

# SAFETY DATA SHEET

## Section 1- Identification

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

**Product code:** X-Small (261sd50)  
Small (261sd51)  
Medium (261sd52)  
Large (261sd53)

**Product description:** Non-sterile, Ambidextrous, Polymer Coated, Powder Free, Natural Rubber Latex Examination Gloves.

**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:** This product contains natural rubber latex which may cause allergic reactions.  
<This caution statement is placed prominently on the dispenser box>

**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

Natural Rubber Latex, Sulfur, Rubber Accelerator, Zinc Oxide, Potassium Hydroxide, Titanium Dioxide.

#### **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 D3578 standard.

**Form:** Soft solid form

**Colour:** White

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

**Stability:** Stable

**Conditions to avoid:** Extremely High Temperatures

**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)).