

**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

01160 CLEAN-EXPERT

green				
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Nitrile industrial glove

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				
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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
water	2 hours 40°C	odour change	no changes
water	2 hours 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%	2 heures 40°C	< 1 mg/dm ²	10 mg/dm ²
acetic acid 3%	2 heures 40°C	< 1 mg/dm ²	10 mg/dm ²
ethanol 20%	2 heures 40°C	< 1 mg/dm ²	10 mg/dm ²
ethanol 50%	2 heures 40°C	< 1 mg/dm ²	10 mg/dm ²
olive oil	2 heures 40°C	< 1 mg/dm ²	10 mg/dm ²

results of the specific migration

compound	simulant solution	Conditioning or other analytical methods	result	limit
Primary aromatic amines (PAA)	acetic acid 3%	2 heures 40°C	not detected	≤ 0,01 mg/kg
Formaldehyde	acetic acid 3%	2 heures 40°C	not detected	≤ 3 mg/kg
Hexamethylenetetramine + Formaldehyd	acetic acid 3%	2 heures 40°C	not detected	≤ 15 mg/kg
Nitrosamines	acetic acid 3%	2 heures 40°C	not detected	≤ 1 µg/dm ²
N-nitrosatable Substances	acetic acid 3%	2 heures 40°C	not detected	≤ 10 µg/dm ²
Zinc	acetic acid 3%	2 heures 40°C	0,9 mg/kg	10 mg/kg
Volatile organic matters		4 hours 105°C	0,46%, m/m	0,50%, m/m

Result total content

compound	simulant solution	Conditioning or other analytical methods	result	limit
peroxides value		European Pharmacopeia 1997, p. 173	not detected	nicht feststellbar

Examination of pigments ((for coloured items))

simulant solution	evaluation
acetic acid 3%	passed, no colour transition
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 40°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium	< 0,1	≤ 1
Antimony	< 0,1	Total <1 (Pb, Cd, Sb, Hg, As)
Arsenic	< 0,1	Total <1 (Pb, Cd, Sb, Hg, As)
Barium	< 0,1	≤ 1,2
Copper	< 0,1	≤ 4
Lead	< 0,1	Total <1 (Pb, Cd, Sb, Hg, As)
Mercury	< 0,1	Total <1 (Pb, Cd, Sb, Hg, As)
Zinc	< 0,01	≤ 5



Testreport-no. and institute: 7191268042-CHM21-02-TSL, SGS
*7191222054-CHM19-TSL, 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, 05.09.2023

This declaration of conformity has a validity until 05.09.2026

Rev. 00