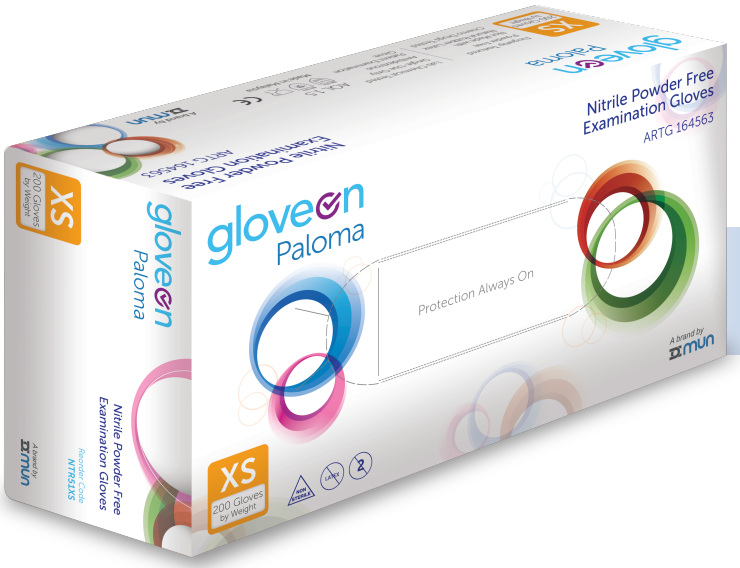
gloveon Paloma



Nitrile Exam Gloves
Powder Free, Standard Cuff

Like the purity of a white Dove, **Paloma**, our white nitrile gloves offers the elegance of touch and feel with strength and dexterity needed for the delicate procedure and jobs.

NON STERILE · LATEX · 2 · EN 374 · EN 374 · CE

	GloveOn Paloma	
Length (mm)		
	≥ 230	
Thickness Measurements (mm)		
Palm (centre of Palm)	0.07 ± 0.02	
Finger (13mm ± 3mm from tip)	0.09 ± 0.02	
Physical Properties	**Before Ageing**	**After Ageing**
Tensile Strength (MPa)	≥ 18	≥ 16
Elongation (%)	≥ 500	≥ 400
Inspection Levels & AQL	**Inspection Level**	**AQL**
Watertightness	G1	1.50
Physical Dimensions	S2	4.00
Tensile Strength	S2	4.00
Visual Inspection (Major)	S4	2.50
Visual Inspection (Minor)	S4	4.00
Particulate Residue	N = 5	≤ 2mg/glove

Chemotherapy Drugs and Concentration (Tested for Resistance to Permeation by Chemotherapy Drugs as per ASTM D6978-05 Test Report PN 116668)	Minimum Breakthrough Detection Time (minutes)
Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	15.1 minutes
Cisplatin, 1.0mg/ml (1,000 ppm)	>240 minutes
Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm)	>240 minutes
Dacarbazine (DTIC), 10.0mg/ml (10,000 ppm)	>240 minutes
Doxorubicin Hydrochloride, 2.0mg/ml (2,000 ppm)	>240 minutes
Etoposide (Toposar), 20.00mg/ml (20,000 ppm)	>240 minutes
Fluorouracil, 50.0mg/ml (50,000 ppm)	>240 minutes
Methotrexate, 25.0mg/ml (25,000 ppm)	>240 minutes
Mitomycin C, 0.5mg/ml (500 ppm)	>240 minutes
Paclitaxel (Taxol), 6.0mg/ml (6,000 ppm)	>240 minutes
Thiotepa, 10.0mg/ml (10,000 ppm)	15.4 minutes
Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	>240 minutes

WARNING: Carmustine and Thiotepa, at the tested concentration, degraded Paloma nitrile glove at 15.1 minutes and 15.4 minutes, respectively. The safe use of gloves in chemotherapy treatment is solely the decision of clinicians authorised to make such decision.

REORDER CODE

NTR51XS	X-SMALL
NTR51SS	SMALL
NTR51MM	MEDIUM
NTR51LL	LARGE
NTR51XL	X-LARGE

FEATURES

- Fingertip textured
- Powder free
- Not made with natural rubber latex
- Chemo drugs tested
- Lab chemical tested
- Ambidextrous
- Standard cuff
- White colour

PACKAGING

200 gloves per box for XS to L
180 gloves per box for XL
10 boxes per carton

REGULATORY COMPLIANCE

TGA - ARTG 164563, FDA 510(k),
MDD 93/42/EEC, REACH,
ROHS Directive 2002/95/EC, EC 10/2011,
REGULATION (EC) No 1935/2004,
PPE 89/686/EEC

STANDARDS

ASTM D6319, EN 455 part 1, 2, 3 & 4 ,
EN 1186, EN 13130, CEN/TS 14234,
EN 420, EN 374 part 1, 2 & 3

MANUFACTURING ACCREDITATIONS

ISO 9001:2008
ISO 13485:2003
EN ISO 13485:2003

Chemotherapy Drugs and Concentration (Tested for Resistance to Permeation by Chemotherapy Drugs as per ASTM D6978-05 Test Report PN 116668)	Minimum Breakthrough Detection Time (minutes)
Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	Not Recommended
Cisplatin, 1.0mg/ml (1,000 ppm)	>240 minutes
Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm)	>240 minutes
Dacarbazine (DTIC), 10.0mg/ml (10,000 ppm)	>240 minutes
Doxorubicin Hydrochloride, 2.0mg/ml (2,000 ppm)	>240 minutes
Etoposide (Toposar), 20.00mg/ml (20,000 ppm)	>240 minutes
Fluorouracil, 50.0mg/ml (50,000 ppm)	>240 minutes
Methotrexate, 25.0mg/ml (25,000 ppm)	>240 minutes
Mitomycin C, 0.5mg/ml (500 ppm)	>240 minutes
Paclitaxel (Taxol), 6.0mg/ml (6,000 ppm)	>240 minutes
Thiotepa, 10.0mg/ml (10,000 ppm)	Not Recommended
Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	>240 minutes

Warning: Don't use with Carmustine and Thiotepa

Features

- Fingertip textured
- Powder free
- Not made with natural rubber latex
- Chemo drugs tested
- Lab chemical tested
- Ambidextrous
- Standard cuff
- White colour

Sizes

- X-Small
- Small
- Medium
- Large
- X-Large

Manufacturing Accreditations

- ISO 9001:2008
- ISO 13485:2003
- EN ISO 13485:2003

EC REP

MDSS GmbH
Schiffgraben 41,30175 Hannover, Germany

MDA Reg No. GMD5635368418A

Protection Always On

Certificates FDA

U.S. FOOD & DRUG ADMINISTRATION

April 25, 2020

Hartalega NGC SDN. BHD.
Nurul Kong
Senior Manager- Quality Assurance
Kawasan Perindustrian Tanjung
Sepang, Selangor 43900
Malaysia

Re: K200581
Trade/Device Name: Paloma Nitrile Powder Free Examination Gloves (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Paloma Powder Free Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: February 27, 2020
Received: March 5, 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,
Elizabeth F. Claverie -S

FDA

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

Certificates CE

MDSS
Medical Device Safety Service

Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Hartalega NGC Sdn. Bhd.
No. 1, Persiaran Tanjung
Kawasan Perindustrian Tanjung
43900 Sepang, Selangor
MALAYSIA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated January 18, 2019

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2019-01-18

Ludger Möller
President
MDSS GmbH

MDSS
Medical Device Safety Service

MDSS · Schiffgraben 41 · 30175 Hannover, Germany

Hartalega NGC Sdn. Bhd.
Khairunnisa Warsito
No. 1, Persiaran Tanjung
Kawasan Perindustrian Tanjung
43900 Sepang, Selangor
MALAYSIA

Schiffgraben 41
30175 Hannover, Germany

Tel: + 49 - 511 - 62 62 86 30
Fax: + 49 - 511 - 62 62 86 33

eMail: info@mdss.com
Internet: www.mdss.com

2019.01.18

Confirmation of CE Registration

Dear Khairunnisa,

It is our pleasure to enclose the new Certificate of CE-Registration for your product.

Please note that registration was performed under § 25 MPG (Medizinproduktegesetz). This is the *Federal Republic of Germany's national interpretation of Medical Device Directive 93/42/EEC.* Registration is therefore in accordance with EU legislation. We remind you that all products must meet the applicable provision of the European and national regulation before they may be placed on the market.

We are looking forward to continuing our good business relationship and wish you a successful product launch in Europe.

Best regards,

Juan Monferrer Tena
Administrative Assistant
Medical Device Safety Service GmbH

Encl.
1 Certificate of CE-Registration
1 Annex A

Annex A dated January 18, 2019
Manufacturer: Hartalega NGC Sdn. Bhd.

UMDNS Code Description Notified Medical Device Product Name & Catalogue Number	UMDNS Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
Gloves, Examination/Treatment	11-882	I	10	DE/CA09/0170/H13/001-01	N.A.	N.A.
Latex Examination Gloves; Nitrile Examination Gloves; Antimicrobial Nitrile Power Free Examination Gloves						
Latex Powder Free Examination Gloves *Latex Powdered Examination Gloves* *Nitrile Powder Free Examination Gloves* *Antimicrobial Nitrile Power Free Examination Gloves*						

Certificates Testing

Testing. Development. Problem Solving.

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

January 5, 2019

· TEST REPORT ·

PN 83672A - Amended

CHEMICAL ANALYTICAL SERVICES

Prepared For:
Hartalega SDN. BDH
Ms. Nurul Aisyah Kong
No. 7 Kawasan Perusahaan Suria
Bestari Jaya
Selangor, 45600
Malaysia

Prepared By: Tiffany L Heller
Chemical Technician

Approved By: Ana C. Barbur, M.S.
Manager, Chemical & Pharmaceutical Services

An A2LA Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02
ISO 9001:2000 Registered
Member of ACIL: The American Council of Independent Laboratories

ACCREDITED
A Testing Lab

ISO 9001:2000
Registered

MEMBER ACIL

www.ardl.com
2887 Gilchrist Rd. | Akron, Ohio 44305 | answers@ardl.com
Toll Free (800) 830-ARDL | Worldwide (330) 794-6600 | Fax (330) 794-6610

January 5, 2019

Ms. Nurul Aisyah Kong
Hartalega SDN. BHD

SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted by the above company. Wire Transfer.

RECEIVED: Glove sample identified as Nitrile Powder Free Examination Gloves (Blue) Code: ABLU.

TESTING CHEMOTHERAPY DRUGS:

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

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU)	Sigma; Lot# 038K4008; Expiration 12/2009
Cisplatin	Sigma; Lot# 59H3657; Expiration 09/2009
Cyclophosphamide (Cytoxan)	Sigma; Lot# 068K1131; Expiration 1/2010
Dacarbazine (DTIC)	Hospira; Lot# U022223AA; Expiration 06/2010
Doxorubicin Hydrochloride	Teva; Lot#07N625; Expiration 10/2009
Etoposide (Toposar)	Teva; Lot# 31303976B; Expiration 9/2011
Fluorouracil	APP; Lot# 203867; Expiration 03/2010
Mitomycin C	Sigma, Lot# 048K1086; Expiration 01/2010
Methotrexate	Hospira; Lot# U024457AA; Expiration 05/2010
Paclitaxel (Taxol)	Dabur Oncology; Lot# PA08H00701; Exp. 05/2010
Thiotepa	Sigma; Lot#078K1526; Expiration 12/2009
Vincristine Sulfate	Hospira, Lot# U037139AA; Expiration 12/2009

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
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
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 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

Ms. Nurul Aisyah Kong
Hartalega SDN. BHD

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

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
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
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
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: Nitrile Powder Free Examination Gloves (Blue) Code: ABLU.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m2)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.080	0.084	0.082	**0.082**	79.2
Cisplatin	0.086	0.082	0.088	**0.085**	79.2
Cyclophosphamide (Cytoxan)	0.087	0.083	0.081	**0.084**	79.2
Dacarbazine (DTIC)	0.086	0.080	0.084	**0.083**	79.2
Doxorubicin Hydrochloride	0.087	0.084	0.082	**0.084**	79.2
Etoposide (Toposar)	0.085	0.088	0.090	**0.088**	79.2
Fluorouracil	0.082	0.082	0.094	**0.086**	79.2
Methotrexate	0.081	0.084	0.087	**0.084**	79.2
Mitomycin C	0.082	0.082	0.084	**0.083**	79.2
Paclitaxel (Taxol)	0.086	0.081	0.082	**0.083**	79.2
Thiotepa	0.084	0.083	0.087	**0.085**	79.2
Vincristine Sulfate	0.088	0.084	0.082	**0.085**	79.2

Ms. Nurul Aisyah Kong
Hartalega SDN. BHD

RESULTS:

Table 5. Permeation Test Results on: Nitrile Powder Free Examination Gloves (Blue) Code: ABLU.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu g/cm^2$/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	35.80 (45.31,30.46,31.63)	1.24 (1.36,1.16,1.20)	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
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
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	Moderate 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)	85.48 (105.33,75.52,75.60)	1.32 (1.33,1.32,1.32)	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

Tiffany L. Heller
Chemical Technician, Chemical Services
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Ana C. Barbur, M.S.
Chemical and Pharmaceutical Services

Certificates Testing

MATERIAL SAFETY DATA SHEET

Hartalega

SECTION 1: PRODUCT IDENTIFICATION

NAME Hartalega Sdn. Bhd.	**ADDRESS** C-G-9, Jalan Dataran SD1, Dataran SD, PJU 9, Bandar Sri Damansara, 52200 Kuala Lumpur
TELEPHONE NUMBER (603) 62771733	**DATE PREPARED** October 15, 2014
COMMON NAME (USED ON LABEL) Nitrile Powder Free Examination Gloves	**CHEMICAL FAMILY** Carboxylated Butadiene Acrylonitrile Polymer Latex
APPLICATION Medical and Dental	**TRADENAME & SYNONYM** GLOVEON PALOMA (NTR51) NITRILE POWDER FREE EXAMINATION GLOVES (WHITE)

SECTION 2: HAZARDOUS INGREDIENTS

HAZARDOUS COMPONENT	CAS #	%(WT)	TLV	PEL
N/A	N/A	N/A	N/A	N/A

PEL : Permissible Exposure Limit established by Occupational Safety and Health Administration (OSHA).
TLV : Threshold Limit Value established by the American Conference of Governmental Industrial Hygienists, 1987-1988

SECTION 3: COMPOSITION/ INFORMATION ON INGREDIENTS

CHEMICAL COMPOSITION
All chemicals used are non-toxic/non-hazardous.
Butadiene-Acrylonitrile Latex, Sodium Dodecylbenzenesulfonate, Sulphur, Titanium Dioxide, Zinc-n-dibutyldithiocarbamate, Zinc Oxide, Paraffin Wax Emulsion

SECTION 4: FIRST AID MEASURE

If reaction in the form of skin irritation is noticed, remove gloves immediately and wash affected part with saline water. If there is no relief, seek medical reactions.

SECTION 5: FIRE FIGHTING MEASURE

FLASHPOINT	AUTOIGNITION TEMPERATURE	FLAMMABLE LIMITS IN AIR
N/A	N/A	N/A

EXTINGUISHING MEDIA
Chemical foam and dry chemical may be used

FIRE-FIGHTING PROCEDURES
Use standard procedures for combustion material fires, including approved self-contained breathing apparatus

FIRE AND EXPLOSION HAZARDS
No fire or explosion hazards are associated with these products. They will melt at elevated temperatures

SECTION 6: ACCIDENTAL RELEASE MEASURES

BIOCOMPATABILITY
The chemical formulation of the gloves and surface lubrication materials does not contain any substances normally known to be harmful to the user or to any person with whom the gloves come into contact.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:
Nitrile Powder Free Gloves are not expected to cause any adverse health effects.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE
Store in a dry, cool and ventilated area. Do not store above 104°F (40°C). Shield open box from direct sunlight, fluorescent lighting and x-rays. Improper storage will decrease usable life.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

EYE PROTECTION Not necessary under conditions of intended use.	**SKIN PROTECTION** Not necessary under conditions of intended use.
RESPIRATORY PROTECTION Not necessary under conditions of intended use.	**VENTILATION** Not necessary under conditions of intended use.

STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED
These products are solid articles and are not subject to leaks or spills.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/ODOR
Ambidextrous, Beaded Cuff, Micro-textured, Chlorinated, Powder Free, White.

DIMENSION	EXTRA-SMALL	SMALL	MEDIUM	LARGE	EXTRA-LARGE
Length (mm)	Minimum 230 (same for all)				
Width (mm)	76±4	86±4	98±4	107±4	115±4

THICKNESS (mm) – SINGLE WALL MEASUREMENT (same for all)	
Finger (mm)	0.09 ± 0.02
Palm (mm)	0.07 ± 0.02

TENSILE PROPERTIES	UNAGED	AGED
Tensile Strength (Mpa)	Min. 14.0 MPa	Min. 14.0 MPa
Ultimate Elongation (%)	Min. 500%	Min. 400%

SECTION 10: STABILITY AND REACTIVITY

BOILING POINT N/A	**VAPOR PRESSURE (mm Hg)** N/A	**VAPOR DENSITY (air=1)** N/A
SPECIFIC GRAVITY (water=1) N/A	**SOLUBILITY IN WATER** Insoluble	**% VOLATILE BY VOLUME** N/A
EVAPORATION RATE N/A	**VISCOSITY** N/A	

SECTION 11: TOXICOLOGICAL INFORMATION

STABILITY Stable	**CONDITIONS TO AVOID** Does not apply

INCOMPATABILITY (MATERIALS TO AVOID)
High polar solvent like methyl ethyl ketone, acetone.

HAZARDOUS DECOMPOSITION PRODUCTS:
In a fire, these products may produce a black smoke. Carbon Dioxide, Carbon Monoxide, Oxides of Nitrogen, aromatic/aliphatic hydrocarbons.

HAZARDOUS POLYMERIZATION
Will not occur

SECTION 12: ECOLOGICAL INFORMATION

NA

SECTION 13: DISPOSAL CONSIDERATION

WASTE DISPOSAL METHOD
Consult current local, state and federal regulations for proper disposal methods.

SECTION 14: TRANSPORT INFORMATION

NA

SECTION 15: REGULATORY INFORMATION

NA

SECTION 16: OTHER INFORMATION

RECOMMENDED USE AND RESTRICTION
The Nitrile Powder Free Gloves is a Single Use device