



WRP Asia Pacific Sdn Bhd

14 7 8 17 V

Lot 1, Jalan 3, Kawasan Perusahaan

Bandar Baru Salak Tinggi,

43900 Sepang,

Selangor Darul Ehsan, MALAYSIA

Office +60-3-8706 1486

Facsimile +60-3-8706 1557

Email customer_wrp@wrpworld.com

Website www.wrpworld.com

DECLARATION OF FOOD CONTACT COMPLIANCE

Regulation : 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

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

Validity : Five (5) Years

Date of Analysis : 25th May – 31st May 2022

OVERALL MIGRATION

METHOD OF TEST:

The sample was analysed for the following tests according to FDA 21 CFR 177.2600 (e) & (f).

1. Preparation of Test Specimen

The sample was cut and tested as received.

2. Total Extractives with Food Stimulants (Ultrapure Water, n-Hexane):

The sample was extracted with the food stimulants and extracted at the reflux temperature for 7 hours and then for another further succeeding 2 hours. The extract was then evaporated to dryness and the total extractives were then measures using an analytical balance.



WRP Asia Pacific Sdn Bhd

14 7 8 17 V

Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinggi,
43900 Sepang,
Selangor Darul Ehsan, MALAYSIA

Office +60-3-8706 1486

Facsimile +60-3-8706 1557

Email customer_wrp@wrpworld.com

Website www.wrpworld.com

RESULTS:

Type of Simulant	Surface Area (in ²)	Volume of Extractant (ml)	Total Extractives (mg/ in ²)	FDA 21 CFR 177.2600 (e) & (f), Total Extractives Requirements (mg/ in ²)	Inferred Result
1. Ultrapure Water at reflux temperature for 7 hours	209.42	250	1.0	≤ 20	PASS
2. Ultrapure Water at reflux temperature for succeeding 2 hours	209.42	250	0.5	≤ 1	PASS
3. n-Henaxe at reflux temperature for 7 hours	211.48	250	0.5	≤ 175	PASS
4. -Henaxe at reflux temperature for succeeding 2 hours	211.48	250	0.1	≤ 4	PASS

End of report


Reference Report : Test Report No.: 7191285772-CHM22-TSL_CR1

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

Prepared by,

Approved by,


.....
Rosnaini Rashidin
Product Management Manager


.....
Angie Ng Geok Chin
Research & Development Manager