# SAFETY DATA SHEET

## **Section 1- Identification**

**Product name:** Sinclair Nitrile Powder-Free Gloves

**Product code:** X-Small (263sd20)

Small (263sd21)

Medium (263sd22)

Large (263sd23)

**Product description:** Non-sterile, Ambidextrous, Single Use, Polymer Coated, Powder

Free, Nitrile Examination Gloves. Blue Colour.

**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:** Sinclair Dental Co. Ltd.

**Address:** 900 Harbourside Dr.

North Vancouver, BC V7P 3T8

Canada

**Phone number:** (604) 986-1544

**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**

**Biological hazards:** Components used in glove manufacturing may cause allergic

reaction in some users.

Hazards related to the re-use of the medical device:

**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, Rubber Accelerator, Zinc Oxide, Potassium Hydroxide, Titanium Dioxide, Blue Pigment.

### **Section 4 - First-aid measures**

None, as glove is non-hazardous.

## <u>Section 5 – Fire-fighting measures</u>

**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

**Feature:** These gloves meet the ASTM D6319 standard.

**Form:** Soft solid form

Colour: Blue

## **Section 10 - Stability and reactivity**

**Stability:** Stable

Conditions 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.

## <u>Section 12 - Ecological information\* (non-mandatory)</u>

N/A

## **Section 13 - Disposal considerations\* (non-mandatory)**

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

## **Section 14 - Transportation information\* (non-mandatory)**

No special transportation requirements.

### <u>Section 15 - Regulatory information\* (non-mandatory)</u>

**Quality Assurance:** Manufactured under following Quality Management System:

1) ISO 13485

2) CAN/CSA ISO 13485

3) ISO 90014) US FDA QSR

## **Section 16 - Other information**

**Date of preparation:** November 7, 2017

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