

## Food Contact Statements - Summary of Results

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For materials intended to come into contact with food

<b>MANUFACTURER</b>	HPC Healthline UK Ltd, Colwood House, 158 Garth Road, Morden, Surrey, SM4 4LZ
<b>PRODUCT</b>	GR01 – Household Rubber Glove
<b>BRAND NAME</b>	Shield

HPC Healthline UK Ltd hereby declares that the above mentioned products are in compliance with the rules of:

- Regulation (EC) 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.  
Foodstuffs and Animal Feed Code: Lebensmittel Bedarfsgegenstände- und Futtermittelgesetzbuch - LFGB §§ 30 and 31.

and meet the demands of:

- Commission Resolution AP (2004) 4, on rubber products intended to come into contact with foodstuffs.
- European Regulation 93/11/EC for the release of N-nitrosamines and N-nitrosatable substances.

and were examined in accordance with:

- Commission Resolution AP(2004) 4, on rubber products intended to come into contact with foodstuffs and EN1186 parts 1, 2, 3 for test method (materials and articles in contact with foodstuffs – plastics).
- Recommendation of the Bundesinstitut für Risikobewertung - BfR no. IX for colour release
- EN455-3 for soluble protein level

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## Test Results:

### Overall Migration Test:

EN1186-1:2002 for selection of conditions and methods; EN1186-9:2002 aqueous food simulants by article filling method:

Simulant Used	Unit	Test Condition	Limit mg/dm <sup>2</sup>	Result mg/dm <sup>2</sup>
Deionized Water	mg/dm <sup>2</sup>	40°C : 10 minutes	10	n.d.
3% Acetic Acid (W/V) Aqueous Solution	mg/dm <sup>2</sup>	40°C : 10 minutes	10	5.0
10% Ethanol (V/V) Aqueous Solution	mg/dm <sup>2</sup>	40°C : 10 minutes	10	3.2
20% Ethanol (V/V) Aqueous Solution	mg/dm <sup>2</sup>	40°C : 10 minutes	10	n.d.
Iso-octane	mg/dm <sup>2</sup>	20°C : 30 minutes	10	n.d.

n.d. not detected

### Colour Migration:

Recommendation of the BfR part IX.

Simulant Used	Test Parameter	Result
Deionized Water	No migration of colour	No colour release
2% Acetic Acid (W/V) Aqueous Solution	No migration of colour	No colour release
10% Ethanol (V/V) Aqueous Solution	No migration of colour	No colour release
Olive Oil	No migration of colour	No colour release

### Soluble Protein:

EN455-3 medical gloves for single use: requirements for biological evaluation

Test	Limit µg/g glove	Result µg/g glove
Soluble protein	< 50	< 30

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**Specific Migration of Nitrosamine:**

N-Nitrosamines: Sample preparation in 3% acetic acid (w/v) in aqueous solution at 40°C for 24 hours (category 2) with reference to EN 13130-1:2004: followed by analysis using Gas Chromatography – Nitrogen Phosphorous Detector (GC-NPD) and Gas Chromatography – Mass Spectrometry (GC-MS).

Specific Migration - N-Nitrosamine	Limit mg/dm <sup>2</sup>	Result mg/dm <sup>2</sup>
N-Nitrosodimethylamine (NDMA)	0.001	Not detected
N-Nitrosodiethylamine (NDEA)	0.001	Not detected
N-Nitrosodipropylamine (NDPA)	0.001	Not detected
N-Nitrosodibutylamine (NDBA)	0.001	Not detected
N-Nitrosomorpholine (NMOR)	0.001	Not detected
N-Nitrosopiperidine (NPIP)	0.001	Not detected
N-Nitrosopyrrolidine(NPYR)	0.001	Not detected
N-Nitrosomethylphenylamine (NMPPhA)	0.001	Not detected
N-Nitrosoethylphenylamine (NEPhA)	0.001	Not detected
N-Nitrosodiisononylamine (NDiNA)	0.001	Not detected
N-Nitrosodibenzylamine (NDBzA)	0.001	Not detected

**Specific Migration of Primary Aromatic Amine:**

Aromatic Amine: Sample preparation in 3% acetic acid (w/v) in aqueous solution at 40°C for 24 hours with reference to DIN 55610:1986.

Specific Migration	Limit µg /L	Result µg /L
Aromatic Amine	50	Not detected

**Specific Migration of Formaldehyde:**

Formaldehyde: Sample preparation in 3% acetic acid (w/v) in aqueous solution at 40°C for 24 hours with reference to EN13130-1:2004; followed by analysis using UV-visible spectrophotometer.

Specific Migration	Limit mg/kg	Result mg/kg
Formaldehyde	3	Not detected

The Shield GR01 household rubber gloves may be used safely in the food industry during the preparation and handling of food and may stand in direct contact with all types of foodstuffs as per the maximum conditions of test within this report and if used as intended.

This declaration is supported by Test Reports 3063419-01; 3063420-01; HKHL1407053545JL; 13267-1-SAT/14/0361; 16920-SAT/14/0446 issued by SGS Institut Fresenius and SGS Hong Kong Ltd.



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