

**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

**01177 STYLE CLEAN OCEAN**

teal green				
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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 and the german recommendation XXI and XXI/1. 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	very slight 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	< 2,5 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%**	10 minutes 40°C	< 3,0 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	
Nitrosamines	acetic acid 3%	HPLC and MS detection	0,4 µg/dm <sup>2</sup>	

**Result total content**

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)	extraction with toluene	Ultrasonic extraction	not detected	1 µg/dm <sup>2</sup>
Phthalates		extraction with THF/ACN followed by GCMS / LC-MS	not detected	
Cadmium		microwave digestion with sulphuric	< 1 mg/kg	< 100 mg/kg
Lead		microwave digestion with sulphuric	< 1 mg/kg	< 100 mg/kg
Formaldehyde	water		passed	

**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:	10 minutes 40°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium	< 0,1	≤ 1
Antimony	-	≤ 0,04
Arsenic	-	≤ 0,01
Barium	< 0,1	≤ 1
Cadmium	-	≤ 0,002
Chromium	-	≤ 0,01
Cobalt	< 0,005	≤ 0,05
Copper	< 0,5	≤ 5
Europium	-	≤ 0,05
Gadolinium	-	≤ 0,05
Iron	< 5	≤ 48
Lanthanum	-	≤ 0,05
Lead	-	≤ 0,01
Lithium	< 0,1	≤ 0,6
Manganese	< 0,1	≤ 0,6
Mercury	-	≤ 0,01
Nickel	< 0,002	≤ 0,02
Terbium	-	≤ 0,05
Zinc	< 3	≤ 5



**Testreport-no. and  
institute:**

**(25419)289-440167, Bureau Veritas  
\*6339/19, 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, 07.11.2023

This declaration of conformity has a validity until 07.11.2026

Rev. 00