

**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

**01033 BASIC-TOUCH**

white				
-------	--	--	--	--

disposable latex 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				
-----------	--	--	--	--

**Restriction**

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

not applicable				
----------------	--	--	--	--

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	5,4 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 95%	10 minutes 40°C	5 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
Isooctane	5 minutes 20°C	8,6 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 10%*	10 minutes 40°C	< 3 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
Primary aromatic amines		LC-QQQ-Analysis	< 0,002 mg/kg	0,02 mg/kg
Formaldehyde	acetic acid 3%	10 minutes 40°C	< 0,02 mg/kg	3 mg/kg

**Result total content**

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)	extraction with toluene	Ultrasonic extraction	passed	
Volatile organic matters		4 hours 105°C	< 0,1% w/w	0,5% w/w
Lead		microwave digestion with sulphuric	< 1 mg/kg	100 mg/kg,
Cadmium		microwave digestion with sulphuric	< 1 mg/kg	100 mg/kg,
Nitrosamines*		LC-QQQ-Analysis	not detected	

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

simulant solution	evaluation
acetic acid 3%	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
Antimony		0,04
Arsenic		0,01
Barium		1
Cadmium		0,002
Chromium		ND
Cobalt		0,05
Copper		5
Europium		0,05
Gadolinium		0,05
Iron		48
Lanthanum		0,05
Lead	<0,01	0,01
Lithium		0,6
Manganese		0,6
Mercury		0,01
Nickel		0,02
Terbium		0,05
Zinc	< 0,5	5



**Testreport-no and  
Institute:**

**(25422)039-506220, Bureau Veritas  
\*7972/1, 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, 15.11.2022

This declaration of conformity has a validity until 15.11.2025

Rev. 00