TEST REPORT: 7191291948-CHM22-01-TSL

PSB Singapore

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SUBJECT

Overall & Specific Migration tests for "Powder Free Latex Examination Glove Double Chlorination" Sample

CLIENT

WRP Asia Pacific Sdn Bhd
Lot 1. Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi
43900 Sepang, Selangor Darul Ehsan
Malaysia

Attn : Mr Jamil Norizan

SAMPLE SUBMISSION DATE

27 Jul 2022

DESCRIPTION OF SAMPLE

One packet of glove sample labelled as follows was received.

S/N	Product Name	Glove Size	Quantity
1	Powder Free Latex Examination Glove Double Chlorination	Medium (M)	50 pcs

Picture 1: "Powder Free Latex Examination Glove Double Chlorination" Sample as received

DATE OF ANALYSIS

29 Aug 2022 – 10 Oct 2022

TÜV SÜD PSB

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METHOD OF TEST

The sample was analysed for the following tests according to EU ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs.

1. Preparation of Test Specimen

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

2. Overall Migration Tests:

a) Aqueous Food Simulant (3% Acetic Acid, 10% Ethanol, 20% Ethanol & 50% Ethanol)

According to BS EN 1186-9:2002 – Test Methods for overall migration into aqueous food simulants by article filling.

b) Fatty Food Simulant (Olive Oil):

According to BS EN 1186-8:2002 – Test Methods for overall migration into olive oil by article filling.

3. Specific Migration Content using Aqueous Food Stimulant (3% Acetic Acid)

According to EU ResAP (2004) 4 with reference to EN 1186-9: 2002 – Test Methods for overall migration into aqueous food stimulants by article filling.

a) Specific Migration of Primary Aromatic Amines (PAAs)

The simulant was extracted by organic solvent and analysed by Gas Chromatography Mass Spectrometry (GC-MS) after proper treatment.

b) Specific Migration of Nitrosamines and Nitrosatable subtances

The simulant was extracted by organic solvent and analysed by Gas Chromatography combined with the Nitrogen Chemiluminescence Detector (GC-NCD) after proper treatment.

RESULTS

Table 1 : Overall Migration Content with Food Simulants for the "Powder Free Latex Examination Glove Double Chlorination" Sample

Type of Simulant	Testing Condition*1	Surface Area (dm^2)	Volume of Extractant (ml)	Overall Migration (mg/dm^2)) *2	Resolution ResAP(2004)4 Requirement for Overall Migration Content (mg/dm^2)
1. 10% Ethanol	40 °C, 2 hours	4.83	245	2.6	<10
2. 3% Acetic Acid	40 °C, 2 hours	4.85	245	2.6	<10
3. 20% Ethanol	40 °C, 2 hours	4.83	245	2.8	<10
4. 50% Ethanol	40 °C, 2 hours	4.89	245	4.8	<10
5. Vegetable Oil (Olive Oil)	40 °C, 2 hours	4.85	245	<1.0	<10

*1 The test condition was specified by the client.
*2 Analytical tolerance is 2 mg/dm^2 or 12 mg/kg for aqueous simulants and 3 mg/dm^2 or 20 mg/kg for fatty food simulants.

Based on the above results, the "Powder Free Latex Examination Glove Double Chlorination" sample met the overall migration requirement under Resolution ResAP(2004)4 – "Rubbers products intended to come into contact with foodstuffs" shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams of total constituents released per dm^2 of food contact surface (mg/dm^2) (overall migration limit)".

RESULTS *(cont'd)*

Table 2: Specific Migration of Primary Aromatic Amines in Food Simulant for "Powder Free Latex Examination Glove Double Chlorination" Sample

Type of Simulant	Testing Condition	Volume of Extractant (ml)	Specific Migration Content of Primary Aromatic Amines (PAAs) (mg/kg)	Regulation EU ResAP (2004) 4 Requirement for Specific Migration of PAA (mg/kg)
3% Acetic Acid	40 °C, 2 hours	245	Not Detected [a]	Not Detected

[a)] The method detection limit was 0.01 mg/kg (milligram per kilogram food in contact with).

Based on the above results, the "Powder Free Latex Examination Glove Double Chlorination" sample met the requirement for Primary Aromatic Amines under EU ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs.

Table 3: Specific Migration of Nitrosamines in Food Simulant for "Powder Free Latex Examination Glove Double Chlorination" Sample

Type of Simulant	Testing Condition	Volume of Extractant (ml)	Specific Migration Content of Nitrosamines (mg/kg)	Regulation EU ResAP (2004) 4 Requirement for Specific Migration of Nitrosamines (mg/kg)
3% Acetic Acid	40 °C, 2 hours	245	Not Detected [b]	< 0.01

[b)] The method detection limit was 0.01 mg/kg.

Table 4: Specific Migration of Nitrosatable substances in Food Simulant for "Powder Free Latex Examination Glove Double Chlorination" Sample

Type of Simulant	Testing Condition	Volume of Extractant (ml)	Specific Migration Content of Nitrosatable substances (mg/kg)	Regulation EU ResAP (2004) 4 Requirement for Specific Migration of Nitrosatable substances (mg/kg)
3% Acetic Acid	40 °C, 2 hours	245	Not Detected [c]	< 0.1

[c)] The method detection limit was 0.1 mg/kg.

Based on the above results, the "Powder Free Latex Examination Glove Double Chlorination" sample met the requirement for Nitrosamines and Nitrosatable substances under EU ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs.

MS TAN SER LING
TECHNICAL EXECUTIVE

DR LI SIHAI
AVP / SENIOR CHEMIST
MICROCONTAMINATION DIAGNOSIS
CHEMICAL & MATERIALS

PSB Singapore

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Effective 26 January 2021