



Safety Data Sheet

Section 1: Identification

Product

Non-sterile, Ambidextrous, Single Use, Powder Free, Nitrile Examination Gloves. Blue Colored, Low Dermatitis.

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.

Manufacturer: Clark Core Services, LLC

Address : 2205 Old Philadelphia Pike, Lancaster, PA 17602

Tel : 1-888-256-6400

Recommended Use

For use in the medical and healthcare environment. Single use only.

Restrictions on use

Do not use for handling organic solvents.

Section 2: Hazard(s) Identification

1) Biological hazards

- Components used in glove manufacturing may cause allergic reaction in some users.

2) 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 / weakening by the cleaning processes leading to increased risk of holes and tear during re-use.

Section 3: Composition/Information on Ingredients

Acrylonitrile Butadiene Rubber, Zinc Oxide, Potassium Hydroxide, 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.

Section 9: Physical and Chemical Properties

1) Feature

These gloves meet the ASTM D6319 & ASTM D6978 standards.

2) Form

Soft solid form

3) Color

Blue

Section 10: Stability and Reactivity

Stability : Stable

Condition to avoid : None

Incompatible Material : None

Section 11: Toxicological Information

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* (non-mandatory)

N/A

Section 13: Disposal Considerations* (non-mandatory)

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

Section 14: Transport Information* (non-mandatory)

No special transportation requirements.

Section 15: Regulatory Information* (non-mandatory)

Quality Assurance:

Manufactured under the following Quality Management Systems:

- 1) ISO 13485
- 2) CAN/CSA ISO 13485
- 3) ISO 9001
- 4) US FDA QSR

Section 16: Other Information

Date of Preparation: 22 September 2015

*Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15(29 CFR 1910.1200(g)(2)).