

Food Contact Statement - Summary of Results

For materials intended to come into contact with food

Manufacturer: HPC Healthline UK Ltd, Colwood House, 158 Garth Road,
Morden, Surrey, SM4 4LZ, UK

Product: GD21 Powder Free Blue Nitrile Disposable Gloves

Brand Name: Shield

HPC Healthline UK Ltd hereby declares that the above mentioned product is 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.
- LFGB – Food stuffs, Consumer Goods and Animal Feed Code on 22 August 2011 (BGBl. I p 1770) last amendment by article of the decree of 03 August 2012 (BGBl. I p 1708); §§ 30 and 31.

and were manufactured in accordance with:

- The requirements of Commission Regulation (EC) No. 2023/2006 relating to manufacturing practice for materials and articles intended to come into contact with food.

and meet the demands of:

- Commission Regulation (EU) No 10/2011 of the Commission of 14 January 2011 on materials and articles made of plastic which are intended to come into contact with food.
- Decree on Consumer Goods of 23 December 1997 (BGBl. 1998 S. 5) last modified by the decree of 13 December 2011 (BGBl. I p 2720).

and were approved in regard to the migration behaviour according to:

- The German recommendation XXI for the health-related evaluation of materials and objects for the contact with foodstuffs in the frame of the Foodstuffs and Animal Feed Code, 13th memorandum, Bundesgesundheitsblatt 5, 403 (1962), including the 213th memorandum Bundesgesundheitsblatt 54, 666-668 (2011), state of 01st March 2011.

The gloves therefore, may be used safely during the preparation and handling of foodstuffs and may stay in direct contact with all types of food for a short period of time.

This declaration is supported by Technical Report 35743 U 13 and Test Report 6251/3-1 issued by – ISEGA, Germany (DAkkS accredited laboratory)

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Summary of Test Results:

Overall Migration:

The determination was carried out according to the methods for the 'examination of consumer goods' of the § 64 LFGB and according to the rules of the series of standards EN1186, EN13130 and CEN/TS 14234 – materials and articles in contact with foodstuffs.

Simulant Used	Limit	Test Condition	Average Result
10% Ethanol (V/V) aqueous solution	10 mg/dm ²	40°C / 2 hours	< 3.0
3% Acetic Acid (W/V) aqueous solution	10 mg/dm ²	40°C / 2 hours	3.7
95% Ethanol (V/V) aqueous solution	10 mg/dm ²	40°C / 2 hours	6.0

Note: The test data is obtained by considering the articles intended for repeated use as per EN1186-1:2002 clause 9.8 – report the 3rd extractive result; this was conducted on three separate samples and the average 3rd extractive result recorded in the table above.

Specific Migration:

The determination was performed in the same food simulants and after a storage period:

N-Nitrosamines: The analysis was made in accordance with the method for the 'determination of the migration of N-nitrosamines from consumer goods into foodstuffs, 53rd memorandum, Bundesgesundheitsblatt 37, 232 (1994) in 10% ethanol.

N-Nitrosamine	Comment	Result µg/dm ²
N-Nitrosodimethylamine		0.026
N-Nitrosomethylethylamine	Not detected	< 0.002
N-Nitrosodiethylamine		0.014
N-Nitrosodipropylamine	Not detected	< 0.002
N-Nitrosodibutylamine	Not detected	< 0.002
N-Nitrosomorpholine	Not detected	< 0.002
N-Nitrosopiperidine	Not detected	< 0.002
N-Nitrosopyrrolidine	Not detected	< 0.002
N-Nitrosodiisobutylamine	Not detected	< 0.002
N-Nitrosomethylphenylamine	Not detected	< 0.01
N-Nitrosoethylphenylamine	Not detected	< 0.01
N-Nitrosodiisononylamine	Not detected	< 0.01
N-Nitrosodibenzylamine	Not detected	< 0.01

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Secondary Aliphatic Amines: The analysis was performed by means of HPLC in the test simulant 10% (v/v) ethanol.

Secondary Aliphatic Amines	Comment	Result mg/dm ²
Diethylamine	Not determinable	< 0.003
Dibutylamine	Not detected	< 0.003

Determination of the Transfer of Antimicrobial Constituents:

The determination of transfer of antimicrobial constituents was performed according to DIN EN 1104. The inhibition zone is expressed as breadth of the visible inhibition zone.

Bacterial Culture	Result
Aspergillus niger	No inhibition zone
Bacillus subtilis	No inhibition zone

No transfer of antimicrobial constituents was detected.

Determination of the Heavy Metals Contents:

The determination was performed after microwave disintegration by AAS/hydride technique and ICP-AES respectively.

Heavy Metals	Comment	Result %
Lead (Pb)	Not determinable	< 0.0005
Zinc (Zn)		1.3

Determination of the Colour Fastness:

The determination was performed according to the method for the testing of coloured consumer goods made of plastics and other polymers for the fastness of their colours, 24th memorandum for the examination of plastics: Bundesgesundheitsblatt 15, 285 (1972).

Test simulants: 3% acetic acid, 10% ethanol, olive oil

Result: The colour fastness is given in contact with all test simulants

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Determination of Butadiene:

The determination was performed by means of headspace gas chromatography according to EN 13130-4.

Chemical	Comment	Result mg/kg
Butadiene	Not determinable	< 0.1

Conclusion of Food Safety Test:

The Shield GD21 powder free blue nitrile examination gloves may be used safely during preparation and handling of foodstuffs and may stand in direct contact with all types of food for a short period of time.



Karen Gunning
QA and Regulatory Affairs Manager

02 November 2015