

TEST REPORT: 7191263804-CHM21-TSL

Date: 27 JUL 2021

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SUBJECT

Overall & Specific Migration for "Nitrile Examination Gloves Powder Free, LYDUS"
Sample

CLIENT

Nathan Trading Co., Ltd.
58 Moo 12 Palan Sub-district
Nathan District, Ubon Ratchathani
34170, Thailand

SAMPLE SUBMISSION DATE

03 Jun 2021

DESCRIPTION OF SAMPLE

One packet of glove sample labelled as follows was received. The test was confirmed to be analysed on 02 Jul 2021.

S/N	Product Description	Brand/Model	Size	Colour	Lot No.	Expiry Date	Sample received (pieces)	Manufacturer
1	Nitrile Examination Gloves Powder Free	LYDUS	L	Blue	MG202006261	May 2023	60	Nathan Trading Co., Ltd



Picture 1: "Nitrile Examination Gloves Powder Free, LYDUS, Lot No: MG202006261" Sample as received

DATE OF ANALYSIS

07 Jul 2021 – 27 Jul 2021



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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 simulants by article filling.

a) Specific Migration of Primary Aromatic Amines (PAAs)

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

b) Specific Migration of Nitrosamines and Nitrosatable substances

The stimulant 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 “Nitrile Examination Gloves Powder Free, LYDUS, Lot No: MG202006261” Sample

Type of Simulant	Testing Condition*	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, 30 minutes	5.08	255	<1.0	<10
2. 3% Acetic Acid	40 °C, 30 minutes	4.97	255	5.0	<10
3. 20% Ethanol	40 °C, 30 minutes	5.01	255	1.1	<10
4. 50% Ethanol	40 °C, 30 minutes	5.08	255	2.9	<10
5. Vegetable Oil (Olive Oil)	40 °C, 30 minutes	5.06	255	<1.0	<10

* The test condition was specified by the client.

² Analytical tolerance is 2 mg/dm² or 12 mg/kg for aqueous simulants and 3 mg/dm² or 20 mg/kg for fatty food simulants.

Based on the above result, the “Nitrile Examination Gloves Powder Free, LYDUS, Lot No: MG202006261” 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”).

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RESULTS (Cont'd)**Table 2: Specific Migration of Primary Aromatic Amines in Food Simulant for "Nitrile Examination Gloves Powder Free, LYDUS, Lot No: MG202006261" 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, 30 mins	255	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 "Nitrile Examination Gloves Powder Free, LYDUS, Lot No: MG202006261" glove sample meets 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 "Nitrile Examination Gloves Powder Free, LYDUS, Lot No: MG202006261" 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, 30 mins	255	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 "Nitrile Examination Gloves Powder Free, LYDUS, Lot No: MG202006261" 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, 30 mins	255	Not Detected ^c	< 0.1

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

Based on the above results, the "Nitrile Examination Gloves Powder Free, LYDUS, Lot No: MG202006261" glove sample meets the requirement for Nitrosamines and Nitrosatable substances under EU ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs..

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Effective 26 January 2021

