

**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

01153 Clean-Comfort

blue				
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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				
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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 dm² per 5kg food in accordance with the German BfR.

sensory evaluation

simulant solution	conditioning	testing	result
water	30 minutes 40°C	odour change	no changes
water	30 minutes 40°C	flavour change	no changes

results of the overall migration

simulant solution	conditioning	overall migration mg/dm ²	limit mg/dm ²
ethanol 10%	10 minutes 40°C	< 3 mg/dm ²	10 mg/dm ²
ethanol 95%	10 minutes 40°C	6,2 mg/dm ²	10 mg/dm ²
Isooctane	10 minutes 40°C	9,4 mg/dm ²	10 mg/dm ²
acetic acid 3%	10 minutes 40°C	4,5 mg/dm ²	10 mg/dm ²

results of the specific migration

compound	simulant solution	Conditioning or other analytical methods	result	limit
Primary aromatic amines	acetic acid 3%	2 heures 40°C	not detected	
Nitrosamines	acetic acid 3%	2 heures 40°C	not detected	1 µg/dm ²
N-nitrosatable Substances	acetic acid 3%	2 heures 40°C	not detected	10 µg/dm ²
Formaldehyde	acetic acid 3%	2 heures 40°C	not detected	3 dm ² /kg
Hexamethylenetetramine	acetic acid 3%	2 heures 40°C	not detected	
Lead	acetic acid 3%	10 minutes 40°C	< 0,1 mg/kg	1 mg/kg
Zinc	acetic acid 3%	10 minutes 40°C	3,41 mg/kg	25 mg/kg
Aluminium	acetic acid 3%	10 minutes 40°C	< 0,01 mg/kg	0,01 mg/kg
Polycyclic aromatic hydrocarbons (PAH)		GC-Analysis	not detected	

Result total content

compound	simulant solution	Conditioning or other analytical methods	result	limit
Bisphenol A		High Performance Liquid Chromatography - Tandem	not detected	< 0,1 mg/kg
Latexproteins			not detected	nicht feststellbar
Volatile organic matters		AppendixIII der French Arrete 25 Nov. 1992	0,2%w/w	0,5%w/w

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:	10 minutes 40°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium		
Antimony	< 0,5	1
Arsenic	0,7	1
Barium		
Cadmium	< 0,5	1
Chromium		
Cobalt		
Copper		
Europium		
Gadolinium		
Iron		
Lanthanum		
Lead	< 0,5	1
Lithium		
Manganese		
Mercury	< 0,5	1
Nickel		
Terbium		
Zinc		



Testreport-no & institute:

T32220262392SC, SGS

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, 28.04.2023

This declaration of conformity has a validity until 28.04.2026

Rev. 01