

# **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**: Noble Products

**Address**: 2205 Old Philadelphia Pike, Lancaster, PA 17602

**Tel** : 717-392-7974 **Fax** : 717-392-8133

#### **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)).