

Issue Date: 25/01/2016
Last Revision Date: 09/04/2024
Superseded Date: 12/04/2018
Version Number: 02

SAFETY DATA SHEET

Product Code: GLVNTM

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SECTION 1 PRODUCT IDENTIFICATION

Product Name: Lincon Nitrile Gloves Examination

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

Ingredients	CAS No.
Synthetic Rubber Nitrile	N/A
Sulfur	7704-34-9
Rubber Accelerator	N/A
Zinc Oxide	1314-12-2
Anionic Wetting Agent	N/A
Potassium Hydroxide	1310-58-3
Antioxidant	N/A
Titanium Dioxide	13463-67-7
Blue Pigment	147-14-8

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

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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.

SECTION 9 PHYSICAL/CHEMICAL PROPERTIES

Feature: These rubber gloves meet the ASTM D 6319 standard.
Form: Soft solid form
Colour: 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

Not applicable

SECTION 13 DISPOSAL CONSIDERATIONS

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

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SECTION 14 TRANSPORT INFORMATION

No special transportation requirements.

SECTION 15 REGULATORY INFORMATION

FDA Establishmen
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