

DECLARATION OF FOOD CONTRACT 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
- ✚ **Overall Migration Content with Modified Polyphenylene Oxide (MPPO / Tenax)**
According to BS EN 1186-13:2002 – Plastics- Test methods for overall migration at high temperatures as reference.

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, 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 |
| 6. Tenax (60-80 mesh) [poly(2,6-diphenyl-p-phenylene oxide)] | 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) for the elemental contents.

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. Barium, Ba | 40 °C, 2 hours | 0.1 | <1 |
| 2. Cobalt, Co | 40 °C, 2 hours | 0.05 | <0.05 |
| 3. Copper, Cu | 40 °C, 2 hours | 0.1 | <5 |
| 4. Iron, Fe | 40 °C, 2 hours | 0.1 | <48 |
| 5. Lithium, Li | 40 °C, 2 hours | 0.1 | <0.6 |
| 6. Manganese, Mn | 40 °C, 2 hours | 0.1 | <0.6 |
| 7. 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. 7191162402-CHM17-01-TSL, 7191162401-CHM17-01-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

Sovent: 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 128177-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 : 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 (4% acetic acid) FAIL
8. Residue after Evaporation Test (Water & 20% ethanol)
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. 4204218, 4204266

Test carried out at : SGS (Thailand) Limited

Best Regards,

Ms. Vanlinee Laohachaiyakul
Product Manager

Approved By:

Ms. Rosna Yensuk
Laboratory manager

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. 7191160482-CHM17-01A-TQY, 7191160482-CHM17-01B-TQY

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

Best Regards,

Ms. Vanlinee Laohachaiyakul
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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.



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. 7191209183-CHM19-01-TSL

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

Best Regards,

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