

**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

**01034 MED-COMFORT Polymer Plus**

white				
-------	--	--	--	--

disposable 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:

acid	aqueous	alcoholic	dry	
------	---------	-----------	-----	--

**Restriction**

The article is not suitable for the following types of food:

fatty				
-------	--	--	--	--

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
coconut oil	10 minutes 40°C	odour change	no changes
coconut oil	10 minutes 40°C	flavour change	no changes
water	10 minutes 40°C	odour change	no changes
water	10 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%	10 minutes 40°C	8,97 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 95%	10 minutes 40°C	< 2,5 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 10%	10 minutes 40°C	2,8 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 10%**			

**results of the specific migration**

compound	simulant solution	Conditioning or other analytical methods	result	limit
Phthalates	ethanol 95%	10 minutes 40°C	not detected	
Formaldehyde	acetic acid 3%	10 minutes 40°C	< 0,02 mg/kg	≤ 3 mg/kg
Polycyclic aromatic hydrocarbons (PAH)	ethanol 95%	10 minutes 40°C	not detected	9 mg/kg
Acrylonitrile*				
Acrylonitrile*				
Butadiene*				
Butadiene*				

**Result total content**

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)		Ultrasonic extraction	not detected	≤ 0,2 mg/kg
Phthalates		GC-MS and/or LC-MS	not detected	
Lead		microwave digestion and analysis by ICP/MS	< 1 mg/kg	≤ 100 mg/kg
Cadmium		microwave digestion and analysis by ICP/MS	< 1 mg/kg	≤ 100 mg/kg
Primary aromatic amines (PAA)		photometric analysis	passed	
Nitrosamines	acetic acid 3%	10 minutes 40°C	0,31 µg/dm <sup>2</sup>	1 µg/dm <sup>2</sup>

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

simulant solution	evaluation

**regulation (EU) 2020/1245**

**heavy metals**

simulant solution:	acetic acid 3%
conditioning:	1 hour 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	< 0,1	≤ 1
Cadmium	< 0,001	≤ 0,002
Chromium	< 0,01	≤ 0,01
Cobalt	< 0,005	≤ 0,05
Copper	< 0,5	≤ 5
Europium	< 0,01	≤ 0,05
Gadolinium	< 0,01	≤ 0,05
Iron	< 5	≤ 48
Lanthanum	< 0,01	≤ 0,05
Lead	< 0,01	≤ 0,01
Lithium	< 0,1	≤ 0,6
Manganese	< 0,1	≤ 0,6
Mercury	< 0,01	≤ 0,01
Nickel	< 0,002	≤ 0,02
Terbium	< 0,01	≤ 0,05
Zinc	0,569	≤ 5



**Testreport-no. and  
institute:**

**(25421)190-490760, Bureau Veritas  
\*(25419)199-436777, Bureau Veritas  
\*\*FUFDCP2017-00420, Intertek**

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, 11.03.2023

This declaration of conformity has a validity until 11.03.2026

Rev. 00