



## DECLARATION OF FOOD CONTACT COMPLIANCE

**Glove Type** : Nitrile Powder free Glove




**Intended Use** : Donning to prevent the likelihood of food contamination during the preparation or Handling and applies to every food handler.

**Shelf life** : 3 years

### 1. Commission Regulation (EU) No 10/2011

#### 1.1 Overall migration

##### Method of Test:

-  **Preparation of test specimen**  
Only the exterior of the glove sample was performed for the test
-  **Overall Migration Content with Aqueous Food Simulant (10% Ethanol ,3% Acetic Acid, 20% Ethanol and 50% Ethanol)**  
According to BS EN 1186-9:2002-Test Methods for overall migration into aqueous food simulants by article filling
-  **Overall Migration Content with Fatty Food Simulant (Olive Oil)**  
According to BS EN 1186-8:2002-Test Method for overall migration into olive oil by article filling

##### Result:

Overall Migration Content with Food Simulant for the “Nitrile Powder free Glove” sample

Type of Simulant	Testing Condition	Commission Regulation (EU) No. 10/2011 Requirement for Overall migration content (mg/dm <sup>2</sup> )
1. 10 % Ethanol	40 °C, 2 hours	<10
2. 3% Acetic Acid	40 °C, 2 hours	<10
3. 20 % Ethanol	40 °C, 2 hours	<10
4. 50 % Ethanol	40 °C, 2 hours	<10
5. Vegetable oil (Olive Oil)	40 °C, 2 hours	<10

Based on the above result, the Nitrile Powder free glove met the overall migration requirement under Commission Regulation (EU) No. 10/2011- “Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities not exceeding 10 milligrams of total constituents released per dm<sup>2</sup> of food contact surface (mg/dm<sup>2</sup>) (overall migration limit)”.

## 1.2 Heavy metal in glove (cont'd)

### Method of Test:



#### Specific Migration of Heavy Metals

The sample was filled with the simulations at 40°C for 2 hours as according to BS EN 1186-9:2002 and BS EN 13130-1:2004 as reference. The simulants were then analysed by inductively Coupled Plasma-Atomic Emission Spectrometry (ICP-AES).

### Result:

Specific Migration of Heavy Metals (in 3% Acetic Acid) for the "Nitrile Powder free Glove" Sample

Test	Testing Condition	Detection Limit (mg/kg)	Commission Regulation (EU) No. 10/2011 Requirement for Specific Migration Limit (mg/kg)*
1. Aluminum, Al	40 °C, 2 hours	0.1	<1
2. Barium, Ba	40 °C, 2 hours	0.1	<1
3. Cobalt, Co	40 °C, 2 hours	0.05	<0.05
4. Copper, Cu	40 °C, 2 hours	0.1	<5
5. Iron, Fe	40 °C, 2 hours	0.1	<48
6. Lithium, Li	40 °C, 2 hours	0.1	<0.6
7. Manganese, Mn	40 °C, 2 hours	0.1	<0.6
8. Nickel, Ni	40 °C, 2 hours	0.01	<0.6
9. Zinc, Zn	40 °C, 2 hours	0.1	<25

Based on the above results, the "Nitrile Powder free Glove" sample met the specific migration of Heavy Metals requirements for the above tests under Commission Regulation (EU) No 10/2011.

**Reference Report :** Test Report No. 7191204275-CHM19-01-TSL

**Test carried out at :** TUV SUD PSB Pte.Ltd., Singapore

Best Regards,



Ms. Vanlinee Laohachaiyakul  
Product Manager

Approved By:



Ms. Rosna Yensuk  
Laboratory manager

## 2. FDA EXTRACTION TEST: CFR 177.2600

Code of Federal Regulation, Title 21

Chapter 1 – food and drug Administration

Part 177.2600 – Rubber articles intended for repeated use

Solvent: Distilled water, n-Hexane

Sample: Nitrile Powder free Glove

### Result:

EXTRACTION TIMES	SOVENT	REQUIREMENT (mg/in. <sup>2</sup> ) max.	PASS/FAIL
First 7 hrs.	Distilled water	20	PASS
Next 2 hrs.	Distilled water	1	PASS
First 7 hrs.	n-Hexane	175	PASS
Next 2 hrs.	n-Hexane	4	PASS

Reference Report : Test Report PN 140230-A

Test carried out at : Akron Rubber Development Laboratory, Inc

Best Regards,



Ms. Vanlinee Laohachaiyakul  
Product Manager

Approved By:



Ms. Rosna Yensuk  
Laboratory manager

### 3. Japan Food Sanitation Law (JFSL) 370 and its amendments

Sample Description : Nitrile Powder free Glove

#### Test Parameter

1. Lead (Total)
2. Cadmium (Total)
3. Phenol (Extractable)
4. Extractable Formaldehyde
5. Extractable Zinc
6. Heavy Metal (as Lead) in 4% acetic acid extraction
7. Residue after Evaporation Test (Water & 20% ethanol)
8. Residue after Evaporation Test (4% acetic acid)
9. Migration of color Extraction (Water & 20% ethanol)
10. 2-Mercaptoimidazoline Content

#### Conclusion

PASS  
PASS  
PASS  
PASS  
PASS  
PASS  
PASS  
FAIL  
PASS  
PASS

#### Test Requested

Japan Ministry of Health and Welfare Notification No. 370 and amendments Part III Section D for the compliance of the provisions of paragraph 1 of Articles 7 and Articles 10 of Japan Food Sanitation Law (Law No.233)

#### MATERIAL TEST

**Method:** with reference of Section III of Japan Ministry of Health and Welfare Notification No. 370 and amendments.

Test Items	Maximum Permissible Limit
Total Lead content	100 ug/g
Total Cadmium content	100 ug/g

\* ug/g: microgram per gram

#### ELUTION TEST

Test Items	Leaching Condition	Leaching Solution	Maximum Permissible Limit
Phenol	60 °C, 30 min	Water	5 ug/mL
Formaldehyde	60 °C, 30 min	Water	Negative
Zinc	60 °C, 30 min	4% acetic acid	15 ug/mL
Heavy Metal (as Lead)	60 °C, 30 min	4% acetic acid	1 ug/mL
Evaporation residue	60 °C, 30 min	Water	60 ug/mL
Evaporation residue	60 °C, 30 min	4% acetic acid	60 ug/mL
Evaporation residue	60 °C, 30 min	20% ethanol	60 ug/mL

\* ug/mL: microgram per millilitre,

"Negative" mean it's not persence of color migration/ "Positive" mean it's persence of color migration

#### ELUTION TEST

Test Items	Leaching Condition	Leaching Solution	Maximum Permissible Limit
Color Migration	60 °C, 30 min	Water	Negative
Color Migration	60 °C, 30 min	4% acetic acid	Negative
Color Migration	60 °C, 30 min	20% ethanol	Negative

**2-MERCAPTOIMIDAZOLINE CONTENT** (cont'd)

Method: with reference of Section III of Japan Ministry of Health and Welfare Notification No. 370 and amendments.

Test Items	Reporting Limit (ug/g)	Requirement
2-Mercaptoimidazoline	20	Negative
Comment	PASS	-

Reference Report : Test Report No. 4234193, 4234192

Test carried out at : SGS (Thailand) Limited

Best Regards,



Ms. Vanlinee Laohachaiyakul  
Product Manager

Approved By:



Ms. Rosna Yensuk  
Laboratory manager

## 4. EU No. 93/11/EEC (BS EN 12868:2017)

### Method of Test:

Sample preparation with reference to BS EN 12868:2017: Child use and care articles – Methods for determining the release of N-Nitrosamines and N-Nitrosatable substances from elastomer or rubber teats and soother, followed by analysis using Gas Chromatography combined with the Nitrogen Chemiluminescence Detector (GC-NCD)

### Result:

The Analytical Results of N-Nitrosamines for "Nitrile Powder Free" Sample

Test	Total Value allowed (93/11/EEC)	Compliance to 93/11/EEC
N-Nitrosatable substances (mg/kg)	Max 0.1 mg/kg	Fail
N-Nitrosamines (mg/kg)	Max 0.01 mg/kg	Pass

Reference Report : Test Report No. 7191200795-CHM19-04-XMH

Test carried out at : TUV SUD PSB Pte.Ltd., Singapore

Best Regards,



Ms. Vanlinee Laohachaiyakul  
Product Manager

Approved By:



Ms. Rosna Yensuk  
Laboratory manager

## 5. BfR Recommendation XXI

### Method of Test:

(Based on Natural and synthetic Rubber-2.3 Category 3)

#### 1. Preparation of test Specimen

Only the exterior of the glove sample was performed for the test.

#### 2. Global migration Content with Aqueous Food Simulant (DI Water, 3% Acetic Acid & 10% Ethanol)

According to BfR Recommendation XXI with reference to EN 1186-9:2002 – Test Methods for overall migration into aqueous food simulants by article filling.

The residue from the above 3% Acetic Acid was further extracted with Hexane for the organic components.

#### 3. Specific Migration Content using Aqueous Food Simulant (DI Water)

According to BfR Recommendation XXI with reference to EN 1186-9:2002 – Test Methods for overall migration into aqueous food simulants by article filling.

##### a) Specific Migration of Formaldehyde

The simulants extracts was analysed by UV Spectrophotometer after derivatization with Acetylacetone.

##### b) Specific Migration of Primary Arylamines and Secondary Arylamines

The stimulant was extracted by organic solvent and analysed by Gas Chromatography Mass Spectrometry after proper treatment.

##### c) Specific Migration of Nitrosamines

The stimulant was extracted by organic solvent and analysed by Gas Chromatography combined with the Nitrogen Chemiluminescence Detector after proper treatment.

#### 4. Lead and Zinc content

According to BfR Recommendation XXI, sample analysis was conducted by acid digestion, followed by ICP-Atomic Emission Spectrometry (ICP-AES).

### Result:

**Table 1: Global Migration Content with Food Simulant for the “Nitrile Powder Free Offline Chlorination Glove” Sample**

Type of simulant	Testing Condition	BfR XXI Category 3 Requirement for Global Migration (mg/dm <sup>2</sup> )
1. DI Water	40°C, 10 mins	10 max
2. 3% Acetic Acid	40°C, 10 mins	50 max
3. 10% Ethanol	40°C, 10 mins	10 max

**Table 2 : Global Migration Content with Food Simulant for the “Nitrile Powder Free Offline Chlorination Glove ” Sample**

Type of simulant	Testing Condition	BFR XXI,2.3 Category 3 Requirement for Global Migration Of Organic Components (mg/dm <sup>2</sup> )
1. 3% Acetic Acid	40°C, 10 mins	10 max

**Table 3 : Specific Migration of Formaldehyde in Food simulant for “Nitrile Powder Free Offline Chlorination Glove ”Sample**

Type of simulant	Testing Condition	BfR XXI Category 3 Requirement for Specific Migration Content (µg/ml)
Distilled Water	40°C, 10 mins	10 max

a) The method detection limit was 1 µg/ml.

**Result:** (cont'd)**Table 4 : Specific Migration of Primary Arylamines in Food simulant for “Nitrile Powder Free Offline Chlorination Glove” Sample**

Type of simulant	Testing Condition	BfR XXI Category 3 Requirement for Specific Migration Content (µg/l)
Distilled Water	40°C, 10 mins	< 20

b) The method detection limit was 10 µg/l

**Table 5 : Specific Migration of Secondary Arylamines in Food simulant for “Nitrile Powder Free Offline Chlorination Glove” Sample**

Type of simulant	Testing Condition	BfR XXI Category 3 Requirement for Specific Migration Content (mg/l)
Distilled Water	40°C, 10 mins	< 1

c) The method detection limit was 0.01 mg/l.

**Table 6 : Specific Migration of Nitrosamines in Food simulant for “Nitrile Powder Free Offline Chlorination Glove” Sample**

Type of simulant	Testing Condition	BfR XXI Category 3 Requirement for Specific Migration Content (µg/dm <sup>2</sup> )
Distilled Water	40°C, 10 mins	< 1

The method detection limit was 0.02 µg/dm<sup>2</sup>**Table 7 : Lead and Zine Contents for “Nitrile Powder Free Offline Chlorination Glove” Sample**

Test	BfR XXI Category 3 Requirement (%)
1. Lead, Pb	< 0.003
2. Zinc, Zn	< 3.0

Based on the above results, the “Nitrile Powder Free Offline Chlorination Glove” sample met the specific migration requirements for the above tests under Commission Regulation (EU) No 10/2011.

**Reference Report :** Test Report No. 7191173479-CHM17-02-TSL**Test carried out at :** TUV SUD PSB Pte.Ltd., Singapore

Best Regards,



Ms. Vanlinee Laohachaiyakul  
Product Manager

Approved By:



Ms. Rosna Yensuk  
Laboratory manager



## 6. Korea Ministry of Food and Drug Safety (KFDA)

### Method of Test:

Standards and Specifications for Food Utensils, Containers and Packages

### Result:

Test	KFDA Requirement	Result
Lead (Pb)	Max 100 mg/kg	Pass
Cadmium (Cd)	Max 100 mg/kg	Pass
Phenol	Max 5 mg/L	Pass
Formaldehyde	Max 4 mg/L	Pass
Zinc (Zn)	Max 15 mg/L	Pass
Heavy metal (as Pb)	Max 1 mg/L	Pass
Evaporation water	Max 60 mg/L	Pass

Reference Report : Test Report No. 2019-11-001607

Test carried out at : Korea Advane Food Research Institute

Best Regards,



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