



WRP Asia Pacific Sdn Bhd

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DECLARATION OF FOOD CONTACT COMPLIANCE

Regulation : Commission Regulation (EU) No. 10/2011

Type of Glove : Nitrile Powder Free Examination Gloves (Orange)

Intended Use : Donning to Prevent the Likelihood of Food Contamination during the Preparation or Handling and Applies to every Food Handler.

Validity : Five (5) Years

Date of Analysis : 7th March – 30th March 2022

OVERALL MIGRATION

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 Test:

2.1) 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.

2.2) Fatty Food Simulant (Olive Oil)

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

3. Specification 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.

3.1) 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.

3.2) Specific Migration of Nitrosamines and Nitrosatable Substances

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



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RESULTS:

1) Overall Migration Content with Food Simulants for the “Nitrile Powder Free Examination Gloves (Orange)” Sample

Type of Simulant	Testing Condition	Resolution ResAP(2004)4 Requirement for Overall Migration Content (mg/dm ²)
10% Ethanol	40 °C, 2 hours	<10
3% Acetic Acid	40 °C, 2 hours	<10
20% Ethanol	40 °C, 2 hours	<10
50% Ethanol	40 °C, 2 hours	<10
Vegetable Oil (Olive Oil)	40 °C, 2 hours	<10

Based on the above result, the “Nitrile Powder Free Examination Gloves (Orange)” 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 dm² of food contact surface mg/dm² (overall migration limit)”, except for 3% Acetic Acid & 50% Ethanol.

2) Specific Migration of Primary Aromatic Amines in Food Simulant for “Nitrile Powder Free Examination Gloves (Orange)” Sample

Type of Simulant	Testing Condition	Volume of Extractant (ml)	Specific Migration Content of Primary Aromatic Amines (PAAs) mg/kg	Resolution ResAP(2004)4 Requirement for Specific Migration of PAA (mg/kg)
3% Acetic Acid	40 °C, 2 hours	280	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 result, the “Nitrile Powder Free Examination Gloves (Orange)” sample meets the requirement for Primary Aromatic Amines under EU ResAP(2004)4 on rubber products intended to come into contact with foodstuffs.



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3) Specific Migration of Nitrosamines in Food Simulant for “Nitrile Powder Free Examination Gloves (Orange)” Sample

Type of Simulant	Testing Condition	Volume of Extractant (ml)	Specific Migration Content of Nitrosamines (mg/kg)	Resolution ResAP(2004)4 Requirement for Specific Migration of Nitrosamines (mg/kg)
3% Acetic Acid	40 °C, 2 hours	280	Not Detected ^b	< 0.01

b) The method detection limit was 0.01 mg/kg

4) Specific Migration of Nitrosatable substances in Food Simulant for “Nitrile Powder Free Examination Gloves (Orange)” Sample

Type of Simulant	Testing Condition	Volume of Extractant (ml)	Specific Migration Content of Nitrosatable substances (mg/kg)	Resolution ResAP(2004)4 Requirement for Specific Migration of Nitrosatable substances (mg/kg)
3% Acetic Acid	40 °C, 2 hours	280	Not Detected ^c	< 0.1

c) The method detection limit was 0.01 mg/kg

Based on the above result, the “Nitrile Powder Free Examination Gloves (Orange)” sample meets the requirement for Nitrosamines and Nitrosatable substances under EU ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs.

End of report

Reference Report : Test Report No.: 7191280776-CHM22-02-TSL

Test Facility : TUV SUD PSB Pte. Ltd., Singapore

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