

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)).