

TEST REPORT

2022TM1307

DATE OF RECEPTION

30/09/2022

DATE TESTS

Starting: 30/09/2022

Ending: 03/11/2022

APPLICANT

HOLIK INTERNATIONAL S.R.O.

ZA DVOREM 612, 763 14

CZ-12 ZLÍN

ZLÍN

Att. Karolína Šnajdarová

IDENTIFICATION AND DESCRIPTION OF SAMPLES

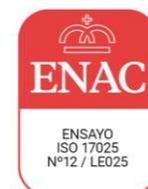
REFERENCES

BLACK NITRILE GLOVES M7002

TESTS CARRIED OUT

- DETERMINATION OF THE OVERALL MIGRATION IN ETHANOL 50 %.
- DETERMINATION OF THE OVERALL MIGRATION IN ACETIC ACID 3 %.
- DETERMINATION OF THE OVERALL MIGRATION IN VEGETAL OIL*.
- DETERMINATION OF SPECIFIC MIGRATION OF METALS*
- DETERMINATION OF PRIMARY AROMATIC AMINES*.

Tests marked with * are not included within the scope of the ENAC accreditation.





SAMPLE DESCRIPTION

PHOTOGRAPHY



Reference⁽¹⁾

BLACK NITRILE GLOVES M7002

LOT number⁽¹⁾

⁽¹⁾ Data provided for the customer

Description according to the customer

Disposable black nitrile glove provided by HOLIK INTERNATIONAL S.R.O

Observations

According to the customer, samples are taken randomly from a production lot. The test conditions agreed with the customer that appear in this report, are selected following the recommendations of the European Commission Guide, Guide Testing conditions for kitchenware items in contact with foodstuffs: Plastics, Metals, Silicone and Rubber, European Commission, 2021 Ispra , JRC125894 as the most stringent foreseeable conditions of use.

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RESULTS

DETERMINATION OF THE OVERALL MIGRATION IN ETHANOL 50 %

Standard: EN 1186-9 :2002

Date: 04/10/2022 – 05/10/2022

Contact form: Filling

Exposition time: 30 min

Temperature: 40 °C

Simulant D1: Ethanol 50 % (v/v)

Relationship of the contact Surface with foodstuffs and the simulant volumen used in migration:
4,8 dm²/400 ml

Number of samples tested: 3

Results:

Sample reference	Individual values of Overall Migration (mg/dm ²)	Average value Overall Migration ⁽¹⁾ (mg/dm ²)
BLACK NITRILE GLOVES M7002	1,8	1,6 ± 0,2
	1,6	
	1,5	

Remarks:

- ⁽¹⁾ Average value (n = 3) ± U (extended uncertainty) for a probability of coverage of 95%.



RESULTS

DETERMINATION OF THE OVERALL MIGRATION IN ACETIC ACID 3 %

Standard: EN 1186:9-2002

Date: 04/10/2022 – 05/10/2022

Contact form: Filling

Exposition time: 30 min

Temperature: 40 °C

Simulant B: Acetic acid 3 % (w/v)

Relationship of the contact Surface with foodstuffs and the simulant volumen used in migration:
4,8 dm²/400 mL

Number of samples tested: 3

Results:

Sample reference	Individual values of Overall Migration (mg/dm ²)	Average value Overall Migration ⁽¹⁾ (mg/dm ²)
BLACK NITRILE GLOVES M7002	2,0	1,8 ± 0,2
	1,8	
	1,7	

Remarks:

- ⁽¹⁾ Average value (n = 3) ± U (extended uncertainty) for a probability of coverage of 95%.



RESULTS

DETERMINATION OF THE OVERALL MIGRATION IN VEGETAL OIL*

Standard: EN 1186-2:2002

Date: 10/10/2022 – 18/10/2022

Contact form: Immersion

Exposition time: 30 min

Temperature: 40 °C

Simulant (D2): Vegetal oil

Relationship of the contact Surface with foodstuffs and the simulant volumen used in migration: 1 dm²/100 ml

Number of samples tested: 4

Resultados / Results:

Reference	Individual values of Overall Migration (mg/dm ²)	Average value of Overall Migration (mg/dm ²)
BLACK NITRILE GLOVES M7002	5,0	4,3
	3,3	
	4,5	
	4,1	

Remark:

- Limit of Detection (LOD) = 1 mg/dm²



RESULTS

DETERMINATION OF SPECIFIC MIGRATION OF METALS*

Standard: In-house method

Date: 07/10/2022 – 10/10/2022

Exposition time: 30 minutes Temperature: 40 °C

Simulant (B): Acetic acid 3 % (v/v)

Relationship of food contact Surface and volumen used in calculations to determine migration: 0.6 dm²/100 ml

Reference: BLACK NITRILE GLOVES M7002

Heavy metals	Result (mg/Kg)	Maximum Limits (mg/Kg) ⁽¹⁾
Barium	< 0.1	1
Cobalt	< 0.01	0.05
Copper	< 0.1	5
Iron	< 0.1	48
Lithium	< 0.1	0.6
Manganese	< 0.1	0.6
Zinc	8.78	5 25 ⁽²⁾
Aluminum	< 0.1	1
Nickel	< 0.01	0.02
Arsenic	ND	N.D
Cadmium	ND	0.002
Chromium	ND	N.D
Europium	< 0.01	0.05
Gadolinium	< 0.01	0.05
Lanthanum	< 0.01	0.05
Terbium	< 0.01	0.05
Lead	ND	N.D
Mercury	ND	N.D
Antimony	<0.01	0.04

Remarks:

- ⁽¹⁾ Maximum limits according to the annex II of Regulation (EU) No. 10/2011 and subsequent amendments.
- ⁽²⁾ This limit is applicable for natural and synthetic rubber gloves according to "Recommendation BfR. XXI/1.Commodities based on natural and synthetic rubber in contact with Food".
- LC < 0.01 mg/kg
- N.D = Not detectable
- LC < 0.01 mg/kg
- LC (Cd) < 0.002 mg/kg



RESULTS

DETERMINATION OF PRIMARY AROMATIC AMINES*

Method: TOF (Q-TOF LC/MS)

Date: 20/10/2022 – 24/10/2022

Contact form: Immersion

Exposition time: 30 minutes / Temperature: 40 °C

Simulant volumen: 100 ml

Simulant (B): Acetic acid 3 % (w/v)

Reference: BLACK NITRILE GLOVES M7002

Results:

Compound	Result (mg/Kg)
1,4 - Phenylenediamine	ND
2,4-xylydine	ND
2,6 -xylydine	ND
2-amino-4-nitrotoluene	ND
2-methoxyaniline	ND
2-naphthylamine	ND
3,3'-dichlorobenzidine	ND
3,3'-dimethoxybenzidine	ND
3,3'-dimethylbenzidine	ND
4,4'-methylenedianiline	ND
4,4'-methylenedi-o-toluidine	ND
4,4'-oxydianiline	ND
4,4'-thiodianiline	ND
4-aminoazobenzene	ND
4-Aminobiphenyl	ND
4-chloroaniline	ND
4-Chloro-o-toluidine	ND
4-methoxy-m-phenylenediamine	ND
4-methyl-m-phenylenediamine	ND
Aniline	ND
Benzidine	ND
o-aminoazotoluene	ND
o-toluidine	ND
p-cresidine	ND

Remarks:

- Requirement according to the Annex II of Regulation UE 10/2011 and Regulation 2020/1245:
Sum of PAA < 0.01 mg/kg.
- ND: not detectable (LC < 0.002 mg/kg).



RESULTS

The following tables summarizes the results obtained:

Reference: BLACK NITRILE GLOVES M7002

Overall Migration Tests	Standard	Results ⁽¹⁾ (mg/dm ²)	Requirement ⁽²⁾ (mg/dm ²)	
DETERMINATION OF THE OVERALL MIGRATION IN ETHANOL 50 % (v/v) (D1)	EN 1186-9:2002	1,6 ± 0,2	10	
DETERMINATION OF THE OVERALL MIGRATION IN ACETIC ACID 3 %(v/v) (B)	EN 1186-9:2002	1,8 ± 0,2	10	
DETERMINATION OF THE OVERALL MIGRATION IN OLIVE OIL *(D2)	EN 1186-2:2002	4,3	10	
Specific Migration Tests	Standard	Results (mg/Kg)	Requirement ⁽²⁾ (mg/Kg)	
SPECIFIC MIGRATION OF METALS*	In-house Method	Ba	< 0.1	1
		Co	< 0.01	0.05
		Cu	< 0.1	5
		Fe	< 0.1	48
		Li	< 0.1	0.6
		Mn	< 0.1	0.6
		Zn	8.78	5 25 ⁽³⁾
		Al	< 0.1	1
		Ni	< 0.01	0.02
		As	ND	N.D
		Cd	ND	0.002
		Cr	ND	N.D
		Eu	< 0.01	0.05
		Gd	< 0.01	0.05
		La	< 0.01	0.05
		Tb	< 0.01	0.05
Pb	ND	N.D		
Hg	ND	N.D		
Sb	<0.01	0.04		
SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINES*	In-house method	< 0.002 mg/kg	Sum PAA's < 0.01 mg/Kg	



RESULTS

Remarks:

- M1: First migration period.
- M2: Second migration period.
- M3: Third migration period

- ⁽¹⁾ Average value ($n = 3$) $\pm U$ (extended uncertainty) for a probability of coverage of 95%.

- ⁽²⁾ Maximum overall and specific migration limit according to Regulation (EU) no 10/2011 of the Commission of 14 January 2011.

- ⁽³⁾ This limit is applicable for natural and synthetic rubber gloves according to "Recommendation BfR. XXI/1. Commodities based on natural and synthetic rubber in contact with Food".

- N.D = Not detectable



RESULTS

- In accordance with Regulation 10/2011 and Regulation (EU) No 2017/752 (8^o amendment of Regulation (EU) n^o 10/2011) Annex III point 4, the assignment of these simulants for demonstrates the conformity with the global migration limit is according to the following food categories:

FOODS COVERED	FOOD SIMULANTS IN WHICH TESTING SHALL BE PERFORMED
All types of food	1) Distilled water or water of equivalent quality or food simulant A (ethanol 10%), 2) Food simulant B (3% acetic acid) 3) Food simulant D2 (vegetal oil)
All types of food except for acidic foods	1) Distilled water or water of equivalent quality or food simulant A (ethanol 10%), 2) Food simulant D2 (vegetal oil)
All aqueous and alcoholic foods and milk products with pH \geq 4.5	Food simulant D1 (ethanol 50%)
All aqueous, acidic and alcoholic foods and milk products with pH $<$ 4.5	1) Food simulant D1 (ethanol 50%) 2) Food simulant B (3% acetic acid)
All aqueous foods and alcoholic foods up to an alcohol content of 20 %	Food simulant C (ethanol 20%)
All aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 %	1) Food simulant C (ethanol 20%) 2) Food simulant B (3% acetic acid)



Judit Sisternes
Head of Health & Hygiene Products Division

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