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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 dm² of food contact surface mg/dm² (overall migration limit)” for 3% Acetic Acid.

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 (Al)	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/dm ²)
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-Methyldiethanolamine (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/dm ²

Result:

Sample 1	mg/dm ²
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/dm ²)
2-Bromo-2-nitropropane-1,3-diol [52-51-7]	0.0002
5-Chloro-2-methyl-4-isothiazolin-3-one [26172-55-4]	
2-Methyl-4-isothiazolin-3-one [2682-20-4]	
1,2-Benzisothiazolin-3-one [2634-33-5]	
2-Octyl-4-isothiazolin-3-one [26530-20-1]	
Dichloro-2-n-octyl-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/dm ²
Not quantifiable < 0.02

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 tristyrenated 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 tristyrenated 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 (C ₁₀ -C ₁₃) benzene sulfonate	app. 0.1 mg/dm ²

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

Polyethyleneglycols as well as ingredients like tocotrienols, tocotrienols esters, fatty acid amides and 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).

Thus, the blue natural rubber gloves **Dermagrip Latex Examination Gloves High Risk D14xx-14** according to the sample material submitted may be used safely in the food industry during the preparation and handling of food. They may stand in direct contact with dry, aqueous, acidic and alcoholic foodstuffs as well as dairy products for a short period of time.

End of report

Reference Report : Test Report No.: 18583/9-1-I
Certificate of Compliance : 56212 U 22
Test Facility : ISEGA, Germany.

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