM of vinyl chloride in the leachate calculated from the vinyl chloride content in the mass

Test results of colour migration – red PVC spiral

(the test results were taken from Test report No. 472107562 from August 28, 2014)

Simulant	Unit	Test result	Requirement
3% acetic acid	description	no migration	¹⁾
20% ethanol	description	no migration	¹⁾

Notes to the 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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INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
Testing Laboratory – D2

ATTEST No. 472110570

Sample identification:

The client supplied for the testing the sample – see table I

Table I: Sample description and identification

ITC's identification number	Sample identification by client	Description of submitted sample
472110570/1	Spiral hose – type Rauspiraflex Liquitec (transparent plasticized PVC with red PVC spiral)	transparent hose with red spiral – see pic. 1

According to the client declaration the product is intended to transport of drinking water and alcoholic beverages with an alcohol content up to 20 %.

Together with the sample the client supplied documents for transparent plasticized PVC including information about substances limited by their specific migration limits (SML). These information were submitted as confidential – the substances are hereafter referred to as substances No. 3 - 5. All documents are stored in the ITC archive.

Work 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 – selected parameter. 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*.

The client requested the prolongation of the Attest No. 472107910 issued by Institut pro testování a certifikaci a.s. Zlín on December 22, 2014. Together with the sample the client supplied the declaration that the manufacturing technology and raw material for production of Spiral hose – type Rauspiraflex Liquitec has not been changed since the last testing in 2014 (issued on September 14, 2017).

The selected parameters – evaluation of overall migrations into 3% acetic acid, determination of Al and Ni into 3% acetic acid and identification of additives by TD-GC-MS method were tested on the representative samples within the attest prolongation. The test results of other parameters were taken from Test report No. 472107562.

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Opinions and interpretations:

The evaluated products „Spiral hose – type Rauspiraflex Liquitec“ are intended to transport of drinking water and alcoholic beverages with an alcohol content up to 20 %.

The requirements for the materials and products intended to come into contact with foodstuffs are given by:

- Decree of the Health Ministry No. 38/2001 Coll., as amended (hereinafter referred to as Decree 38/2001)
- Commission Regulation (EU) 10/2011 (hereinafter referred to as 10/2011)
- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council (hereinafter referred to as 1935/2004)

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

Materials and articles shall be manufactured in compliance with good manufacturing practice 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 deterioration in the organoleptic characteristics thereof. The sensorial test verifies that the evaluated sample does not negatively influence the organoleptic characteristic of the food under the test conditions (see the table on the page 4 of the Attest). The transfer of the constituents is discussed in the following articles.

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. 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 samples. Primary aromatic amines were not detected at the detection limit of 0,01 mg/kg. The test results of colour migration are listed on the page 9 of this attest.

Requirements for plastic products – Decree 38/2001, Regulation 10/2011

Only the monomers and other basic substances listed in the supplement Decree 38/2001 and Regulation 10/2011 can be used for the manufacturing of the plastic products intended to come into contact with foodstuffs, complying with defined limitation. The client supplied documents for transparent plasticized PVC including information about substances limited by their specific migration limits (SML). These information were submitted as confidential – the substances are hereafter referred to as substances No. 3 - 5. The documentation for red PVC spiral has not been supplied.

TD-GC-MS method was carried out on the samples to identify low-molecular additives – sample contains 2 substances limited by their specific migration limits, hereafter referred to as substances No. 1 and 2 (see the table on the page 5 of this attest).

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 No. 1 - 5, including migration conditions and food simulants are mentioned in the table on the page 8 of this attest. All measured values of the specific migrations meet the required limit values.

Complete assessment of raw materials as required under the article 5 and the Annex I to Commission Regulation 10/2011 is not a part of this attest.

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 (limit of overall migration). The

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test results of overall migration tests including the migration conditions and food simulants are mentioned in the table on the page 6 of the Attest.

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

Materials and articles shall not release metals: Ba, Co, Cu, Fe, Li, Mn, Zn, Al, Ni 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 7 of this attest.

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

- contact for up to 2 hours at a temperature of 40 °C
- contact with aqueous, acidic and alcoholic foods up to an alcohol content of 20 %, ratio: 60 cm² of product area/100 g (ml) of food (or more)

Evaluated by:

MUDr. Beata Frydrychová, on November 1, 2017.

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. Věra Vilímková
Head of the laboratory of analytical chemistry and microbiology

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