WRP Asia Pacific Sdn Bhd
14 7 817 V
Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinggi,
43900 Sepang,
Selangor Darul Ehsan, MALAYSIA

Office +60-3-8706 1486
Facsimile +60-3-8706 1557
Email customer_wrp@wrpworld.com
Website www.wrpworld.com

DECLARATION OF FOOD CONTACT COMPLIANCE

Regulation : Commission Regulation (EU) No. 10/2011

Type of Glove : Dermagrip Latex Examination Gloves High Risk

Intended Use : Donning to Prevent the Likelihood of Food Contamination during the Preparation or Handling and Applies to every Food Handler.

Validity : Five (5) Years

OVERALL MIGRATION

1. Determination of the Overall Migration

The determination was performed as a determination in duplicate according to the series of standards EN 1186:2002-07, in connection with the prEN 1186-2:2020-05, the prEN 1186-3:2020-05 as well as the EN 13130-1:2004-08.

The test simulants as well as the contact conditions were chosen in accordance with the requirements of BfR Recommendation XXI/1 as well of the JRC121622, 2020,, Testing conditions for kitchenware articles in contact with foodstuffs: Plastics and Metals".

Result:

Type of Simulant	**Testing Condition**	**Commission Regulation (EU) No. 10/2011 Requirement for Overall Migration Content (mg/dm^2)**
Acetic Acid 3%	10 minutes at 40 °C	Not quantifiable <3
Ethanol 10%	10 minutes at 40 °C	Not quantifiable <3
Ethanol 50%	10 minutes at 40 °C	Not quantifiable <3
Ethanol 95%	10 minutes at 40 °C	4.5
Isooctane	10 minutes at 40 °C	32
Testing Procedure		One-sided contact exterior side

Based on the above result, the Dermagrip Latex Examination Gloves High Risk met the overall migration requirement under Commission Regulation (EU) No. 10/2011 – "Plastic materials and articles shall not transfer their constituents if foodstuffs in quantities not exceeding 10 milligrams of total constituents released per dm^2 of food contact surface mg/dm^2 (overall migration limit)" for 3% Acetic Acid.

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2. Determination of the Specific Migration

2.1 N – Nitrosamines

The determination was performed according to SOP 162.200 by means of LCMS in the simulant water. The following compounds were considered:

Type of Test Simulant	Testing Condition	Type of Compounds	
Water Vegetable oil (Food simulant D2)	10 minutes at 40 °C	N-Nitrosodimethylamine	[62-75-9]
		N-Nitrosodiethylamine	[55-18-5]
		N-Nitrosodipropylamine	[621-64-7]
		N-Nitrosodibutylamine	[924-16-3]
		N-Nitrosomorpholine	[59-89-2]
		N-Nitrosopiperidine	[100-75-4]
		N-Nitrosodiisobutylamine	[997-95-5]
		N-Nitrosomethylphenylamine	[614-00-6]
		N-Nitrosoethylphenylamine	[612-64-6]
		N-Nitrosodiisononylamine	[1207995-62-7]
		N-Nitrosodibenzylamine	[5336-53-8]
Testing Procedure		One-sided contact exterior side	
Limit of quantitation: 0.05 pg/ dm^2			

Result: None of the above-listed compounds were quantifiable

2.2 Elements

The determination was performed by means of ICP-OES or ICP-MS in the simulant Acetic acid 3%.

Result:

Testing Acetic	Conclusion (mg/dm^2)
Arsenic (As)	Not determinable < 0.0002
Cadmium (Cd)	Not determinable < 0.0001
Chromium (Cr)	Not determinable < 0.001
Mercury (Ng)	Not determinable < 0.0001
Lead (Pb)	Not determinable < 0.0005
Aluminium (AI)	Not determinable < 0.01
Titanium (Ti)	Not determinable < 0.002
Zinc (Zn)	0.1

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2.3 Reaction product of 4-methylphenol with Isobutylene and Dicyclopentadiene [68610-51-5]

The determination was performed according to SOP 162.200 by means of HPLC-UV in the simulants ethanol 95% and isooctane.

Result:

Testing Acetic	Conclusion (mg/dm²)
Ethanol 95%	0.9
Isooctane	7.2

2.4 Alkanolamines

The determination was performed according to SOP 162.200 by means of LCMS in the simulant ethanol 95%. The following compounds were considered:

Type of Test Simulant	Testing Condition	Type of Compounds	
Water Vegetable oil (Food simulant D2)	10 minutes at 40 °C	2-Aminoethanol	[141-42-5]
		Diethanolamine (DEA)	[111-42-2]
		Triethanolamine (TEA)	[102-71-6]
		1-Amino-2-propanol	[78-96-6]
		2-(Diethylamino)ethanol	[100-37-8]
		N-Methyidiethanolamine (MDEA)	[105-59-9]
		2-Dimethylaminoethanol (DMAE)	[108-01-0]
		2-Amino-2-methyl-1-propanol (AMP)	[124-68-5]
		2-Methylamino-2-methyl-1-propanol	[27646-80-6]
Limit of Quantitation		0.001 mg/dm²	

Result:

Sample 1	mg/dm²
2-Aminoethanol	0.01
Diethanolamine (DEA)	0.001

* The remaining compounds were not quantifiable

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2.5 Biocides

The determination was performed according to SOP 162.200 by means of LCMS in the simulant acetic acid 3%. The following compounds were considered:

Sample 1		Limit of Quantitation (mg/dm²)
2-Bromo-2-nitropropane-1,3-dioI	[52-51-7]	0.0002
5-Chloro-2-methyl-4-isothiazoIin-3-one	[26172-55-4]	
2-Methyl-4-isothiazoIin-3-one	[2682-20-4]	
1,2-Benzisothiazolin-3-one	[2634-33-5]	
2-OctyI-4-isothiazoIin-3-one	[26530-20-1]	
DichIoro-2-n-octyI-4-isothiazolin-3-one	[64359-81 5]	

Result: None of the compounds mentioned above were quantifiable

2.6 Formaldehyde [50-00-0]

The determination was performed photometrically according to CEN/TS 13130-23:2005-05 according to the acetylacetone method in the simulant acetic acid 3%.

Result:

mg/dm²
Not quantifiable < 0.02

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2.7 LC-TOF-Screening

The determination was performed according to SOP 162.200 by means of LC-TOF in the simulant ethanol 95 %. Primarily, a screening for ethoxylated alkyl alcohols, ethoxylated alkyl phenols and ethoxylated mono-, di- or tristyrinated phenols was carried out. In addition, further substances were identified using their exact mass; they were evaluated semi-quantitatively against adequate standards.

The following compounds could be quantified:

Target Analysis	Result
Ethoxylated primary alcohols (C_8-C_9)	not detected
Ethoxylated primary alcohols (C_{10}-C_{13})	< 0.1 mg/dm^2
Ethoxylated primary alcohols (C_{14}-C_{15})	not detected
Ethoxylated primary alcohols (C_{16}-C_{18})	app. 0.3 mg/dm^2
Ethoxylated octylphenol	< 0.1 mg/dm^2
Ethoxylated nonylphenol	app. 0.1 mg/dm^2
Ethoxylated mono-, di- or tristyrinated phenols	not detected
Di(dodecyl)thiodipropionate	not detected
CAS [68610-51-5]	app. 1.1 mg/dm^2
1,2-Benzisothiazolin-3(2H)one	not detected
Di (ethylhexyl) sulphosuccinate	not detected
Alkyl (C10-C13) benzene sulfonate	app. 0.1 mg/dm^2

Non-target Analysis	Result
Diethylamine	app. 0.2 mg/dm2
Dibutylamine	app. 0.1 mg/dm2
Diethyl phthalate	app. 0.03 mg/dm2
N-octylbutanamide	app. 0.003 mg/dm2
Diisobutyl phthalate	app. 0.006 mg/dm2
Di-(2-ethylhexy) phthalate	app. 0.006 mg/dm2
Penta(methoxymethyl)melamine	app. 0.06 mg/dm2
Sum of degration products of vulcanization accelerators	app. 0.6 mg/dm2

Polyethylenglycols as well as ingredients like tocotrienols, tocotrienols esters, fatty acid amids ad steroids which are typical for natural rubber products have been detected.

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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, 24'h memorandum for the examination of plastics: Bundesgesundheitsblatt 15, 285 (1972).

Result:

The colour fastness is given in contact with all test simulants.
Method: As test medium, water, 3% acetic acid, 10 % ethanol and olive oil were used.

4. Analysis of the Transition if Taste by direct Contact *

The examination was performed according to the DIN 10566:2004-06.

The sensory testing condition were chosen according to the procedure "disposable gloves" as of 2016_04 from the *Collection of Methods for Sensor Testing of Foods Contact Materials* of the Joint Working Group "Sensory Evaluation of Consumer Products" of DGSens e.V and EUROLAB-D.

The glove was turned inside out and filled with water preheated to 40°C so that the test food was only in contact with the exterior side. After a storage time of 10 minutes at 40°C, possible off-flavours of the water were evaluated by six assessors in an extended triangular test according to DIN ISO 4120:2004-06. Water which had been treated and stored the same way but had not been in contact with the sample, served as reference.

Result:

No different with statistical significance could be noticed between the water which had been in contact with the glove and the water which had not been in contact with the sample.
Evaluation (median): < 1

Scale of intensity
0 = no perceptible deviation in taste
1 = just perceptible deviation in taste (still difficult to define)
2 = slight deviation in taste
3 = clear deviation in taste
4 = strong deviation in taste

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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

Reference Report : Test Report No.: 18583/9-1-I
Test Facility : ISEGA, Germany.

Prepared by,

.....
Rosnaini Rashidin
Product Management Manager

Approved by,

.....
Angie Ng Geok Chin
Research & Development Manager