

Declaration of Conformity

the manufacturer:
 Ampri Handelsgesellschaft mbH
 Benzstr. 16
 21423 Winsen (Luhe)
 Germany

confirms the conformity of article

01166 EpidermProtect by MED-COMFORT

blue			
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disposable nitrile gloves, powderfree

with the rules of the
 Regulation (EC) 1935/2004,
 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:

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	10 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 mg/dm ²

results of the specific migration

compound	simulant solution	Conditioning or other analytical methods	result	limit
Primary aromatic amines (PAA) CMR	acetic acid 3%	1 hour 40°C	< 2 µg/kg	< 0,002 mg/kg
Primary aromatic amines (PAA) not CMR Cat 1. 1A/B- PAAs	acetic acid 3%	1 hour 40°C	< 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 with gas chromatograph-mass	< 0,2 mg/kg	≤ 1 mg/kg

Examination of pigments:

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:	1 hour 40°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium	< 0,6	1
Antimony	< 0,01	0,04
Arsenic	< 0,01	ND
Barium	< 0,6	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



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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“

Dual-use substances are substances that are approved both as additives for plastics and as food additives. No such substances are contained.

The traceability according to the regulation (EC) No. 1935/2004 is ensured by the batch number.

Winsen, 31.08.2022

This declaration of conformity has a validity until 31.08.2025

Rev. 04