



# INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.

třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

TESTING LABORATORY - TESTING DIVISION

issues

## ATTEST

### No. 472114078-01

On sample:

**Plastic gasket from material  
ELVAX™ 550A with 2% ELVAX™ CE9619-1 (clear)**

Client:

**VINOLOK, a.s.**

**Opletalova 3197/17, 466 01 Jablonec nad Nisou, Czech Republic**

**ID: 06812759**

#### Evaluation of the measured parameters:

The evaluated parameters mentioned on the pages 2 – 5 of the Attest meet hygienic requirements for the **products made of plastics intended for the repeated use** 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 14<sup>th</sup> January 2011** on plastic materials and articles intended to come into contact with food, as amended.

#### Food contact conditions:

- Contact with aqueous, acid and alcoholic foodstuff types and with the other ones for which the migrations into food simulants B, C and 95% ethanol shall be performed.
- Long-time contact above 6 months at room or lower temperatures, including hot-fill conditions and/or heating up to  $70\text{ °C} \leq T \leq 100\text{ °C}$  for up to the maximum contact time  $t = 120/2^{((T-70)/10)}$  minutes; repeated use
- Ratio: 3.81 cm<sup>2</sup>/200 ml (or more) of food

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

- According to the Annex I of Commission Regulation 10/2011: vinyl-acetate, PM/Ref. No. 10120, CAS 108-05-4, SML=12 mg/kg and 2,6-di-tert-butyl-p-cresol, PM/Ref. No. 46640, CAS 128-37-0, SML=3 mg/kg.
- According to the Annex II of Commission Regulation 10/2011: metals and primary aromatic amines.

The evaluated sample does not cause a deterioration in 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. 472114078-01 issued on May 28, 2021.

**Issued on:** May 28, 2021

**Valid till:** May 31, 2024



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

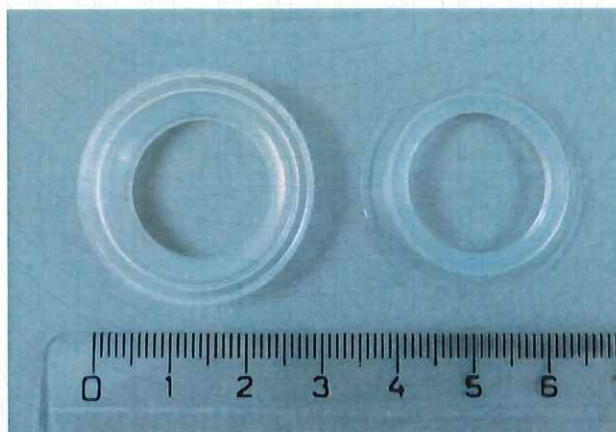
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**ATTEST**  
**No. 472114078-01**  
**Submitted sample:**



**Figure No. 1: Plastic gasket ELVAX™ 550A with 2% ELVAX™ CE9619-1 (clear)**

**Evaluated parameters:**

**Assessment of organoleptic properties**

Food, contact conditions		Drinking water, (40±2) °C / 48 h	
Assessor No.	Unit	Odour	Flavour
1	level	0	0
2	level	0	0
3	level	1	1
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 = Slightly perceptible off-odour or off-taste
- 3 = Clearly perceptible off-odour or off-taste
- 4 = 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 cause deterioration in the organoleptic characteristics of food.

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### Identification of low-molecular substances by method TD-GC-MS

Substance name <sup>1)</sup>	CAS	FCM	Comment
2,6-di-tert-butyl-p-cresol	128-37-0	315	Substance listed in Annex I with SML=3 mg/kg
Erucamide	112-84-5	271	Substance listed in Annex I with no SML
Stearamide	124-26-5	306	Substance listed in Annex I with no SML

#### Notes to the 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 %.

FCM = Food Contact Material No.

CAS No. = unique numerical identifier assigned by the Chemical Abstracts Service

Annex I = Annex I of Commission Regulation (EU) 10/2011 – list of authorised substances

SML = specific migration limit

### Overall migration expressed in mg/dm<sup>2</sup>

#### applying the total contact surface of plastic gasket and sealed bottle (279.81 cm<sup>2</sup>)

	Unit	Value obtained <sup>1)</sup>		Analytical tolerance <sup>2)</sup>	Limit <sup>3)</sup>	Evaluation <sup>4)</sup>
		Single results	Mean			
Migration conditions		3% acetic acid; OM2 (40°C/10 days); by total immersion				
1 <sup>st</sup> migration	mg/dm <sup>2</sup>	0.2; 0.2; 0.3	0.2	1	-	-
2 <sup>nd</sup> migration	mg/dm <sup>2</sup>	<0.1; <0.1; <0.1	<0.1	1	-	-
3 <sup>rd</sup> migration	mg/dm <sup>2</sup>	<0.1; <0.1; <0.1	<0.1	1	10	compliance
Migration conditions		20% ethanol; OM2 (40°C/10 days); by total immersion				
1 <sup>st</sup> migration	mg/dm <sup>2</sup>	0.3; 0.4; 0.3	0.3	3	-	-
2 <sup>nd</sup> migration	mg/dm <sup>2</sup>	0.1; 0.1; <0.1	- <sup>5)</sup>	3	-	-
3 <sup>rd</sup> migration	mg/dm <sup>2</sup>	0.1; 0.1; 0.1	0.1	3	10	compliance
Migration conditions		95% ethanol; OM2 (40°C/10 days); by total immersion				
1 <sup>st</sup> migration	mg/dm <sup>2</sup>	0.4; 0.4; 0.4	0.4	3	-	-
2 <sup>nd</sup> migration	mg/dm <sup>2</sup>	0.2; 0.1; 0.2	0.2	3	-	-
3 <sup>rd</sup> migration	mg/dm <sup>2</sup>	0.1; <0.1; 0.1	- <sup>5)</sup>	3	10	compliance

#### Notes to the table:

1) Symbol „<“ means LOQ (limit of quantification) of the analytical method

2) Analytical tolerance according to ČSN EN 1186-1, article 12.3

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

4) According to EN 1186-1 a material or article that exceeds the overall migration limit by an amount not greater than the analytical tolerance should therefore be deemed to be in compliance. If the mean value of the second and the third migration tests do not exceed the mean value of the first test by an amount higher than the analytical tolerance (1mg/dm<sup>2</sup> or 6mg/kg for aqueous simulants)

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and 3mg/dm<sup>2</sup> or 20mg/kg for fatty food simulants and substitute fatty food simulants), the subsequent test results are not considered as a migration increase.

- 5) It is not possible to calculate the mean value because some of the values are below LOQ

### Test results of specific migration of monomers and additives

Substance	Unit <sup>1)</sup>	Test result <sup>2)</sup>			Limit <sup>3)</sup>
		1 <sup>st</sup> migration	2 <sup>nd</sup> migration	3 <sup>rd</sup> migration	
Specific migration into 3% acetic acid, (60±2) °C / 10 days					
Vinyl acetate, PM/Ref. No. 10120, CAS 108-05-4	mg/kg	< 0.2	< 0.2	< 0.2	max. 12
2,6-di-tert-butyl-p-cresol, PM/Ref. No. 46640, CAS 128-37-0	mg/kg	< 0.1	< 0.1	< 0.1	max. 3
Specific migration into 20% ethanol, (60±2) °C / 10 days					
Vinyl acetate, PM/Ref. No. 10120, CAS 108-05-4	mg/kg	< 0.2	< 0.2	< 0.2	max. 12
2,6-di-tert-butyl-p-cresol, PM/Ref. No. 46640, CAS 128-37-0	mg/kg	< 0.1	< 0.1	< 0.1	max. 3
Specific migration into 95% ethanol, (60±2) °C / 10 days					
Vinyl acetate, PM/Ref. No. 10120, CAS 108-05-4	mg/kg	< 0.2	< 0.2	< 0.2	max. 12
2,6-di-tert-butyl-p-cresol, PM/Ref. No. 46640, CAS 128-37-0	mg/kg	< 0.1	< 0.1	< 0.1	max. 3

#### Notes to the table:

- 1) Expressed as mg of substance per kg of food simulant for the real use ratio: 3.81 cm<sup>2</sup>/200 ml
- 2) Symbol „<“ means less than LOD (limit of detection) of the analytical method. The test results are expressed including the expanded uncertainty for coverage factor k = 2, which for a normal distribution corresponds to a coverage probability of approximately 95%. The test results of the 3<sup>rd</sup> migration are compared with the limit value.
- 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, as amended

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# ATTEST

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### Specific migration of metals according to Commission Regulation (EU) No 10/2011, Annex II

Element	Unit	Test results <sup>1)</sup>			Limit <sup>2)</sup>
		1 <sup>st</sup> migration	2 <sup>nd</sup> migration	3 <sup>rd</sup> migration	
Specific migration into 3% acetic acid, (60±2) °C / 10 days					
Aluminium Al	mg/kg	< 0.10	< 0.10	< 0.10	max. 1
Barium Ba	mg/kg	< 0.05	< 0.05	< 0.05	max.1
Cobalt Co	mg/kg	< 0.005	< 0.005	< 0.005	max. 0.05
Copper Cu	mg/kg	< 0.05	< 0.05	< 0.05	max. 5
Iron Fe	mg/kg	< 0.10	< 0.10	< 0.10	max. 48
Lithium Li	mg/kg	< 0.01	< 0.01	< 0.01	max. 0.6
Manganese Mn	mg/kg	< 0.01	< 0.01	< 0.01	max. 0.6
Nickel Ni	mg/kg	< 0.01	< 0.01	< 0.01	max. 0.02
Antimony Sb	mg/kg	< 0.005	< 0.005	< 0.005	max. 0.04
Zinc Zn	mg/kg	< 0.10	< 0.10	< 0.10	max. 5
Europium Eu	mg/kg	< 0.001	< 0.001	< 0.001	max. 0.05
Gadolinium Gd	mg/kg	< 0.001	< 0.001	< 0.001	max. 0.05
Lanthanum La	mg/kg	< 0.001	< 0.001	< 0.001	max. 0.05
Terbium Tb	mg/kg	< 0.001	< 0.001	< 0.001	max. 0.05
Sum of Lanthanides	mg/kg	< 0.004	< 0.004	< 0.004	max. 0.05
Arsenic As	mg/kg	< 0.001	< 0.001	< 0.001	N.D. (0.01)
Cadmium Cd	mg/kg	< 0.001	< 0.001	< 0.001	N.D. (0.002)
Chromium Cr	mg/kg	< 0.005	< 0.005	< 0.005	N.D. (0.01)
Lead Pb	mg/kg	< 0.005	< 0.005	< 0.005	N.D. (0.01)
Mercury Hg	mg/kg	< 0.002	< 0.002	< 0.002	N.D. (0.01)

#### Notes to table:

- <sup>1)</sup> Symbol „<“ means less than limit of detection of the analytical method. Expressed as mg of the element per kg of food simulant for the real use ratio: 3.81 cm<sup>2</sup>/200 ml. The test results of the 3<sup>rd</sup> migration are compared with the limit value. When the limit = N.D., all test results shall fulfil the limit.
- <sup>2)</sup> Limit values according to Commission Regulation (EU) 10/2011 as amended  
N.D. = not detectable; for limit of detection see the value in brackets

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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. 472114078-01

**Sample description and identification:**

ITC's number	Sample identification by client	Description of submitted sample
14078/1	Plastic gaskets from material ELVAX™ 550A with 2% ELVAX™ CE9619-1 (clear)	Transparent plastic gaskets – see the fig. No 1 on the page 2

The client also provided the following information to the sample:

- surface of the plastic gasket coming into contact with food: 3.81 cm<sup>2</sup>
- surface of the whole plastic gasket: 19.72 cm<sup>2</sup>
- volume of the bottle: 200 ml, inner surface of the bottle: 221 cm<sup>2</sup>

Together with the sample a set of documents was supplied. The documentation includes following items (below marked by letter D):

- D1 – declaration of material „ELVAX™ 550A ethylene vinyl acetate copolymer“ conformity with Commission Regulation (EU) No 10/2011, issued by DOW Europe GmbH, Switzerland, on September 10, 2020
- D2 – declaration of material „ELVAX™ CE9619-1 ethylene vinylacetate copolymer“ conformity with Commission Regulation (EU) No 10/2011, issued by DOW Europe GmbH, Switzerland, on September 10, 2020

**Work requested:**

Evaluation of hygienic properties of the sample for the repeated use according to the Decree of Health Ministry No. 38/2001 Coll. *for articles intended into a contact with foodstuffs*, as amended, in compliance with the 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* and Commission Regulation EU No. 10/2011 *on plastic materials and articles intended to come into contact with food*, as amended.

**Opinions and interpretations:**

The evaluated product “**Plastic gaskets from material ELVAX™ 550A with 2% ELVAX™ CE9619-1 (clear)**” is intended for a direct contact with foodstuffs. According to the client declaration the product is in the long-term contact above 6 months at room temperature and below with aqueous, acid and alcoholic foodstuff types and can be repeated used.

The requirements for products intended into direct contact with foodstuffs are given by Decree of the Health Ministry No. 38/2001 Coll., as amended (hereinafter Decree 38/2001), by Commission Regulation EU No. 10/2011 (hereinafter Regulation 10/2011) and by European Parliament and Council Regulation No. 1935/2004 (hereinafter 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 2 of this attest). The constituent transferring is discussed further.

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

Only the monomers and other basic substances listed in the supplement Decree 38/2001 or Regulation 10/2011 can be used for the manufacturing of the plastic products intended into contact

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with foodstuffs, complying with defined limitation. The client supplied the set of documents (see D1 – D2) confirming the conformity of raw materials with the requirements of the legislation.

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/dm<sup>2</sup>) (limit of overall migration). The test results of the overall migration including migration conditions are mentioned on the page 3 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 specific migrations of vinyl acetate, PM/Ref. No. 10120, CAS 108-05-4 and 2,6-di-tert-butyl-p-cresol, PM/Ref. No. 46640, CAS 128-37-0 were verified on the submitted sample. The test results of the specific migration of these substances including migration conditions are mentioned in the table on the page 4 of this attest. All measured values of specific migration meet the required limit value.

General restrictions on plastic materials and articles according to 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. The presence of primary aromatic amines is not expected in clear material of this type. Compliance with specific migration limit of metals was verified experimentally and is shown in the table on the page 5 of this attest.

Identification of NIAS by GC-MS method after thermal desorption of the sample was performed as a part of NIAS evaluation. The substances identified by TD-GC-MS are listed in the table on the page 3 of this attest.

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

- **Contact with aqueous, acid and alcoholic foodstuff types and with the other ones for which the migrations into food simulants B, C and 95% ethanol shall be performed.**
- **Long-time contact above 6 months at room or lower temperatures, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for up to the maximum contact time  $t = 120/2^{(T-70)/10}$  minutes; repeated use**
- **Ratio: 3.81 cm<sup>2</sup>/200 ml (or more) of food**

**The opinion expressed and interpretation made by:**

Dipl. Ing. Šárka Kopečková, May 28, 2021

**Conclusion:**

The comparison of the obtained results with the limits of Decree No. 38/2001 Coll., as amended, of Commission Regulation (EU) No. 10/2011, as amended 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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