

Issue Date: 23/02/2009
Last Revision Date: 02/08/2023
Superseded Date: 06/10/2020
Version Number: 05

SAFETY DATA SHEET

Product Code: GLVNTRLC100L**PAGE 1 OF 2**

SECTION 1 PRODUCT IDENTIFICATION

Product Name: Ni-Tek 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

Biological Hazards Components used in glove manufacturing may cause allergic reaction in some user.

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 contamination and infection increases due to improper cleaning process,
iii) Damages caused by cleaning processes could lead to risk of holes and tear during re-use.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Synthetic Rubber Nitrile, Sulfur, Rubber Accelerator, Zinc Oxide, Anionic Wetting Agent, Potassium Hydroxide, Antioxidant, Titanium Dioxide, Blue 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

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

None

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SECTION 9 PHYSICAL/CHEMICAL PROPERTIES

Feature: These rubber gloves meet the AS/NZS 4011.1:2014 standard.
Form: Soft solid form
Color: Blue

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.

SECTION 12 ECOLOGICAL INFORMATION

None

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

FDA Establishment Registration No.: 3005632797
FDA 510(k) Notification No.: K060771, CLASS 1
FDA Device Listing No.: D032493

SECTION 16 OTHER INFORMATION

Reason for Revision: To bring to date

END OF SDS

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