

Issue Date: 28/06/2016
Last Revision Date: 02/08/2023
Superseded Date: 28/02/2019
Version Number: 03

SAFETY DATA SHEET

Product Code: GLVNTRPF100L-M

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SECTION 1 PRODUCT IDENTIFICATION

Product Name: Ni-Tek Nitrile Premium Gloves

Product Description: Synthetic Rubber Nitrile Examination Gloves

Intended use A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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

Similar type of powder free examination gloves have been tested for following study and no irritation was observed:

Skin irritation study in rabbit
Sensitisation study in guinea pig

Gloves Usage Recommendation

- Wear gloves that fit well and trim fingernails for effective use.
- Gloves are for single use only.
- Change gloves frequently, wash and dry hands thoroughly in between changes.
- Apply any suitable non-greasy hand lotion periodically.
- User is responsible for determining the proper application of the gloves in any given procedure or practice.
- Gloves are easily contaminated while in contact with copper materials.
- If during use, irritation, allergic contact dermatitis or other signs of discomfort occur, discontinue use immediately and consult a physician

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Primary Material Gloves are made from Butadiene Acrylonitrile (NBR) Copolymer

Ingredient	CAS No.
Nitrile Rubber	Proprietary
Zinc Oxide	1314-13-2
Sulphur	7704-34-9
Zinc Diethyl Dithiocarbamate	14324-55-1
Zinc Dibutyl Dithiocarbamate	136-23-2
Titanium Dioxide	13463-67-7
Potassium Hydroxide	1310-58-3
Colour	Proprietary

SECTION 4 FIRST AID MEASURES

None, as glove is non-hazardous.

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SECTION 5 FIRE FIGHTING MEASURES

Extinguishing media: Foam, Carbon Dioxide and Water

Flash point: N/A

SECTION 6 ACCIDENTAL RELEASE MEASURES

No data available

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.

Ventilation is not necessary under normal storage condition.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

No data available

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Colour Non-Sterile, Solid with textured surface , Powder free with polymer coating/ chlorinated, colour blue / deep blue / black / white

Reactivity in Water Non-Reactive

Dimensions:

Glove Size	Palm Width (mm)	Length (mm)
Extra Small	75±5	240±2 min
Small	85±5	240±2 min
Medium	95±5	240±2 min
Large	105±5	240±2 min
Extra Large	115±5	240±2 min

Thickness (single wall) min. 0.05 Cuff (25 mm from bead)
Palm (centre of palm)
Finger (13 mm from tip)

Inspection level S2

AQL 4.0

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Tensile Properties:

Criteria	Before Ageing	After Ageing
Tensile Strength (MPa)	min. 14	min. 14
Elongation (%)	min. 500	min. 400
Force at Break (N)	min. 6	min. 6

Inspection level

S2

AQL

4.0

Freedom from Holes

Water tight Test

Inspection level

G1

AQL

1.5

Visual Defects Major

Lump $\geq$ 2 mm, Dirt $\geq$ 1.5 mm, Sticky Pleat $\geq$ 5 mm, Sticky, Visible Hole (Non-inflated), Discolouration, Mix Surface, Incomplete Bead, Wrong Orientation

Inspection level

S4

AQL

2.5

Visual Defects Minor

Lump < 2 mm, Dirt < 1.5 mm, Sticky Pleat < 5 mm, Rolled Bead, Powder Mark

Inspection level

S4

AQL

4.0

Powder Residue

Max. 2.0 mg/glove

Inspection level

N = 5

AQL

N/A

Inspection Method

ASTM 06319 (latest version), ASTM 6124 (latest version), EN 455 (latest version)

SECTION 10 STABILITY AND REACTIVITY

Stability :

Stable

Condition to avoid :

None

Incompatible Material :

None

SECTION 11 TOXICOLOGICAL INFORMATION

Animal safety test for potential skin irritation and delayed skin sensitization showed that the glove is neither a skin irritant nor potential skin sensitizer

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SECTION 12 ECOLOGICAL INFORMATION

No data available

SECTION 13 DISPOSAL CONSIDERATIONS

The gloves are biodegradable product where no special decommissioning or disposal is required.

SECTION 14 TRANSPORT INFORMATION

No special transportation requirements

SECTION 15 REGULATORY INFORMATION

No data available

SECTION 16 OTHER INFORMATION

Reason for Revision: To bring to date

END OF SDS