

**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

**01080-L-90 MED-COMFORT**

orange				
--------	--	--	--	--

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 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				
-----------	--	--	--	--

**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
butter cookies	30 minutes 40°C	odour change	no changes
butter cookies	30 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%	2 heures 70°C	4 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 95%	2 heures 60°C	3 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
Isooctane	30 minutes 40°C	< 2 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
Polycyclic aromatic hydrocarbons (PAH)	Isooctane	5 minutes 20°C	not detected	-

## Result total content

compound	simulant solution	Conditioning or other analytical methods	result	limit
Phthalates		Ultrasonic extraction	not detected	-
Nonylphenol		GC-Analysis	not detected	-
Cadmium		ICP-OES	< 10 mg/kg	≤ 100 mg/kg

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

simulant solution	evaluation
water	passed, no colour transition
acetic acid 3%	passed, no colour transition
ethanol 50%	passed, no colour transition
olive oil	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
Barium	< 0,1	≤ 1
Cobalt	< 0,01	≤ 0,05
Copper	< 0,1	≤ 5
Iron	< 1	≤ 48
Lithium	< 0,1	≤ 0,6
Manganese	< 0,1	≤ 0,6
Zinc	< 1	≤ 5



Testreport-no. and  
institute:

0154183220b 001, TÜV Rheinland

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, 09.12.2024

This declaration of conformity has a validity until 13.09.2027

Rev. 00