

This test report supersedes report number VNHL1712015525HG dated January 18, 2018

MUTEXIL SARL

11 IMPASSE JUTON, 4400 NANTES, FRANCE

The following sample(s) was/were submitted and identified by/on behalf of the client as:

SGS Job No. : VNHL1712015525HG-01
Sample Description : DISPOSABLE POWDER FREE NITRILE GLOVES
Reference of Order : 888.69.30
888.77.77
Color : BLUE
Manufacturer : VIET GLOVE CORPORATION
Country of Origin : VIETNAM
Country of Destination : FRANCE
Sample Receiving Date : DECEMBER 29, 2017
Final confirmed Date : DECEMBER 29, 2017
Testing Period : DECEMBER 29, 2017 TO JANUARY 18, 2018
Test Requested : PLEASE REFER TO THE RESULT SUMMARY.
Test Results : PLEASE REFER TO NEXT PAGE(S).
Result Summary :

Test Request	Conclusion
1. French Arrêté du 9 November 1994, French Décret 2007-766 with amendments and DGCCRF Methodological Document DM/4B/COM/003.	--
a) Rubber – Overall Migration	PASS
b) Rubber – Specific Migration of Primary Aromatic Amine	PASS
d) Rubber – Specific Migration of Nitrosamine and Nitrosatable Substances	PASS
e) Rubber – Specific Migration of Formaldehyde	PASS
g) Rubber – Volatile Organic Matter	PASS
2. French Décret 92-631, French Décret 2007-766 and its amendments, DGCCRF Methodological Document File organic materials – synthetic matter and European Commission Regulation (EU) No 10/2011 of 14 January 2011 and its amendments. (Selected test as specified by Client)	--
a) Plastic – Specific Migration of Acrylonitrile	PASS
3. French Arrêté du 9 November 1994, French Décret 92-631, French Décret 2007-766 and its amendments and DGCCRF Methodological Document File Organic Materials – Synthetic Matter. (Selected test as specified by Client)	--
a) Rubber – Overall Migration	PASS
b) Rubber – Peroxide Value	PASS

Signed for and on behalf of

SGS Vietnam LTD



Wong Cho Wing

Hardline and E&E Lab Manager

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Test result(s):
Test Part Description: 1. BLUE NITRILE

1. French Arrêté du 9 November 1994, French Décret 2007-766 with amendments and DGCCRF Methodological Document DM/4B/COM/003

a) Rubber – Overall migration

 Method: With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-9:2002 aqueous food simulants by article filling method (1st Migration);

Simulant Used	Test Condition	Result (mg/dm ²)	Reporting Limit (mg/dm ²)	Permissible Limit (mg/dm ²)
		1		
3% Acetic Acid (W/V) Aqueous Solution	02 hours at 40°C	5.09	3.0	10
10% Ethanol (V/V) Aqueous Solution	02 hours at 40°C	ND	3.0	10
Comment	--	PASS	--	--

 Note : 1. mg/dm² = milligram per square decimeter

2. °C = degree Celsius

3. ND = Not Detected

4. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

Remark:

- Analytical tolerance of aqueous simulants is 2mg/dm² or 12mg/kg
- Analytical tolerance of fatty food simulants is 3mg/dm² or 20mg/kg

b) Rubber – Specific migration of Primary Aromatic Amine

Method: With reference to EN 13130-1:2004 and BfR Recommendation XXI. Analysis was performed by UV-vis Spectrophotometer.

Simulant Used: 3% acetic acid (w/v) in aqueous solution

Test Condition: 40 °C for 02 hours (1st Migration)

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
	1		
Specific migration of Primary Aromatic Amine	ND	0.01	1
Comment	PASS	--	--

- Note :
1. mg/kg = milligram per kilogram of foodstuff in contact with
 2. °C = degree Celsius
 3. ND = Not Detected
 4. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

c) Rubber – Specific migration of Nitrosamines and Nitrosatable substances

Method: With reference to EN 13130-1:2004. Analysis was performed by GC-NPD and GC-MS.

Simulant Used: 3% acetic acid (w/v) in aqueous solution

Test Condition: 40 °C for 02 hours (1st Migration)

Test Item	Result (mg/dm ²)	Reporting Limit (mg/dm ²)	Permissible Limit (mg/dm ²)
	1		
Nitrosamines	ND	0.001	0.001
Nitrosatable substances	ND	0.01	0.01
Comment	PASS	--	--

- Note :
1. Nitrosamines tested: N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosodipropylamine (NDPA), N-nitrosodibutylamine (NDBA), N-nitrosopiperidine (NPIP), N-nitrosopyrrolidine (NPYR), N-nitrosomorpholine (NMOR), N-nitrosodibenzylamine (NDBZA), N-nitroso-N-methyl-N-phenylamine (NMPHA), N-nitroso-N-ethyl-N-phenylamine (NEPHA) and N-nitrosodiisononylamine (NDiNA).
 2. mg/dm² = milligram per square decimeter
 3. ND = Not Detected
 4. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

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d) Rubber – Specific migration of Formaldehyde

Method: With reference to EN 13130-1:2004. Analysis was performed by UV-vis Spectrophotometer.
 Simulant Used: 3% acetic acid (w/v) in aqueous solution
 Test Condition: 40°C for 02 hours (1st Migration)

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
	1		
Specific migration of Formaldehyde	ND	0.1	3
Comment	PASS	--	--

Note: 1. Mg/kg = milligram per kilogram of foodstuff in contact with
 2. ND = Not Detected
 3. Permissible Limit is according to French Arrêté du 9 Novembre 1994.

e) Rubber – Volatile organic matter

Method: With reference to French Arrêté du 25 Novembre 1992 Annex III at 105°C for 04 hours

Test Item	Result (% w/w)	Reporting Limit (% w/w)	Permissible Limit (% w/w)
	1		
Volatile Organic Matter (VOM)	0.27	0.1	0.5
Comment	PASS	--	--

Note: 1. % w/w = percentage of weight by weight
 2. ND = Not Detected

Remark This / these test(s) was / were performed by SGS Chemical Lab
 Test condition & simulant were specified by client.

2. French Décret 92-631, French Décret 2007-766 and its amendments, DGCCRF Methodological Document File Organic Materials – Synthetic Matter and European Commission Regulation (EU) No 10/2011 of 14 January 2011 and its amendments.
Plastic – Specific Migration of Acrylonitrile

Method: Sample preparation in 3% acetic acid (w/v) in aqueous solution at 40°C for 2 hours; followed by analysis using SPME-GC/MS (1st migration).

Test Item	Result (mg/kg)	Reporting Limit (mg/kg)	Permissible Limit (mg/kg)
	1		
Specific Migration of Acrylonitrile	ND	0.01	0.01
Comment	PASS	--	--

Note: 1. mg/kg = milligram per kilogram of foodstuff in contact with
 2. ND = Not Detected

Remark:

1. Compliance is based on the 1st migration result only as per described in Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex V.
2. Test condition were specified by client

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3. French Arrêté du 9 November 1994, French Décret 92-631, French Décret 2007-766 and its amendments and DGCCRF Methodological Document File Organic Materials – Synthetic Matter.

a) Rubber – Overall Migration

Method: With reference to EN 1186-1:2002 for selection of conditions and test methods (1st migration); EN 1186-2:2002 olive oil by total immersion method.

Simulant Used	Test Condition	Result (mg/dm ²)	Reporting Limit (mg/dm ²)	Permissible Limit (mg/dm ²)
		1		
Rectified Olive Oil	2 hours at 40 °C	ND	3.0	10
Comment	--	PASS	--	--

Note: mg/dm² = milligram per square decimeter
 °C = degree Celsius
 ND = Not Detected

b) Rubber – Peroxide Value

Method: With reference to European Pharmacopoeia, 2005.

Test Item	Result	Requirement
	1	
Peroxide Value	Absent	Absent
Comment	PASS	--

Remark Test condition & simulant were specified by client.
 This / these test(s) was / were performed by SGS HONGKONG Lab

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PHOTO OF SUBMITTED SAMPLE



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*****End of Report*****

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