

**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

**120-020 pura comfort white**

white				
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 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:

not applicable				
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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
bisquit	1 hour at room temperature	odour change	no changes
bisquit	1 hour at room temperature	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%	1 hour 40°C	2,9 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 50%	1 hour 40°C	< 2 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
olive oil	1 hour 40°C	< 2 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
Tenax	1 hour 40°C	< 2 mg/dm <sup>2</sup>	60 mg/kg mg/dm <sup>2</sup>

results of the specific migration

compound	simulant solution	Conditioning or other analytical methods	result	limit
Primary aromatic amines (PAA)	acetic acid 3%	1 hour 40°C	not detected	-
#BEZUG!	#BEZUG!	#BEZUG!	#BEZUG!	#BEZUG!

Result total content

compound	simulant solution	Conditioning or other analytical methods	result	limit
Nitrosamines		1 hour 40°C	< 0,05 mg/kg	-
N-nitrosatable Substances		1 hour 40°C	< 0,08 mg/kg	-
Formaldehyde		extraction with water	not detected	> 3 µg/ml extract
Acrylonitrile		GC-Analysis	not detected	< 1 mg/kg
Butadiene		GC-Analysis	not detected	< 0,1 mg/kg
Volatile organic matters ethanol*		GC-MS	0,5 mg/kg	-
Volatile organic matters propylene glycol*		GC-MS	0,2 mg/kg	-
Polycyclic aromatic hydrocarbons (PAH)		GC-MS	< 0,2 mg/kg	< 1 mg/kg

Examination of pigments ((for coloured items)

simulant solution	evaluation

regulation (EU) 2020/1245  
heavy metals

simulant solution:	acetic acid 3%
conditioning:	30 minutes 40°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium	< 0,6	1
Antimony	< 0,01	0,04
Arsenic	< 0,01	0,01
Barium	< 0,6	1
Cadmium	< 0,002	0,002
Chromium	< 0,01	0,1
Cobalt	< 0,03	0,05
Copper	< 0,1	5
Europium	< 0,05	0,05
Gadolinium	< 0,05	0,05
Iron	< 1	48
Lanthanum	< 0,05	0,05
Lead	< 0,01	0,01
Lithium	< 0,4	0,6
Manganese	< 0,4	0,6
Mercury	< 0,01	0,01
Nickel	< 0,02	0,02
Terbium	< 0,05	0,05
Zinc	2,3	5



Testreport-no & AR-21-J015949-02, eurofins  
 institute: \*4432/4-1, Isega  
 \*\*CHM0307207/2102/LC/A, Satra

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, 18.05.2023

This declaration of conformity has a validity until 18.05.2026

Rev. 00