

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		
	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		

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 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	very slight changes



results of the overall migration

simulant solution	conditioning	overall migration mg/dm ²	limit mg/dm ²
acetic acid 3%	2 houres 70°C	< 3 mg/dm ²	10 mg/dm ²
ethanol 95%	2 houres 70°C	< 3 mg/dm ²	10 mg/dm ²
Isooctane	30 minutes 40°C	< 3 mg/dm ²	10 mg/dm ²
ethanol 10%	2 houres 70°C	< 3 mg/dm ²	10 mg/dm ²

results of the specific migration

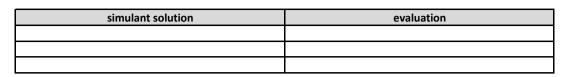
compound	simulant solution	Conditioning or other analytical methods	result	limit
Primary aromatic amines (PAA)	acetic acid 3%	10 minutes 40°C	< 0,02 mg/l	≤ 0,02 mg/l
Polycyclic aromatic hydrocarbons (PAH)	Isooctane	GC-Analysis	not detected	≤ 10 µg/kg
Formaldehyde	acetic acid 3%	10 minutes 40°C	< 0,02 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	iicht feststellba
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)



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	RefNo. (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