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

215-011 pura comfort cobalt

blue				

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, 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				

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
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/dm²	limit mg/dm²
acetic acid 3%	1 hour 40°C	< 2 mg/dm²	10 mg/dm²
ethanol 50%	1 hour 40°C	< 2 mg/dm²	10 mg/dm²
Tenax	1 hour 40°C	< 2 mg/dm²	60 mg/kg mg/dm²
olive oil	1 hour 40°C	< 2 mg/dm²	10 mg/dm²

results of the specific migration

compound	simulant solution	Conditioning or other analytical methods	result	limit
Primary aromatic amines (PAA)	acetic acid 3%	1 hour 40°C	< 0,01 mg/kg	0,01 mg/kg
Acrylonitrile	acetic acid 3% and vegetable oil	EN 13130-3:2004-08	< 0,001 mg/dm2	
Butadiene	acetic acid 3% and vegetable oil	EN 13130-3:2004-08	< 0,001 mg/dm2	
Formaldehyde	acetic acid 3%	CEN/TS 13130-23:2005-05	< 0,02 mg/dm2	

Result total content

compound	simulant solution	Conditioning or other analytical methods	result	limit
Nitrosamines		EN 71-12 1 hourStunde 40°C	0,07 mg/kg	
N-nitrosatable Substances		EN 71-12 1 hourStunde 40°C	0,10 mg/kg	
Polycyclic aromatic hydrocarbons (PAH)		GC-Analysis	< 0,2 mg/kg	1 mg/kg (0,0001% by mass)

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:	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	0,01
Barium	< 0,16	1
Cadmium	< 0,002	0,002
Chromium	< 0,01	ND
Cobalt	< 0,03	0,05
Copper	< 1	5
Europium	< 0,05	0,05
Gadolinium	< 0,05	0,05
Iron	< 1	48
Lanthanum	< 0,05	0,05
Lead	< 0,01	0,01
Lithium	< 0,4	0,6
Manganese	< 0,4	0,6
Mercury	< 0,01	0,01
Nickel	< 0,02	0,02
Terbium	< 0,05	0,05
Zinc	1,7	5

Testreport-no: **CHM0307207/2102/LC/A**
AR-21-JR-015948-02
14432/13

issued by: **Satra**
eurofins
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, 06.12.2022

This declaration of conformity has a validity until 06.12.2025

Rev. 00