

**Declaration of Conformity  
in accordance with Regulation (EC) 1935/2004**

the manufacturer:  
Ampri Handelsgesellschaft mbH  
Benzstr. 16  
21423 Winsen (Luhe)  
Germany

confirms the conformity of article

**191-012 Black 300**

black				
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disposable nitrile gloves, powderfree

with the rules of the  
Regulation (EC) 1935/2004 - article 3, 5, 11, 15 and 17-,  
german feed and food code – LFGB,  
Regulation (EC) 10/2011, with regard to the migration behaviour,  
and the german recommendation XXI of the Federal Institute for Risk Assessment (BfR).

**Specification of the intended use or limitations**

The above-mentioned article can be used safely in the preparation and treatment of food. In this process, they may be in direct contact with the following types of food for a short time:

all types				
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**Restriction**

The article is not suitable for the following types of food:

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The valuation basis for the glove-application is a surface-to-volume ratio of 8,4 dm<sup>2</sup> per 5kg food in accordance with the German BfR.

**sensory evaluation**

simulant solution	conditioning	testing	result
coconut oil	10 minutes 40°C	odour change	no changes
coconut oil	10 minutes 40°C	flavour change	no changes
water	10 minutes 40°C	odour change	no changes
water	10 minutes 40°C	flavour change	no changes

**results of the overall migration**

simulant solution	conditioning	overall migration mg/dm <sup>2</sup>	limit mg/dm <sup>2</sup>
acetic acid 3%	10 minutes 40°C	<2,5 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 95%	10 minutes 40°C	5,9 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
Isooctane	5 minutes 20°C	<2,5 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 10%**	2 heures 40°C	< 1 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
olive oil	2 heures 40°C	< 1 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>

**results of the specific migration**

compound	simulant solution	Conditioning or other analytical methods	result	limit
Phthalates	ethanol 95%	10 minutes 40°C	not detected	
Primary aromatic amines (PAA)	acetic acid 3%	2 heures 40°C	< 0,01 mg/kg	≤ 3 mg/kg
Formaldehyde	acetic acid 3%	2 heures 40°C	1,2 mg/kg	3 mg/kg
Nitrosamines	acetic acid 3%	2 heures 40°C	< 1 µg/dm <sup>2</sup>	1 µg/dm <sup>2</sup>
#BEZUG!	#BEZUG!	#BEZUG!	#BEZUG!	#BEZUG!

**Result total content**

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)		Ultrasonic extraction	not detected	≤ 0,2 mg/kg
Phthalates		GC-MS and/or LC-MS	not detected	
Lead		microwave digestion and analysis by ICP/MS	< 1 mg/kg	≤ 100 mg/kg
Cadmium		microwave digestion and analysis by ICP/MS	< 1 mg/kg	≤ 100 mg/kg
Primary aromatic amines (PAA)		UV-analysis	passed	< 0,002 mg/kg
Volatile organic matters		Room temperature for 48 hrs and then 105oC for 4hrs	0,15% (w/w)	0,5% (w/w)
peroxides value		titration with sodiumthiosulphate	not detected	
Bisphenol A		Solvent extraction and analysis by gas	not detected	

**Examination of pigments ((for coloured items))**

simulant solution	evaluation
acetic acid 3%	passed, no colour transition
ethanol 10%	passed, no colour transition
olive oil	passed, no colour transition

**regulation (EU) 2020/1245**

**heavy metals**

simulant solution:	acetic acid 3%
conditioning:	1 hour 40°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium	< 0,1	≤ 1
Barium	< 0,1	≤ 1
Cobalt	< 0,005	≤ 0,05
Copper	< 0,5	≤ 5
Iron	< 5	≤ 48
Lithium	< 0,1	≤ 0,6
Manganese	< 0,1	≤ 0,6
Nickel	< 0,002	≤ 0,02
Zinc	< 3	≤ 5



Testreport-no. and  
institute:

**(25419)248-441301, Bureau Veritas**  
**\*TST-230421-011-FE, LNE-LP Asia**  
**\*\*6339/24, Isega**

When used as specified, the overall migration as well as the specific migration do not exceed the legal limits.

The examination was conducted in accordance with  
 Regulation (EC) No. 10/2011 (Annex V), including all current amendments and corrections.

The requirements for materials and raw materials of the Plastic Regulation (EC) No. 10/2011 is not applicable  
 for elastomer-protective gloves.

**regulation (EC) 2023/2006**

The above article is manufactured in accordance with Good Manufacturing Practices (GMP), i.e. they are produced and controlled with the assurance of compliance with applicable regulations and quality standards.

**Ingredients with limited use in food**

**„dual use substances“**

not applicable

Name of the substance	Ref.-No. (CAS- EINECS-PM and/or E-No)	Limit value [mg/kg]

The traceability according to the regulation (EC) No. 1935/2004 is ensured by the batch number.

Winsen, 03.04.2023

This declaration of conformity has a validity until 03.04.2026

Rev. 00