

DECLARATION OF FOOD CONTACT COMPLIANCE

Glove Type : Latex Powdered Glove

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

Shelf life : 5 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 "Latex Powdered 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, 5 mins	<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 Latex powder glove did not meet 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) " for 3% Acetic Acid.

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).

Result:

Specific Migration of Heavy Metals (in 3% Acetic Acid) for the "Latex Powdered 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. Zinc, Zn	40 °C, 2 hours	0.1	<25

Based on the above results, the "Latex Powdered 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. 7191192769-CHM18-06-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



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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: Latex Powdered 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 143502-B

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 : Latex Powdered 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. 3920560

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 12868:1999)

Method of Test:

Sample preparation with reference to BS EN 12868:1999 : 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 “Latex powdered” Sample

Test	BS EN 12868: 1999 (E), N-Nitrosamines and N-Nitrosatable Release and Tolerances	Inferred Result
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. 7191160481-CHM17-01A-TQY, 7191160481-CHM17-01B-TQY

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 “Latex Powdered Glove” Sample

Type of simulant	Testing Condition	BfR XXI Category 3 Requirement for Global Migration (mg/dm ²)
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 “Latex Powdered Glove” Sample

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

Table 3 : Specific Migration of Formaldehyde in Food simulant for “Latex Powdered 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.



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Result: (cont'd)

Table 4 : Specific Migration of Primary Arylamines in Food simulant for “Latex Powdered 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 “Latex Powdered 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 “Latex Powdered Glove ” Sample

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

The method detection limit was 0.02 µg/dm²

Table 7 : Lead and Zine Contents for “Latex Powdered Glove” Sample

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

Based on the above results, the “Latex Powdered Glove” sample met the specific migration requirements for the above tests under Commission Regulation (EU) No 10/2011.

Reference Report : Test Report No. 7191196436-CHM18-01-TSL

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

Best Regards,

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