

# SAFETY DATA SHEET

## Section 1- Identification

<b>Product name:</b>	<b>Sinclair Nitrile Powder-Free Gloves</b>
<b>Product code:</b>	X-Small (263sd20) Small (263sd21) Medium (263sd22) Large (263sd23)
<b>Product description:</b>	Non-sterile, Ambidextrous, Single Use, Polymer Coated, Powder Free, Nitrile Examination Gloves. Blue Colour.
<b>Intended use:</b>	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.
<b>Manufacturer:</b>	Sinclair Dental Co. Ltd.
<b>Address:</b>	900 Harbourside Dr. North Vancouver, BC V7P 3T8 Canada
<b>Phone number:</b>	(604) 986-1544
<b>Recommended use:</b>	For use in the medical and healthcare environment. Single use only.
<b>Restrictions on use:</b>	Do not use for handling organic solvents.

## Section 2 - Hazard(s) identification

<b>Biological hazards:</b>	Components used in glove manufacturing may cause allergic reaction in some users.
<b>Hazards related to the re-use of the medical device:</b>	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.

#### **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**

**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.

**Section 12 - Ecological information\* (non-mandatory)**

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.

**Section 15 - Regulatory information\* (non-mandatory)**

**Quality Assurance:** Manufactured under following Quality Management System:  
1) ISO 13485  
2) CAN/CSA ISO 13485  
3) ISO 9001  
4) 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)).