

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

AL-001 ALPHA Extreme Grip

orange				
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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:

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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
water	30 minutes 40°C	odour change	no changes
water	30 minutes 40°C	flavour change	no changes

results of the overall migration

simulant solution	conditioning	overall migration mg/dm ²	limit mg/dm ²
ethanol 10%	30 minutes 40°C	12 mg/kg	60 mg/kg
olive oil	30 minutes 40°C	< 10 mg/kg	60 mg/kg

results of the specific migration

compound	simulant solution	Conditioning or other analytical methods	result	limit
Nitrosamines	acetic acid 3%	30 minutes 40°C	< 0,01 mg/kg	0,01 mg/kg
N-nitrosatable Substances	acetic acid 3%		< 0,10 mg/kg	0,10 mg/kg
Primary aromatic amines (PAA)	acetic acid 3%	30 minutes 40°C	< 0,01 mg/kg	< 0,01 mg/kg
Acrylonitrile	ethanol 10%	30 minutes 40°C	< 0,01 mg/kg	< 0,01 mg/kg
Acrylonitrile	acetic acid 3%	30 minutes 40°C	< 0,01 mg/kg	< 0,01 mg/kg
Butadiene	ethanol 10%	30 minutes 40°C	< 0,02 mg/kg	< 0,02 mg/kg
Butadiene	acetic acid 3%	30 minutes 40°C	< 0,02 mg/kg	< 0,02 mg/kg
Formaldehyde*	acetic acid 3%	2 heures 40°C	< 0,5 mg/kg	15 mg/kg

Result total content*

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)		GC-Analysis	not detected	

Examination of pigments ((for coloured items))*

simulant solution	evaluation
acetic acid 3%	passed, no colour transition

regulation (EU) 2020/1245

heavy metals*

simulant solution:	acetic acid 3%
conditioning:	30 minutes 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	< 0,01	1
Cadmium	< 0,001	0,002
Chromium	< 0,01	0,1
Cobalt	< 0,01	0,05
Copper	< 0,04	5
Europium	< 0,1	0,05
Gadolinium	< 0,01	0,05
Iron	< 0,04	48
Lanthanum	< 0,01	0,05
Lead	< 0,005	0,005
Lithium	< 0,01	0,6
Manganese	< 0,01	0,6
Mercury	< 0,01	0,01
Nickel	< 0,01	0,02
Terbium	< 0,01	0,05
Zinc	1,8	5



Testreport-no. and
institute:

GZHH00464737, Intertek
*EFUZ25061113-CG-01, Eurofins

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, 11.06.2025

This declaration of conformity has a validity until 11.06.2028

Rev. 2025-00