

**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

**01251 Med Comfort VitriLe disposable glove Copolymer Vinyl/Nitril**

with the rules of the

Regulation (EC) 1935/2004,

german feed and food code – LFGB,

Regulation (EC) 10/2011, (EC) 2017/752 with regard to the migration behaviour,

and the german recommendation XXI of the german feed and food code.

**Specification of the intended use or limitations**

The vitril gloves can be used uncritical during the preparation and treatment of food. They can come into direct contact with dry, aqueous, acid and alcoholic foods for a short time

Tested with following simulant solutions: Acetic Acid 3%, Ethanol 10%, Ethanol 20%

under the following test conditions: 2 hours 70°C

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**Results of the overall migration:**

Simulant solution	Conditioning	Overall migration mg/dm <sup>2</sup>	Migration limit mg/dm <sup>2</sup>
Acetic Acid 3%	2 h 70°C	< 3 – below the limit of detection	10
Ethanol 10%	2 h 70°C	4,2	10
Ethanol 20%	2 h 70°C	3,8	10

**Results of the specific migration / conditioning 2 hours 70° C:**

Compound	Simulant solution	Result	Limit mg/dm <sup>2</sup>
Bisphenol A	Acetic Acid 3%	0,01 mg/kg	0,05 mg/kg
Benzylbutylphthalat BBP	Acetic Acid 3%	0,003%	0,1%
Di-(2-ethylhexyl)-Phthalat DEHP	Acetic Acid 3%	0,003%	0,1%
Dibutylphthalate DBP	Acetic Acid 3%	0,003%	< 0,05%
Diisonyl Phthalate DINP	Acetic Acid 3%	0,01%	0,1%

**Results of migration specific / conditioning 2 h 70°C:**

Compound	Simulant solution	result mg/kg	Limit mg/kg
Barium	Acetic Acid 3%	< 0,25	1
Cobalt	Acetic Acid 3%	< 0,01	0,05
Copper	Acetic Acid 3%	< 0,25	5
Iron	Acetic Acid 3%	< 0,25	48
Litium	Acetic Acid 3%	< 0,5	0,6
Manganese	Acetic Acid 3%	< 0,25	0,6
Zinc	Acetic Acid 3%	< 0,5	5

**Testing of dyes:**

Simulant solution	Evaluation
Water	passed, no transition
Acetic acid 3%	passed, no transition
Ethanol 10%	passed, no transition

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**Restriction: not suitable for fats**

The valuation basis for the glove-application is a surface-to-volume ratio of 8,4 dm<sup>2</sup> per 5kg food in accordance with the German BfR.



**test report TSNEC200080-6609 ,6602, 6601, 6607, 6606, 6611,**

**Issued by SGS China**

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, (EC) 2017/752 is not applicable for protective gloves.

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

Winsen, 01.10.2020

A handwritten signature in black ink, appearing to read 'Johanna Hühn'.

Johanna Hühn

Scientific laboratory manager

This declaration of conformity has a validity until 01.10.2021