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Aschaffenburg, 17 March 2016

From: Dr. Hillmann
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REPORT

Order No.: 4432/2-2 **Page 1 of 8 pages**

Client: Kossan International Sdn. Bhd.
Wisma Kossan, Lot 782, Jalan Sungai Putus,
Off Batu 3 3/4 Jalan Kapar
42100 Klang, Selangor / Malaysia

Date of order: 24 July 2015

Receipt of sample material: 31 July 2015

Origin of sample material: From the client

Purpose: Analysis of two nitrile gloves for their compliance with the demands on food contact materials

(Dr. Derra)

(Dr. Hillmann)
Food chemist

The present report refers exclusively to the samples as laid out therein. Information and statistical data on the results can be obtained on request.

Sample Material

For analysis the following sample material was in hand:

Sample 1: Powder Free Nitrile Examination Gloves, Blue Colored, Non-Sterile, Lot: 04065902,

Sample 2: Powder Free Nitrile Examination Gloves, White Colored, Non-Sterile, Lot: 170615-01-2-03

Carrying out of the Tests

Examination period: 1 February 2016 to 8 March 2016

1. Determination of the Overall Migration *

The determination was carried out according to the methods for the "Examination of consumer goods" corresponding to the directives B 80.30, 1 to 3 (EG) of the Official Collection of Analytical Methods according to § 64 LFGB and according to the rules of the series of standards EN 1186, EN 13130 and CEN/TS 14234 „Materials and articles in contact with foodstuffs - Plastics".

If not stated differently, the values result from a single-fold determiantion.

A) Conditions: 2 hours at 40 °C

Test simulants:
acetic acid 3 % (w/w)
ethanol 10 % (v/v)
ethanol 95 % (v/v) (Screening)
isooctane (Screening)
olive oil (food simulant D2)

Testing procedure: one-sided contact (exterior side)

Results:

Sample 1:	acetic acid 3% (w/w):			14	mg/dm²
	ethanol 10 % (v/v):	not determinable	<	3	mg/dm²
	ethanol 95 % (v/v):			15	mg/dm²
	isooctane:			4.3	mg/dm²
	olive oil:	not determinable	<	3	mg/dm²
Sample 2:	acetic acid 3% (w/w):			10	mg/dm²
	ethanol 10 % (v/v):	not determinable	<	3	mg/dm²
	ethanol 95 % (v/v):			18	mg/dm²
	isooctane:	not determinable	<	3	mg/dm²
	olive oil:	not determinable	<	3	mg/dm²

2. Determination of the Specific Migration

The determination was performed in the same food simulants and after a storage period as indicated in point 1.

B) Conditions: 10 minutes at 40 °C

Test simulants: acetic acid 3 % (w/w)
ethanol 95 % (v/v)
isooctane (Screening)

Testing procedure: one-sided contact (exterior side)

Isothiazolinones *: The determination was performed in the migration solution according to SOP 162.200 by HPLC and UV-detection.

Result:

acetic acid 3% (w/w) – A) conditions:

Sample 1:

2-methyl-4-isothiazoline-3-one *	not determinable	<	0.001	mg/dm²
5-chloro-2-methyl-4-isothiazoline-3-one *	not determinable	<	0.002	mg/dm²
1,2-Benzisothiazolin-3-one *			0.007	mg/dm²
Dichlor-2-n-octyl-4-isothiazolinon-3-on	not determinable	<	0.002	mg/dm²

Sample 2:

2-methyl-4-isothiazoline-3-one *	not determinable	<	0.001	mg/dm²
5-chloro-2-methyl-4-isothiazoline-3-one *	not determinable	<	0.002	mg/dm²
1,2-Benzisothiazolin-3-one *			0.007	mg/dm²
Dichlor-2-n-octyl-4-isothiazolinon-3-on	not determinable	<	0.002	mg/dm²

acetic acid 3% (w/w) – B) conditions:

Sample 1:

2-methyl-4-isothiazoline-3-one *	not determinable	<	0.001	mg/dm²
5-chloro-2-methyl-4-isothiazoline-3-one *	not determinable	<	0.002	mg/dm²
1,2-Benzisothiazolin-3-one *			0.02	mg/dm²
Dichlor-2-n-octyl-4-isothiazolinon-3-on	not determinable	<	0.002	mg/dm²

Sample 2:

2-methyl-4-isothiazoline-3-one *	not determinable	<	0.001	mg/dm²
5-chloro-2-methyl-4-isothiazoline-3-one *	not determinable	<	0.002	mg/dm²
1,2-Benzisothiazolin-3-one *			0.04	mg/dm²
Dichlor-2-n-octyl-4-isothiazolinon-3-on	not determinable	<	0.002	mg/dm²

p-Methylphenol, reaction product with dicyclopentadiene and isobutylene *: The determination was performed according to SOP 162.200 in the migration solution by means of HPLC/UV.

Result:

ethanol 95 % (v/v) – A) conditions:

Sample 1:			3.8	mg/dm²
Sample 2:			3.8	mg/dm²

ethanol 95 % (v/v) – B) conditions:

Sample 1:			1	mg/dm²
Sample 2:			1	mg/dm²

isooctane – A) conditions:

Sample 1:			1	mg/dm²
Sample 2:			1	mg/dm²

isooctane – B) conditions:

Sample 1:			0.41	mg/dm²
Sample 2:	not determinable	<	0.25	mg/dm²

Methacrylic acid *: The determination was performed according to SOP 162.200 in the migration solution by means of HPLC/UV.

Result:

ethanol 95 % (v/v) – A) conditions:

Sample 1:	not determinable	<	0.1	mg/dm²
Sample 2:	not determinable	<	0.1	mg/dm²

ethanol 95 % (v/v) – B) conditions:

Sample 1:	not determinable	<	0.1	mg/dm²
Sample 2:	not determinable	<	0.1	mg/dm²

Zinc *: The determination was performed in the migration solution by ICP-AES.

Result:

acetic acid 3% (w/w) – A) conditions:

Sample 1:	2.2	mg/dm²
Sample 2:	1.8	mg/dm²

acetic acid 3% (w/w) – B) conditions:

Sample 1:	0.2	mg/dm²
Sample 2:	0.1	mg/dm²

Copper *: The determination was performed by AAS/hydride technique or ICP-AES, respectively.

Result:

acetic acid 3% (w/w) – A) conditions:

Sample 1:	not determinable	<	0.002	mg/dm²
Sample 2:	not determinable	<	0.002	mg/dm²

acetic acid 3% (w/w) – B) conditions:

Sample 1:	not determinable	<	0.002	mg/dm²
Sample 2:	not determinable	<	0.002	mg/dm²

GC-MS-Screening: The migration solution was examined gas chromatographically according to SOP 160.200 by means of mass spectrometric detection. For the specific identification of the signals in the chromatogram a commercial mass spectra library was used. A semiquantitative estimation was performed using deuterated nonadecane (C_{19}) as internal standard.

Result:

ethanol 95 % (v/v) – A) conditions:

Sample 1:

The following compounds could be identified:

Sum Alkanes	0.8	mg/dm²
Analytically created degradation product of Di(dodecyl)thiodipropionate	0.1	mg/dm²
Degradation products of Dithiocarbamates	0.02	mg/dm²

Sample 2:

The following compounds could be identified:

Sum Alkanes	0.9	mg/dm²
Analytically created degradation product of Di(dodecyl)thiodipropionate	0.09	mg/dm²
Degradation products of Dithiocarbamates	0.03	mg/dm²

N-Nitrosamines: The analysis was made in co-operation with Isconlab according to the method for the „Determination of the migration of N-nitrosamines from consumer goods into foodstuffs", 53rd memorandum, Bundesgesundheitsblatt 37, 232 (1994).

Result:

acetic acid 3% (w/w) / A) Conditions :

Sample 1 :

N-Nitrosodimethylamine			0.003	µg/dm²
N-Nitrosomethylethylamine	not detected	<	0.001	µg/dm²
N-Nitrosodiethylamine			0.002	µg/dm²
N-Nitrosodipropylamine	not detected	<	0.002	µg/dm²
N-Nitrosodibutylamine			0.07	µg/dm²
N-Nitrosomorpholine	not detected	<	0.002	µg/dm²
N-Nitrosopiperidine	not detected	<	0.002	µg/dm²
N-Nitrosopyrrolidine	not detected	<	0.002	µg/dm²
N-Nitrosodiisobutylamine	not detected	<	0.002	µg/dm²
N-Nitrosomethylphenylamine	not detected	<	0.01	µg/dm²
N-Nitrosoethylphenylamine	not detected	<	0.01	µg/dm²
N-Nitrosodiisononylamine	not detected	<	0.01	µg/dm²
N-Nitrosodibenzylamine	not detected	<	0.01	µg/dm²

Sample 2 :

N-Nitrosodimethylamine			0.003	µg/dm²
N-Nitrosomethylethylamine	not detected	<	0.001	µg/dm²
N-Nitrosodiethylamine	not detected	<	0.001	µg/dm²
N-Nitrosodipropylamine	not detected	<	0.002	µg/dm²
N-Nitrosodibutylamine			0.06	µg/dm²
N-Nitrosomorpholine	not detected	<	0.002	µg/dm²
N-Nitrosopiperidine			0.005	µg/dm²
N-Nitrosopyrrolidine	not detected	<	0.002	µg/dm²
N-Nitrosodiisobutylamine	not detected	<	0.002	µg/dm²
N-Nitrosomethylphenylamine	not detected	<	0.01	µg/dm²
N-Nitrosoethylphenylamine	not detected	<	0.01	µg/dm²
N-Nitrosodiisononylamine	not detected	<	0.01	µg/dm²
N-Nitrosodibenzylamine	not detected	<	0.01	µg/dm²

3. Determination of Butadiene *

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

Result:

Sample 1+2: not determinable < 0.1 mg/kg

4. 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).

As test simulants water, 3% acetic acid, 10 % ethanol and olive oil were used.

Result:

Sample 1: The colour fastness is given in contact with all test simulants.

5. Determination of Acrylonitrile *

The determination was performed according to the method B 80.68-1 within the Official Collection of Analytical Methods according to § 64 LFGB for consumer goods by means of headspace gas chromatography and mass-selective detection.

Result:

Sample 1+2: not determinable < 1 mg/kg

6. Determination of Volatile Organic Compounds (Headspace-GC/MS-Screening) *

The determination was performed according to SOP 160.200 by means of head space chromatography and mass spectrometric detection after a storage of 60 minutes at 80 °C. The air space above the sample material was examined for volatile components and was identified against a spectrum library and additionally according to the retention times.

If not stated differently, a semiquantitative estimation of the signals was performed against the internal standard Trichlorotrifluoroethane.

Result:

Evaluation of the compounds estimated against the internal standard:

Sample 1:

Ethanol	0.7	mg/kg
Acetone	0.4	mg/kg
Carbondisulfide	1.1	mg/kg
Silanol	0.3	mg/kg
Propylene glycole	0.3	mg/kg
Siloxane	0.2	mg/kg

Sample 2:

Methanol	0.2	mg/kg
Ethanol	0.6	mg/kg
Acetone	0.2	mg/kg
Carbondisulfide	1.5	mg/kg
Silanol	0.3	mg/kg
Propylene Glycole	0.4	mg/kg
Siloxane	0.2	mg/kg

The accreditation applies to the methods marked with * in the test report (Register no. D-PL-14160-01-01 and D-PL-14160-01-02).

End of report