

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 ²)
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 dm² of food contact surface (mg/dm²) (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-Mass Spectrometry (ICP-MS) for the elemental contents.

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. 7191207897-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. ²) 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 134681-D

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
PASS
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. 4204221, 4204227

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-CHM19-03-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