

**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

**01251 Med-Comfort**

blue				
------	--	--	--	--

disposable gloves, vinyl-nitrile-mix

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
bisquit	1 hour at room temperature	odour change	no changes
bisquit	1 hour at room temperature	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	<3 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 10%	2 heures 70°C	3,8 mg/dm <sup>2</sup>	10 mg/dm <sup>2</sup>
ethanol 20%	2 heures 70°C	4,2 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
Bisphenol A	acetic acid 3%	2 heures 70°C	not detected	0,05 mg/kg
Primary aromatic amines (PAA)	acetic acid 3%	2 heures 70°C	not detected	0,01 mg/kg

**Result total content**

compound	simulant solution	Conditioning or other analytical methods	result	limit
Bisphenol A		LC-MSMS	not detected	-
Phthalates		GC-MS	not detected	-
Vinyl chloride monomer		HS-GC-MS	not detected	1 mg/kg

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

simulant solution	evaluation
water	passed, no colour transition
ethanol 10%	passed, no colour transition

**regulation (EU) 2020/1245**

**heavy metals**

simulant solution:	acetic acid 3%
conditioning:	2 heures 70°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium	< 0,1	1
Barium	< 0,25	1
Cobalt	< 0,01	0,05
Copper	< 0,25	5
Iron	< 0,25	48
Lithium	< 0,5	0,6
Manganese	< 0,25	0,6
Nickel	< 0,01	0,02
Zinc	< 0,5	5



**Testreport-no &  
institute:**

**TSNEC200080-6609, 6602, 6601, 6605, 6607, 6606, 6610, 6611, SGS  
\*TSNEC2002408001, TSNEC2002408012, 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, 01.04.2023

This declaration of conformity has a validity until 01.04.2026

Rev. 00