

Declaration of Conformity in accordance with Regulation (EC) 1935/2004

the

AMPri Handelsgesellschaft mbH

Benzstr. 16

21423 Winsen (Luhe)

Germany

confirms the conformity of article

970-033 MPROTECT disposable nitrile gloves

with the rules of the

Regulation (EC) 1935/2004,

Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch – LFGB,

Regulation (EC) 10/2011, with regard to the migration behaviour,

and the Deutsche Empfehlung XXI des Lebensmittel- und Futtermittelgesetzbuches.

Specification of the intended use or limitations

The nitrile gloves can be used uncritical during the preparation and treatment of food. They can come into direct contact with all kind of foods for a short time

Tested with following simulant solutions: Acetic Acid 3%, Ethanol 10%, Ethanol 95%, Isooctane, olive oil

under the following test conditions: 2 hours 40°C



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Results of the overall migration:

Simulant solution	Conditioning	Overall migration
		mg/dm ²
Acetic Acid 3%	2 hours 40° C	14,00
Ethanol 10%	2 hours 40° C	< 3 – below the limit of detection
Ethanol 95%	2 hours 40° C	15,00
Isooctane	2 hours 40° C	4,3
Olive oil	2 hours 40° C	< 3 – below the limit of detection

Results of the specific migration / contitioning 2 hours 40° C:

Compound	Simulant solution	Result
		mg/dm ²
2-methyl-4-isothiazolin	Acetic acid 3%	below the limit of detection
1,2 Benzisothiazolin	Acetic acid 3%	below the limit of detection
Methyl-acrylic-acid	Ethanol 95%	below the limit of detection
Zinc	Acetic acid 3%	2,2
acrylonitrile	Headspace analysis	Below the limit of detection

Examination of pigments:

Simulat solution	Evaluation
Water	Passed, no migration
Acetic Acid 3%	Passed, no migration
Ethanol 10%	Passed, no migration
Olive oil	Passed, no migration

Restriction: nonexistent

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.



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Certificate of compliance no. 4432/2-2 Issued by ISEGA, Aschaffenburg

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)

The requirements for materials and raw materials of the Plastic Regulation (EC) No. 10/2011 is not applicable for protective gloves.

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

Winsen, 14.01.2020

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Johanna Hühn

Scientific laboratory manager

This declaration of conformity has a validity until 14.01.2021