

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

01169 Epiderm Protect BLUE PLUS

blue				
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disposable nitrile 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 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 dm² 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 ²	limit mg/dm ²
acetic acid 3%	1 hour 40°C	3,2 mg/dm ²	< 2 mg/dm ²
ethanol 50%	1 hour 40°C	< 2 mg/dm ²	10 mg/dm ²
olive oil	1 hour 40°C	9 mg/dm ²	10 mg/dm ²
Tenax	1 hour 40°C	< 2 mg/dm ²	60 mg/kg

results of the specific migration

compound	simulant solution	Conditioning or other analytical methods	result	limit
#NV	acetic acid 3%	1 hour 40°C	< 2 µg/kg	< 0,002 mg/kg
#NV	acetic acid 3%		< 10 µg/kg	< 0,01 µg/kg
Acrylonitrile	vegetable oil	GCMS	not detectable	-
Butadiene	vegetable oil	GCMS	not detectable	-
Formaldehyde	acetic acid 3%	CEN/TS 13130-23:2005-05	not detectable	-

Result total content

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)		Solvent extraction and analysis by gas	< 0,2 mg/kg	≤ 1 mg/kg

Examination of pigments ((for coloured items))

simulant solution	evaluation
acetic acid 3%	passed, no colour transition
ethanol 10%	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
Aluminium	< 0,01	1
Antimony	< 0,03	0,04
Arsenic	< 0,02	ND
Barium	< 0,05	1
Cadmium	< 0,002	ND (LOD 0,002)
Chromium	< 0,01	ND
Cobalt	< 0,03	0,05
Copper	< 0,02	5
Europium	< 0,05	0,05
Gadolinium	< 0,05	0,05
Iron	< 1	48
Lanthanum	< 0,05	0,05
Lead	< 0,01	ND
Lithium	< 0,4	0,6
Manganese	< 0,4	0,6
Mercury	< 0,01	ND
Nickel	< 0,03	0,02
Terbium	< 0,05	0,05
Zinc	< 2,8	5



Testreport-no. and institute:

**AR-21-JR-015947-03, Eurofins
14432/13, ISEGA**

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, 01.09.2023

This declaration of conformity has a validity until 01.09.2026

Rev. 00