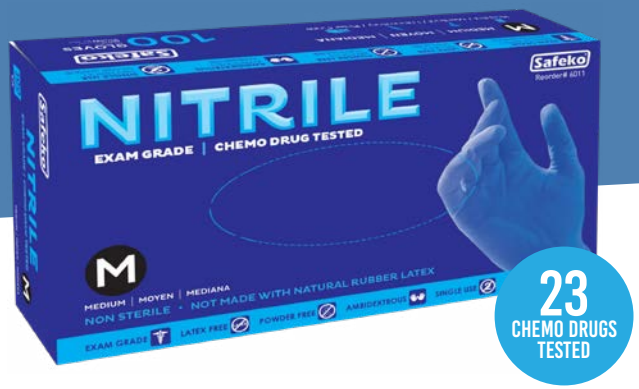
SAFEKO Nitrile Chemo Fentanyl Examination

Tested for Use with Chemotherapy Drugs and Fentanyl Resistant



100 Gloves / Box - Medical Grade
Hartalega 510(K) - K200019

Active Ingredient
Acrylonitrile Butadiene Rubber (Nitrile)

Storage
Store in a cool, dry place. Avoid direct sunlight, luorescent lighting. Store below 30ºC (100F)

- ASTM D6978
- ASTM D6319
- ASTM F1671
- ASTM D6124
- FDA 21 CFR 177
- 510(K) - K200019
- COLOR: Citrate (Blue)
- AQL: 1.5
- 100% Latex Free
- POWDER: Powder Free
- TEXURED: Fingers Only
- Product Code: LZA, LZC, QDO

PRODUCT INFORMATION

SIZE: Small
REORDER #: 6010
SKU: SK-1009-NEF-BL-S-100

SIZE: Medium
REORDER #: 6011
SKU: SK-1009-NEF-BL-M-100

SIZE: Large
REORDER #: 6012
SKU: SK-1009-NEF-BL-L-100

SIZE: X-Large
REORDER#: 6013
SKU: SK-1009-NEF-BL-XL-100

PACKING INFORMATION

120 Cases (1,200 boxes) / Pallet

4,000 Cases (40,000 boxes) / Truck

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (μg/cm²/minute)	OTHER OBSERVATIONS
5-Azacitidine, 25 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation
Carboplatin (Paraplatin), 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	23.3 (23.3, 25.6, 24.5)	0.3 (0.2, 0.2, 0.5)	Slight swelling and no degradation
Cisplatin,1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (μg/cm²/minute)	OTHER OBSERVATIONS
Cyclophosphamide, 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Dacarbazine, 10mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Docetaxel, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Doxorubicin, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Epirubicin (Ellence), 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Fluorouracil (Adrucil), 50 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Gemcitabine (Gemzar), 38 mg/ml (38,000 ppm)	>240	N/A	Slight swelling and no degradation
Ifosfamide, 50 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Irinotecan, 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	>240	N/A	Slight swelling and no degradation
Mitoxantrone, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Oncovin (Vincristine Sulfate), 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Oxaliplatin, 5 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	>240	N/A	Slight swelling and no degradation
Thiotepa (THT), 10 mg/ml (10,000 ppm)	58.2 (58.2, 58.9, 66.6)	0.4 (0.4, 0.3, 0.4)	Slight swelling and no degradation
Vinorelbine, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation

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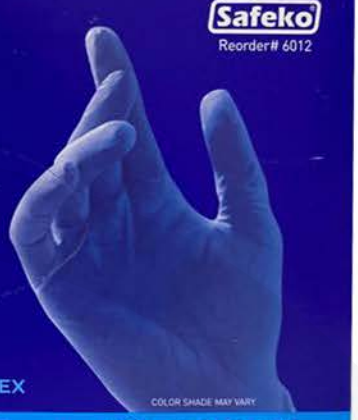
203.930.2154 sales@liloclean.com

NITRILE

EXAM GRADE | CHEMO DRUG TESTED

Safeko®
Reorder# 6012



L

LARGE | GRAND | GRANDE

NON STERILE • NOT MADE WITH NATURAL RUBBER LATEX

EXAM GRADE | LATEX FREE | POWDER FREE | AMBIDEXTROUS | SINGLE USE | 100 BLUE GLOVES

ASTM F1671 STANDARD TEST METHOD FOR RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD - BORN PATHOGENS USING PHI - X174 BACTERIOPHAGE PENETRATION AS A TEST SYSTEM

ASTM D6319 STANDARD SPECIFICATION FOR NITRILE EXAMINATION GLOVES FOR MEDICAL APPLICATION

COMPLIES WITH FDA 21 CFR 177.2600 FOR USE IN CONTACT WITH FOOD

- NOT MADE WITH NATURAL RUBBER LATEX
- SINGLE USE • DO NOT REUSE
- EXAMINATION GRADE • AQL 1.5

WARNING: Carmustine and Thiotepa, at the tested concentration, degraded the Safeko nitrile glove at 12.8 minutes and 45.7 minutes, respectively.

Gloves used for protection against chemotherapy drug exposure should be selected specifically for the type of chemicals being used. Due to the variety and concentration of chemotherapy drugs used in treatments, the resistance table shown does neither warrant nor imply the safe use of the gloves against chemotherapy drug resistance in every case. The safe use of gloves in chemotherapy treatment is solely the decision of clinicians authorized to make such a decision.

Storage: Store under cool, dry conditions. Avoid direct sunlight.

TESTED FOR RESISTANCE TO PERMEATION BY CHEMOTHERAPY DRUGS AS PER ASTM D6978

TESTED CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Minutes)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	12.8
Cisplatin, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 minutes
Cyclophosphamide, 20 mg/ml (20,000 ppm)	No breakthrough up to 240 minutes
Dacarbazine, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 minutes
Doxorubicin HCl (Adriamycin), 2 mg/ml (2,000 ppm)	No breakthrough up to 240 minutes
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	No breakthrough up to 240 minutes
Fluorouracil (Adrucil), 50 mg/ml (50,000 ppm)	No breakthrough up to 240 minutes
Methotrexate, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 minutes
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 minutes
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	No breakthrough up to 240 minutes
Thiotepa (THT), 10 mg/ml (10,000 ppm)	45.7
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 minutes

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EXAM GRADE | LATEX FREE | POWDER FREE | AMBIDEXTROUS | SINGLE USE

L LARGE | GRAND | GRANDE

Hospital / Medical / Laboratory / Elder Care

Safeko®

100 GLOVES

Safeko®

Lot#

Manufacture Date#

100 Gloves (by weight)

Item#/d'Article
SK-1009-NEF-BLU-100

- SINGLE USE
- DO NOT REUSE
- EXAMINATION GRADE
- AQL 1.5
- NOT MADE WITH NATURAL RUBBER LATEX

MADE IN MALAYSIA

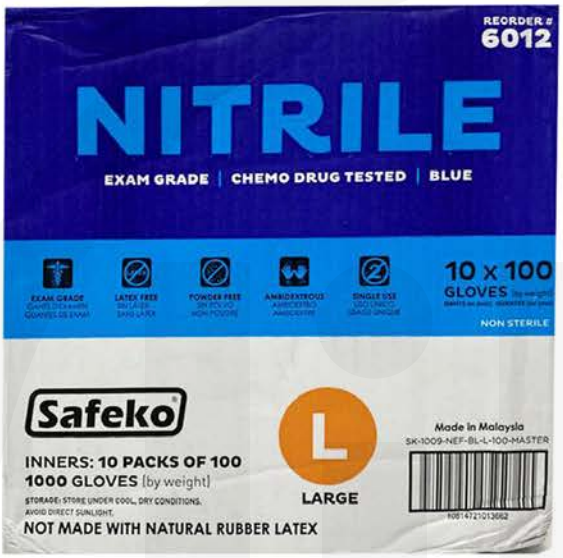
Safeko®

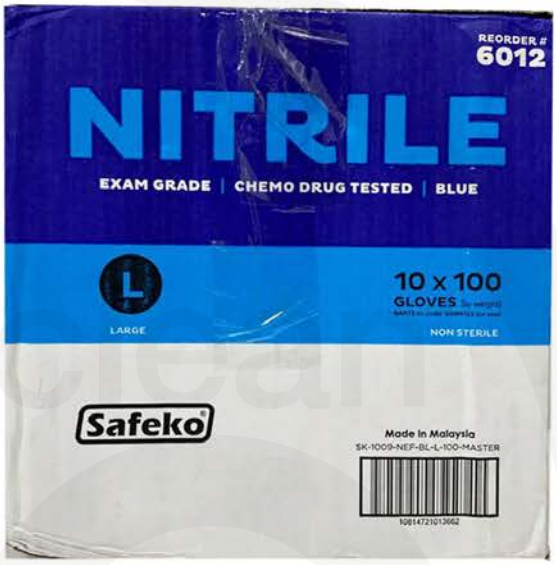
NITRILE **L**

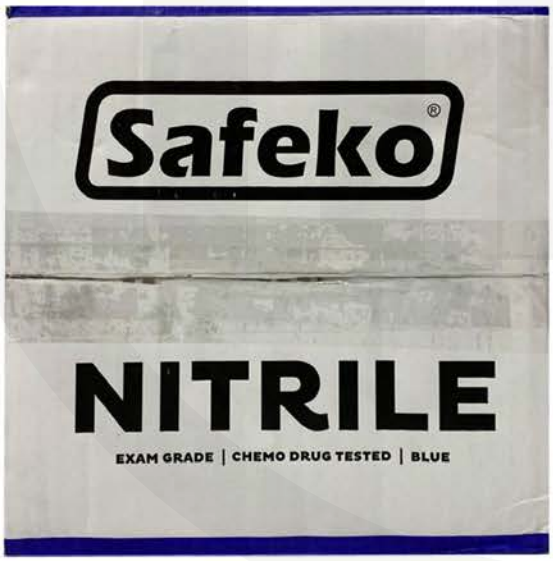
EXAM GRADE | CHEMO DRUG TESTED

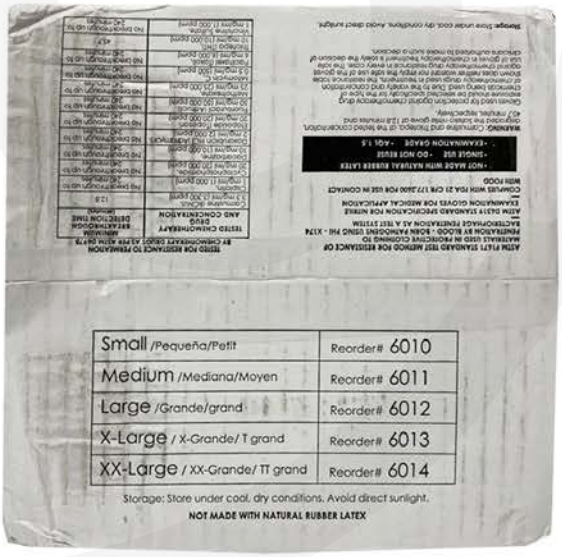
100 GLOVES BLUE

LARGE | GRAND | GRANDE


REORDER #
6012
NITRILE
EXAM GRADE | CHEMO DRUG TESTED | BLUE
10 x 100
GLOVES
NON STERILE
Safeko
L
LARGE
Made in Malaysia
SK-1009-NEF-BL-L-100-MASTER
INNERS: 10 PACKS OF 100
1000 GLOVES (by weight)
STORAGE: STORE UNDER COOL, DRY CONDITIONS.
AVOID DIRECT SUNLIGHT.
NOT MADE WITH NATURAL RUBBER LATEX


REORDER #
6012
NITRILE
EXAM GRADE | CHEMO DRUG TESTED | BLUE
L
LARGE
10 x 100
GLOVES
NON STERILE
Safeko
Made in Malaysia
SK-1009-NEF-BL-L-100-MASTER


Safeko
NITRILE
EXAM GRADE | CHEMO DRUG TESTED | BLUE


Small /Pequeña/Petit
Reorder# 6010
Medium /Mediana/Moyen
Reorder# 6011
Large /Grande/grand
Reorder# 6012
X-Large / X-Grande/ T grand
Reorder# 6013
XX-Large / XX-Grande/ TT grand
Reorder# 6014
Storage: Store under cool, dry conditions. Avoid direct sunlight.
NOT MADE WITH NATURAL RUBBER LATEX

September 5, 2019

▪TEST REPORT▪

PN 148358A

PHARMACEUTICAL SERVICES

Prepared For:

Siti Iylia Zarith Binti Hasan
Hartalega NGC Sdn. Bhd.
No. 1 Persiaran Tanjung
Kawasan Perindustrian Tanjung
43900 Sepang
Selangor Darul Ehsan
Malaysia

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

Rev 101218

September 5, 2019

Siti Iylia Zarith Binti Hasan
Hartalega NGC Sdn. Bhd.

SUBJECT: Permeation testing per ASTM D 6978 on sample submitted by the above company.

RECEIVED: One (1) glove type identified as; Nitrile Powder Free Examination Glove Tested for use with Chemotherapy Drug and Fentanyl Citrate (Blue), Batch No A04/20190424/M, Serial No 2190289031.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
5-Azacitidine, 25 mg/ml (25,000 ppm)	USP; Lot# R056T0; Expiration 02/2020
Carboplatin (Paraplatin), 10 mg/ml (10,000 ppm)	Teva; Lot# 17I110A; Expiration 09/2019
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Lot # 018M4057V; Exp. 02/2020
Cisplatin, 1 mg/ml (1,000 ppm)	WG Critical Care; Lot# 8D05666; Expiration 09/2019
Cyclophosphamide, 20 mg/ml (20,000 ppm)	Sandoz Inc.; Lot# 17101325; Expiration 10/12/2019
Dacarbazine, 10 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Docetaxel, 10 mg/ml (10,000 ppm)	LC Labs; Lot# BDC-117; Expiration 01/2025
Doxorubicin, 2 mg/ml (2,000 ppm)	Actavis Pharma; Lot# 7LJ5121; Expiration 07/2019
Epirubicin (Ellence), 2 mg/ml (2,000 ppm)	USP; Lot# R06270; Lot# Expiration 02/2020
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fluorouracil (Adrucil), 50 mg/ml (50,000 ppm)	Intas Pharmaceuticals; Lot# PX04154; Expiration 07/2019
Gemcitabine (Gemzar), 38 mg/ml (38,000 ppm)	LC Labs; Lot# GMC-105; Expiration 1/6/2025
Ifosfamide, 50 mg/ml (50,000 ppm)	USP; Lot# H0F233; Expiration 05/2020
Irinotecan, 20 mg/ml (20,000 ppm)	LC Labs; Lot# RCN-105; Expiration 03/2024
Methotrexate, 25 mg/ml (25,000 ppm)	Sigma Aldrich; Lot# LRAA9182; Expiration 04/2020
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# MKCD6056; Expiration 03/2020
Mitoxantrone, 2 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# MKBR2210V; Expiration 04/2021
Oncovin (Vincristine Sulfate), 1 mg/ml (1,000 ppm)	USP; Lot# Y06331; Lot# 05/2020
Oxaliplatin, 5 mg/ml (5,000 ppm)	LC Labs; Lot# XAP-111; 12/2019
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	Hospira; Lot# F066865AA; Expiration 08/31/2020
Thiotepa (THT), 10 mg/ml (10,000 ppm)	Sigma Aldrich; Lot# SLBZ3176, Expiration 05/2020
Vinorelbine, 10 mg/ml (10,000 ppm)	USP; Lot# R087S0; Expiration 04/2021
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	USP; Lot# Y06331; Lot# 05/2020

COLLECTION MEDIA:
Table 2. Collection Media for Test Drug

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
5-Azacitidine, 25 mg/ml (25,000 ppm)	Distilled Water
Carboplatin (Paraplatin), 10 mg/ml (10,000 ppm)	Distilled Water
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide, 20 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine, 10 mg/ml (10,000 ppm)	Distilled Water
Docetaxel, 10 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin, 2 mg/ml (2,000 ppm)	Distilled Water
Epirubicin (Ellence), 2 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil (Adrucil), 50 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Gemcitabine (Gemzar), 38 mg/ml (38,000 ppm)	Distilled Water
Ifosfamide, 50 mg/ml (50,000 ppm)	Distilled Water
Irinotecan, 20 mg/ml (20,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2 mg/ml (2,000 ppm)	Distilled Water
Oncovin (Vincristine Sulfate), 1 mg/ml (1,000 ppm)	Distilled Water
Oxaliplatin, 5 mg/ml (5,000 ppm)	Distilled Water
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa (THT), 10 mg/ml (10,000 ppm)	Distilled Water
Vinorelbine, 10 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff

DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING DRUG	WAVELENGTH (nm)
5-Azacitidine, 25 mg/ml (25,000 ppm)	201
Carboplatin (Paraplatin), 10 mg/ml (10,000 ppm)	192
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1 mg/ml (1,000 ppm)	199
Cyclophosphamide, 20 mg/ml (20,000 ppm)	200
Dacarbazine, 10 mg/ml (10,000 ppm)	320
Docetaxel, 10 mg/ml (10,000 ppm)	231
Doxorubicin, 2 mg/ml (2,000 ppm)	232
Epirubicin (Ellence), 2 mg/ml (2,000 ppm)	233 & 253
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	205
Fluorouracil (Adrucil), 50 mg/ml (50,000 ppm)	269
Gemcitabine (Gemzar), 38 mg/ml (38,000 ppm)	202
Ifosfamide, 50 mg/ml (50,000 ppm)	200
Irinotecan, 20 mg/ml (20,000 ppm)	200
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2 mg/ml (2,000 ppm)	242
Oncovin (Vincristine Sulfate), 1 mg/ml (1,000 ppm)	220
Oxaliplatin, 5 mg/ml (5,000 ppm)	199
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	231
Thiotepa (THT), 10 mg/ml (10,000 ppm)	199
Vinorelbine, 10 mg/ml (10,000 ppm)	212
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: Nitrile Powder Free Examination Glove Tested for use with Chemotherapy Drug and Fentanyl Citrate (Blue), Batch No A04/20190424/M, Serial No 2190289031.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
5-Azacitidine	0.054	0.052	0.057	0.054
Carboplatin (Paraplatin)	0.057	0.054	0.056	0.055
Carmustine (BCNU)	0.054	0.055	0.054	0.055
Cisplatin	0.054	0.053	0.054	0.054
Cyclophosphamide	0.054	0.055	0.056	0.055
Dacarbazine	0.059	0.052	0.055	0.055
Docetaxel	0.053	0.051	0.057	0.054
Doxorubicin	0.054	0.056	0.056	0.056
Epirubicin (Ellence)	0.055	0.056	0.055	0.055
Etoposide (Toposar)	0.060	0.057	0.055	0.057
Fluorouracil (Adrucil)	0.053	0.057	0.055	0.055
Gemcitabine (Gemzar)	0.055	0.056	0.054	0.055
Ifosfamide	0.056	0.057	0.054	0.056
Irinotecan	0.055	0.057	0.053	0.055
Methotrexate	0.055	0.056	0.058	0.056
Mitomycin C	0.055	0.057	0.057	0.056
Mitoxantrone	0.057	0.054	0.055	0.055
Oncovin (Vincristine Sulfate)	0.051	0.054	0.053	0.053
Oxaliplatin	0.053	0.055	0.057	0.055
Paclitaxel (Taxol)	0.054	0.055	0.057	0.055
Thiotepa (THT)	0.057	0.054	0.054	0.055
Vinorelbine	0.057	0.054	0.056	0.056
Vincristine Sulfate	0.054	0.052	0.056	0.054
Weight/Unit Area (g/m²)	**56.5**			

RESULTS:

Table 5.1 Permeation Test Results on testing of: Nitrile Powder Free Examination Glove Tested for use with Chemotherapy Drug and Fentanyl Citrate (Blue), Batch No A04/20190424/M, Serial No 2190289031.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
5-Azacitidine, 25 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation
Carboplatin (Paraplatin), 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	23.3 (23.3,25.6,24.5)	0.3 (0.2,0.2,0.5)	Slight swelling and degradation
Cisplatin, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation

RESULTS cont.:

Table 5.2 Permeation Test Results on testing of: Nitrile Powder Free Examination Glove Tested for use with Chemotherapy Drug and Fentanyl Citrate (Blue), Batch No A04/20190424/M, Serial No 2190289031.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Cyclophosphamide, 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Dacarbazine, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Docetaxel, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Doxorubicin, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Epirubicin (Ellence), 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Fluorouracil (Adrucil), 50 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Gemcitabine (Gemzar), 38 mg/ml (38,000 ppm)	>240	N/A	Slight swelling and no degradation
Ifosfamide, 50 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Irinotecan, 20 mg/ml (20,000 ppm)	>240	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	>240	N/A	Slight swelling and no degradation
Mitoxantrone, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Oncovin (Vincristine Sulfate), 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Oxaliplatin, 5 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	>240	N/A	Slight swelling and no degradation
Thiotepa (THT), 10 mg/ml (10,000 ppm)	58.2 (58.2,58.9,66.6)	0.4 (0.4,0.3,0.4)	Slight swelling and degradation
Vinorelbine, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

October 15, 2019

▪TEST REPORT▪

PN 148358G

Pharmaceutical Services

Prepared For:

Siti Iylia Zarith Binti Hasan
Hartalega NGC SDN BHD
No.1 Persiaran Tanjung
Kawasan Perindustrian Tanjung
43900 Sepang, Selangor
Malaysia

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana Barbur
Vice President, Analytical & Chemical Services

Rev 101218

October 15, 2019

Siti Iylia Zarith Binti Hasan
Hartalega NGC SDN BHD

SUBJECT: Permeation testing per ASTM D 6978 on samples submitted by the above company.

RECEIVED: One (1) glove type identified as; Nitrile Powder Free Examination Gloves Tested for use with Chemotherapy Drug and Fentanyl Citrate (Blue), Batch No. A37/20190402/M, Serial No. 2190228371, Size M.

TEST DRUG:

Table 1. List of the Testing Drugs, Sources, and Expiration Dates

TESTING DRUG	DRUG SOURCE
Fentanyl Citrate Injection, 100mcg/2mL	WestWard; Lot# 059334; Expiration 06/2022

COLLECTION MEDIA:

The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Fentanyl Citrate Injection, 100mcg/2mL	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area
Deviation from Standard Test Method:	Used 1" Permeation Cell

October 15, 2019

Siti Iylia Zarith Binti Hasan
Hartalega NGC SDN BHD

DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:
Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TEST DRUG	WAVELENGTH (nm)
Fentanyl Citrate Injection, 100mcg/2mL	199

SAMPLE CHARACTERISTICS:
Table 4. Cuff thickness characteristics for the tested specimens: Nitrile Powder Free Examination Gloves Tested for use with Chemotherapy Drug and Fentanyl Citrate (Blue), Batch No. A37/20190402/M, Serial No. 2190228371, Size M.

Testing Chemical	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m^2)
	Sample 1	Sample 2	Sample 3		
Fentanyl Citrate Injection	0.046	0.047	0.044	0.046	46.7

RESULTS:
Table 5. Permeation Test Results on: Nitrile Powder Free Examination Gloves Tested for use with Chemotherapy Drug and Fentanyl Citrate (Blue), Batch No. A37/20190402/M, Serial No. 2190228371, Size M.

TEST DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm^2/minute)	OTHER OBSERVATIONS
Fentanyl Citrate Injection, 100mcg/2mL	No Breakthrough up to 240 minutes	N/A	Slight swelling; no degradation

Prepared By: _____ Approved By: _____

Tiffany Heller
Manager, Pharmaceutical Services

Ana Barbur
Vice President, Analytical & Chemical Services

April 6, 2020

Hartalega NGC Sdn. Bhd.
Nurul Kong
Senior Manager - Quality Assurance
Kawasan Perindustrian Tanjung
Sepang, 43900 My

Re: K200019
Trade/Device Name: Nitrile Powder Free Examination Gloved Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Blue), Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: January 10, 2019
Received: January 15, 2020

Dear Nurul Kong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200019

Device Name
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Blue)

Indications for Use *(Describe)*
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Blue) is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	23.3
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	58.2
Vincristine Sulfate (1.0 mg/ml)	>240
Azacytidine (25.0 mg/ml)	>240
Carboplatin (10.0 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Epirubicin (2.0 mg/ml)	>240
Gemcitabine (38 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Oncovin (1.0 mg/ml)	>240
Oxaliplatin (5 mg/ml)	>240
Vinorelbine (10 mg/ml)	>240

Please note that Carmustine and Thiotepa have extremely low permeation times of 23.3 minutes and 58.2 minutes respectively.

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100 mcg/2ml)	>240

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200019

Device Name
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black)

Indications for Use *(Describe)*
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Black) is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	25.0
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	55.7
Vincristine Sulfate (1.0 mg/ml)	>240
Azacytidine (25.0 mg/ml)	>240
Carboplatin (10.0 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Epirubicin (2.0 mg/ml)	>240
Gemcitabine (38 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Oncovin (1.0 mg/ml)	>240
Oxaliplatin (5 mg/ml)	>240
Vinorelbine (10 mg/ml)	>240

Please note that Carmustine and Thiotepa have extremely low permeation times of 25.0 minutes and 55.7 minutes respectively.

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100 mcg/2ml)	>240

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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