



## Safety Data Sheet

### Section 1: Identification

**Product**

Non-sterile, Ambidextrous, Single Use, On-line Chlorinated, Powder Free, Nitrile Examination Gloves. Blue Colored.

**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, Sulfur, Accelerators, 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: 01 July 2016

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