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Version Number: 02

SAFETY DATA SHEET

Product Code: GLVNTRPFAFM

SECTION 1 PRODUCT IDENTIFICATION

Product Name	Ni-Tek Nitrile Accelerator Free Gloves,
Product Description	Non-sterile, Ambidextrous, Single Use, Finger Textured Surface, On-line Single Chlorination, Powder Free, Nitrile Examination Gloves, Blue Coloured, Accelerator Free.
Intended use	A powder free nitrile examination glove is a disposable glove made of nitrile that intended to wear on the hands for medical examination to provide a barrier against cross contamination and other contaminants.
Recommended Use	For use in medical and healthcare environment. Single use only.
Restrictions on use	Do not use for handling organic solvents.

SECTION 2 HAZARD IDENTIFICATION

Biological Hazards The gloves do not contain accelerators agents, and will help to reduce any delayed and/or long term use effects and provide lower risk.

Hazards Related To The Re-Use Of The Medical Device

Re-use of the non-sterile single use medical glove, leading to
i) Loss of product lot traceability.
ii) Risk of cross-contamination due to improper cleaning process.
iii) Increased risk of holes and tears, loss of glove integrity during re-use due to the glove damaged by the cleaning process.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS Number
Synthetic Rubber Nitrile	---
Zinc Oxide	1314-13-2
Titanium dioxide	13463-67-7
Potassium hydroxide	1310-58-3
Pigment	---

SECTION 4 FIRST AID MEASURES

None, as glove is non-hazardous.

SECTION 5 FIRE FIGHTING MEASURES

Extinguishing media : Foam, Carbon Dioxide and Water

Flash point : N/A

SECTION 6 ACCIDENTAL RELEASE MEASURES

None

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SECTION 7 HANDLING AND STORAGE

- The product should be stored in a cool dry place avoiding exposure to direct sunlight, high temperature and humidity .
- After the package is open, direct sunlight, fluorescent lighting and devices generating ozone should be avoided, and the product should be kept away from X-ray apparatus.
- Do not store these gloves with organic solvents as these solvents can degrade the gloves .

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

None

SECTION 9 PHYSICAL/CHEMICAL PROPERTIES

Feature: These nitrile examination gloves meet the ASTM D 6319 and D 6978-05 standards.

Form: Soft solid form

Color: Blue

Permeation testing per ASTM D 6978-05

TESTING CHEMOTHERAPY DRUGS:

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

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU)	Sigma Aldrich; Lot# 015M4004V; Expiration 04/2016
Cisplatin	APP; Lot# 6108842; Expiration 11/2015
Cyclophosphamide (Cytoxan)	Sigma Aldrich; Lot# SLBG4216V; Expiration 02/2016
Cytarabine	USP; Lot# H1M420; expiration 02/2016
Dacarbazine (DTIC)	Teva; Lot# 31317605B; Expiration 11/2016
Doxorubicin Hydrochloride	Teva; Lot# 31316885B; Expiration 06/2015
Etoposide (Toposar)	Teva; Lot# 31317608B; Expiration 02/2017
Fluorouracil	APP; Lot# 6108250; Expiration 10/2015
Ifosfamide	Sigma Aldrich; Lot# 106K1063V; Expiration 02/2016
Methotrexate	Hospira; Lot# B024457AA; Expiration 04/2016
Mitomycin C	Sigma; Lot# SLBH6728V; Expiration 03/2016
Mitoxantrone	USP; Lot# J0F278; Expiration 02/2016
Paclitaxel (Taxol)	Hospira; Lot# B026865AA; Expiration 04/2016
Thiotepa	Sigma Aldrich; Lot# SLBM7142V; Expiration 02/2016
Vincristine Sulfate	USP; Lot# R0K248; Expiration 02/2016

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
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 area
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

COLLECTION MEDIA:

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

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

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 CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	200
Cytarabine, 100 mg/ml (100,000 ppm)	272
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Ifosfamide, 50.0 mg/ml (50,000 ppm)	200
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	242
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens: Powder Free Nitrile Examination Gloves: Blue

TESTING CHEMOTHERAPY DRUGS	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m²)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.053	0.052	0.055	0.053	54.5
Cisplatin	0.053	0.052	0.054	0.053	
Cyclophosphamide (Cytoxan)	0.054	0.056	0.056	0.055	
Cytarabine	0.053	0.054	0.053	0.053	
Dacarbazine (DTIC)	0.055	0.055	0.057	0.056	
Doxorubicin Hydrochloride	0.054	0.056	0.053	0.054	
Etoposide (Toposar)	0.056	0.057	0.054	0.056	
Fluorouracil	0.055	0.055	0.056	0.055	

Ifosfamide	0.054	0.053	0.053	0.053	54.5
Methotrexate	0.053	0.054	0.054	0.054	
Mitomycin C	0.057	0.057	0.055	0.056	
Mitoxantrone	0.054	0.053	0.054	0.054	
Paclitaxel (Taxol)	0.058	0.055	0.055	0.056	
Thiotepa	0.054	0.054	0.055	0.054	
Vincristine Sulfate	0.053	0.054	0.055	0.054	

RESULTS:

Table 5. Permeation Test Results on: Powder Free Nitrile Patient Examination Gloves: Blue Colored: Non-Sterile:

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm2/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10.4 (20.3, 10.4, 10.4)	0.8 (0.6, 0.7, 1.1)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	90.5 (90.6, 90.5, 95.1)	0.2 (0.2, 0.2, 0.1)	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

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SECTION 10 STABILITY AND REACTIVITY

Stability: Stable
Condition to avoid: None
Incompatible Material: None

SECTION 11 TOXICOLOGICAL INFORMATION

None

SECTION 12 ECOLOGICAL INFORMATION

None

SECTION 13 DISPOSAL CONSIDERATIONS

The gloves are non-biodegradable product where special decommissioning or disposal is required.

SECTION 14 TRANSPORT INFORMATION

No special transportation requirements.

SECTION 15 REGULATORY INFORMATION

None

SECTION 16 OTHER INFORMATION

Reason for revision: To bring to date.

END OF SDS