

**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

**19-001-L-B Med-Comfort**

blue				
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disposable PE gloves

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 dm<sup>2</sup> 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 20°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%	30 minutes 40°C	<3,0 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 10%	30 minutes 40°C	<3,0 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
olive oil	30 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
Bisphenol A*	acetic acid 3%	30 minutes 40°C	< 0,05 mg/kg	< 0,05 mg/kg
Formaldehyde*	acetic acid 3%	30 minutes 40°C	< 0,02 mg/kg	< 15 mg/kg
Primary aromatic amines (PAA)	acetic acid 3%	30 minutes 40°C	< 0,002 mg/kg	< 0,01 mg/kg

**Result total content**

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)*	extraction with toluene	30 minutes 40°C	< 0,02 mg/kg	0,2 mg/kg

**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:	30 minutes 40°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium	<0,1	1
Antimony	<0,01	0,04
Arsenic	<0,01	0,01
Barium	<0,25	1
Cadmium	<0,002	0,002
Chromium	< 0,01	0,1
Cobalt	< 0,01	0,05
Copper	<0,25	5
Europium	<0,025	0,05
Gadolinium	<0,025	0,05
Iron	< 5	48
Lanthanum	<0,025	0,05
Lead	< 0,01	0,01
Lithium	< 0,1	0,6
Manganese	< 0,1	0,6
Mercury	< 0,01	0,01
Nickel	< 0,01	0,02
Terbium	< 0,025	0,05
Zinc	<0,5	5



**Testreport-no &  
institute:**

**TAOHG2103449701, SGS  
\*(25422)305-531062, Bureau Veritas**

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, 07.03.2023

This declaration of conformity has a validity until 07.03.2026

Rev. 00