



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

issues

ATTEST
No. 472114118-01

On sample:

LDNG 19- disposable examination nitrile gloves-blue
nitrile disposable gloves – blue

Client:

Polska Grupa Tekstylna Sp.z.o.o.,
Zeusa 27, 01 497 Warsaw, Poland
ID: 0156334446

Values obtained and the assessment of the technical parameters

Evaluated parameters mentioned on the pages 2 - 4 **meet** requirements for **products from elastomers and materials based on natural and synthetic rubber – category IV** given by Health Ministry Decree No. 38/2001 Coll., *relating to hygienic requirements for the articles intended to come into contact with foodstuffs*, as amended.

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. 472114118-01 issued on May 20, 2021.

Date of issue: May 20, 2021

Attest is valid to: May 31, 2024



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

Conditions for use of the Attest and associated information:

- 1. The Attest applies only to the sample tested by our laboratory.*
- 2. The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
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ATTEST
No. 472114118-01
Submitted sample:



Assessment of organoleptic properties
LDNG 19- disposable examination nitrile gloves-blue

Food, contact conditions		boiled and cooled drinking water; (40±2) °C / 0.5 h; 8 g/ 100 ml	
Assessor No.	Unit	Odour	Flavour
1	level	1	2
2	level	1.5	1.5
3	level	1	2
4	level	1	1.5
5	level	0	0
6	level	0	1
Mean	level	1	1.5

Notes to Table:

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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ATTEST

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Values obtained:

Evaluation of the aqueous leachate – the rubber of category IV: 40 °C / 0.5 h
LDNG 19- disposable examination nitrile gloves-blue

Parameter	Unit	Value obtained ¹⁾	Limit ²⁾
Reducing compounds	0.002 mol.l ⁻¹ KMnO ₄ /50ml	4.71±0.48	max. 30
Dry residua	mg/dm ²	<0.5; 0.5; 0.6 ³⁾	max. 10
Primary aromatic amines - proof	-	negative	negative
Ammonia ions - proof	-	negative	negative
Sulphides, acid sulphides - proof	-	negative	negative
Thiosulphates - proof	-	negative	negative
Barium - proof	-	negative	negative
Secondary aliphatic amines - proof	-	negative	negative

Notes to the table:

- 1) Symbol „<“ means less than LOD (limit of detection) of the analytical method. The test results are expressed including the reported expanded uncertainty based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%
- 2) Limit values according to Decree of Health Ministry No. 38/2001 Coll., as amended
- 3) It is not possible to calculate the mean value because some of the values are below LOD

Determination of toxic elements
LDNG 19- disposable examination nitrile gloves-blue

Parameter	Unit	Test result ¹⁾	Limit
Pb	mg/kg	<10	2)
Cd	mg/kg	<10	2)
Hg	mg/kg	<10	2)
Cr	mg/kg	<10	2)
Sb	mg/kg	<20	2)
As	mg/kg	<10	2)
Se	mg/kg	<10	2)

Notes to the table:

- 1) Symbol „<“ means less than LOD (limit of detection) of the analytical method
- 2) According to Decree of Health Ministry No. 38/2001 Coll., as amended pigments and fillers shall not contain compounds based on these elements – Pb, Hg, Cd, Cr, Sb, Se and As.

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ATTEST

No. 472114118-01

Values obtained:

Test results of colour migration LDNG 19- disposable examination nitrile gloves-blue

Simulant	Unit	Test result	Requirement
10% ethanol	description	no migration	1)
3% acetic acid	description	no migration	1)
Olive oil	description	no migration	1)

Note 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

Test results of overall migration LDNG 19- disposable examination nitrile gloves-blue

Food simulant	Unit	Value obtained ¹⁾		Analytical tolerance ²⁾	Limit ³⁾
		Single results	Average		
10 % ethanol, (40±2) °C / 10 min	mg/dm ²	1.8; 1.3; 1.4	1.5	1	max. 10
3 % acetic acid, (40±2) °C / 10 min	mg/dm ²	1.3; <1,0; 1.4	- ⁴⁾	1	max. 10
Distilled water, (40±2) °C / 10 min	mg/dm ²	1.2; 1.0; 1.2	1.1	1	max. 10

Notes to Tables:

- 1) Symbol „<“ means less than the 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 BfR XXI
- 4) It is not possible to calculate the mean value because some of the values are below LOQ



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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. 472114118-01

Sample description and identification:

ITC's identification number	Sample identification by client	Description of submitted sample
14118/1	LDNG 19- disposable examination nitrile gloves-blue	disposable gloves – blue see the figure No. 1 on the page 2

Work request:

Evaluation of hygienic properties of the sample according to Health Ministry Decree No. 38/2001 Coll. of the Ministry of Health *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 and Regulation (EC) No. 1935/2004 of the European Parliament and of the Council *on materials and articles intended to come into contact with food*.

Opinions and interpretations:

The evaluated product "**LDNG 19- disposable examination nitrile gloves-blue**" is intended into 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) and by European Parliament and Council Regulation No. 1935/2004 (hereinafter referred to as Regulation 1935).

General requirements - Decree 38/2001, Regulation 1935

The products intended to come into 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 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).

Requirements for products made of elastomers and materials based on natural and synthetic rubber - Decree 38/2001

Requirements for products from elastomers and materials based on natural and synthetic rubber are listed in § 15 and § 16 of decree 38/2001. According to § 15 elastomers and materials based on natural and synthetic rubber are classified into categories I to V. Evaluated product belongs to the category IV, which includes products with the expected contact time with foodstuffs up to 10 minutes.

According to the requirements of article 16 paragraph 1 for products made of elastomers of category IV only compounds listed in the annex No. 7 part A and B can be used. Assessment of raw materials is not part of this attest.

Products made of elastomers and materials based on natural and synthetic rubber category IV shall meet the hygiene requirements given by point 9.2 of Annex 7 (see § 16 paragraph 2). The obtained values are listed on the page 3 of this attest. The evaluated product meets all required limits for rubber category IV.

Requirements for the colour pigments - Decree 38/2001 and Regulation 1935

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 did not submit any document confirming a fulfilment of the pigment purity requirements as above mentioned. Determinations of toxic elements and within the testing of the rubber aqueous leachate the proof of primary aromatic amines and determination of colour migration into food simulants were performed on the supplied sample. The presence of primary aromatic amines was not proven. The contents of toxic elements were below the detection limit of the analytical method (XRF) – unit mg/kg. The test results of the toxic element

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Testing Laboratory - D2

Attest No. 472114118-01

contents are listed in the table on the page 3 of this attest. The test results of the colour migration are mentioned on the page 4 of this attest.

The tests of overall migration were performed in accordance with BfR XXI (category 3) on the client request. The evaluated product meets all required limits. The test results are listed in the table on the page 4 of this attest.

Evaluated by:

Dipl. Ing. Ludmila Zálešáková on May 20, 2021

Conclusion:

Comparison of the obtained values of the sample with the requirements of Health Ministry Decree No. 38/2001 Coll. as amended and of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council and evaluations of the conformity with these regulations are listed on the page 1 of this attest.

Dipl. Ing. Věra Vilímková
Head of the analytical
and microbiological laboratory

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