# NM Laboratory Sdn Bhd S63845-P

78 & 80, Lorong Perda Selatan 1, Bandar Perda, 14000 Bukit Mertajam, PENANG, MALAYSIA. t 604-538 8081 • 538 8082 • 537 8082 | f 604-537 8084 | e enquiry@nmlab.com.my www.nmlab.com.my



# TEST REPORT

**Report No.** : IP1601-0237

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Date of Issue : 21/01/2016

### The following sample(s) was(were) identified by the customer as :

PRODUCT DESCRIPTION: POWDER FREE NITRILE

EXAMINATION GLOVE.

BLUE COLORED.

NON-STERILE.

LOT#: 63-225PF

SIZE: S

QUANTITY: 6 PIECES

Date of Sample Received : 14/01/2016

Date of Testing : 14/01/2016 to 21/01/2016

#### Objective :

To perform overall migration for Glove sample according to FDA 21 CFR Part 177.2600-Rubber articles intended for repeated use.

#### Test Procedure as per CFR 177.2600

Glove sample was extracted at below specific condition:

- a) Distilled water at reflux temperature for 7 hours and additional 2 hours
- b) n-Hexane at reflux temperature for 7 hours and additional 2 hours

The extract was then evaporated to dryness and the overall migration was then measured using an analytical balance.

Test Performed by : Nurul Fitriyah

Signed for and on behalf of NM LABORATORY SDN. BHD.

Que

Yeap Cheo Mooi, M.Sc., AMIC Consulting Chemist IKM No. A/1913/4300/2002

NM Laboratory Sdn Bhd 563845-P 78 & 80, Lorong Perda Selatan 1, Bandar Perda, 14000 Bukit Mertajam, PENANG, MALAYSIA. t 604-538 8081 • 538 8082 • 537 8082 f 604-537 8084 e enquiry@nmlab.com.my www.nmlab.com.my



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### Sample Photograph(s):

Date Of Issue : 21/01/2016



## Overall migration for Glove sample

Extraction Conditions	Overall migration for Glove sample (mg/in²)	Requirements of 21 CFR Part 177.2600 Rubber articles intended for repeated use for Overall migration for Glove sample (mg/in²)	Inferred Result
Distilled water at reflux temperature for 7 hours	ND(<0.5)	20	Comply
Distilled water at reflux temperature for 9 hours (additional 2 hours from initial 7 hours extraction)	ND(<0.5)	NML NML NML NML NML NML NML L NML NML NML NML NML NML NML NML NML NML NML NML NML NML NML NML NML	Comply
n-Hexane at reflux temperature for 7 hours	0.7	L NML NML NML 175 L NML NML NML NML	Comply
n-Hexane at reflux temperature for 9 hours (additional 2 hours from initial 7 hours extraction)	ND(<0.5)	NML	Comply

Signed for and on behalf of NM LABORATORY SDN. BHD.



Yeap Cheo Mooi, M.Sc., AMIC Consulting Chemist IKM No. A/1913/4300/2002

- End of Report -

NM Laboratory Sdn Bhd 563645-P 78 & 80, Lorong Perda Selatan 1, Bandar Perda, 14000 Bukit Mertajam, PENANG, MALAYSIA. t 604-538 8081 • 538 8082 • 537 8082 f 604-537 8084 e enquiry@nmlab.com.my www.nmlab.com.my



# NM Laboratory Sdn Bhd 5635645-P

78 & 80, Lorong Perda Selatan 1, Bandar Perda, 14000 Bukit Mertajam, PENANG, MALAYSIA. t 604-538 8081 • 538 8082 • 537 8082 | f 604-537 8084 | e enquiry@nmlab.com.my



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