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Date

March 11, 2011

your ref.

Nitrile Gloves / 327372

Our ref.

G06861/JH

Test report – Migration

Sample material

	300001/311
Identification	One sample of nitrile gloves to be tested for overall and specific migration
Sample receipt	February 7, 2011
Number / type	1 sample identified as:
	Lab no. G06861: Sample no 327372 Gants Nitrile Gloves
Analytical period	February 7 – March 11, 2011

Applied methods

Method nor.	Parameter	Principle	Limit of detection	U _m (%) ①
EN 1186-4	Overall migration to olive oil	Gravimetric + GC/FID	2 mg/dm ²	30%
EN 1186-5	Overall migration to 3% acetic acid	Gravimetric	1 mg/dm ²	20%
EN 13130	Zinc	Migration simulant analyzed by ICP/MS	1 mg/kg	20%
EN 13130	Formaldehyde	Migration simulant analyzed by HPLC/DAD/UV	1 mg/kg	20%
MK72053	Primary aromatic amines	Migration simulant analysed by UV-spectrofotometry	0.01 mg/kg	30%
EN 12868	Nitrosamines	Solvent extraction and GC/MS 2 µg/kg analyses		30%
ISO 16000	VOC emission	Micro chamber heated to 40 °C and the air emission collected on ATD and analysed by ATD/GC/MS	0.01 μg/g/hour	30%

The migration was performed in accordance with EN 1186 part 4: Test methods for overall migration into olive oil by cell and EN 1186 part 5: Test methods for overall migration into aqueous food simulants by cell.

Principle

Olive oil: The sample was exposed for 30 minutes at 40 °C by cell. At the end of the test period, the sample was removed from the food simulant. The sample was weighed and extracted with pentane by means of Soxhlet extraction for 7 hours. The amount of extracted olive oil was determined by gaschromatography with flame ionisation detection (GC/FID). The loss of weight was adjusted the excessive oil extracted from the sample and the calculated loss equals the total migration.

3% acetic acid: The sample was exposed for 30 minutes at 40 °C. At the end of the test period, the sample was removed from the food simulant. The simulant was then evaporated and the dry matter determined by weighing.

Specific migration: An aliquot of the food simulant is analysed for the specific compounds as listed above.

The test was performed with triplicates.

① U_m (%): The expanded uncertainty U_m is equal to 2 x RSD%, see also <u>www.eurofins.dk</u>. Keyword: Uncertainty



Analytical results

Results

The determined overall migration from the sample to the simulant is given in the table below. The result is an average of the three determinations. As described in the standard EN 1186 all results are given in total mg/dm².

Table 1: Overall migration.

Unit: mg/dm ² / Sample id:	Gants Nitrile Gloves / 327372				
Simulant	Single determinations			Average	OML value
3% acetic acid	1.4	2.0	2.0	1.8	10
Olive oil	2.3	5.7	3.8	3.9	10

<: means less than

Table 2: Specific migration

Unit: mg/kg / Sample id:	Gants Nitrile Gloves / 327372				
Parameter	Single determinations			Average	SML value
Zinc to olive oil	< 1	< 1	< 1	< 1	25
Zinc to 3% acetic acid	6.3	-	-	6.3	25
Formaldehyde					15
Primary aromatic amines					0.01

<: means less than

Table 3: N-nitrosamines and N-nitrosable compounds

Unit: µg/kg	Sample	Requirement
Parameter	Gants Nitrile Gloves / 327372	Limit value
Nitrosamines		
N-nitrosodimethylamine	8.8	
N-nitrosodiethylamine	3.7	
Other N-nitrosamine	Not detected	
Sum of N-nitrosamines	12.5	10
Sum of N-nitrosamines (corrected)	2.5	10
N-Nitrosable compounds		
N-nitrosodimethylamine	360	
N-nitrosodiethylamine	130	
N-nitrosodibutylamine	34	
Other N-nitrosamine	Not detected	
Sum of N-nitrosamines	524	100
Sum of N-nitrosamines (corrected)	424	100

<: means less than



Analytical results

Table 4. VOC emission in µg/g/hour

Table 4. VOC emission in pg/g/nour		Gants Nitrile Gloves /
Compound	Cas no	327372
Methylethylketon (MEK) (2-butanon)	78-93-3	
Hexanal	66-25-1	
2-Propenoic acid, 2-methyl-	79-41-4	
4-Cyanocyclohexene	100-45-8	
Limonene (terpen)	138-86-3	
Benzenemethanol, .alpha.,.alphadimethyl-	617-94-7	
n-Undecane	1120-21-4	
n-Tridecane	629-50-5	
n-Tetradecane	629-59-4	
n-Pentadecane	629-62-9	
Sum of C9-aromate		
Sum af unidentified, RT C11-C14		
Total VOC		

Conclusion:

The threshold value for overall migration is 10 mg/dm² and the results show that the product tested **complies** with the regulations in EU directive 2002/72/EC as amended by 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC and regulation 975/2009/EC on plastic material and articles intended to come into contact with food for the above mentioned test conditions.

Also the specific migration analysis shows that results are below SML values and the sample tested complies with the above mentioned Directives

The VOC emission on 28 μ g/g/hour is very low and it is mainly parafines and with traces of solvents and aldehydes.

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