

## 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

### 07028 MED-COMFORT

transparent				
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PE-overboots

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:

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 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%	2 heures 70°C	< 3 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 95%	2 heures 70°C	< 3 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
Isooctane	30 minutes 40°C	< 3 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 10%	2 heures 70°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 (PAA)	acetic acid 3%	10 minutes 40°C	< 0,02 mg/l	≤ 0,02 mg/l
Polycyclic aromatic hydrocarbons (PAH)	Isooctane	GC-Analysis	not detected	≤ 10 µg/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)	Isooctane	#NV	not detected	nicht feststellbar
Nonylphenol		#BEZUG!	not detected	≤ 0,1 mg/kg
Phthalates		#NV	not detected	0,05 / 0,1%
Cadmium	#NV	#NV	not detected	≤ 100 mg/kg

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

simulant solution	evaluation

## 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	---	1
Antimony	---	0,04
Arsenic	---	0,01
Barium	< 0,1	1
Cadmium	---	0,002
Chromium	---	ND
Cobalt	< 0,01	0,05
Copper	< 0,1	5
Europium	---	0,05
Gadolinium	---	0,05
Iron	< 1,0	48
Lanthanum	---	0,05
Lead	---	0,01
Lithium	< 0,1	0,6
Manganese	< 0,1	0,6
Mercury	---	0,01
Nickel	---	0,02
Terbium	---	0,05
Zinc	< 1,0	5



Testreport-no. and  
institute:

0154112248b 001, TÜV Rheinland  
TAOHG1902684501, 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, 14.04.2025

This declaration of conformity has a validity until 14.04.2028

Rev. 00