

SAFETY DATA SHEETS

This SDS packet was issued with item:

071214436

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071214345 071214410 071214428 071214444



SAFETY DATA SHEET

HandPRO® Fortis500™ Extended Cuff Nitrile Exam Gloves

Section 1: Identification

Product

Non-sterile, Ambidextrous, Single Use, Powder-Free, Nitrile Examination Gloves, Black Colored, Low Dermatitis Potential.

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.

Manufactured For: Hourglass International Inc. & Kosline Inc.
5100 E. 2nd St
Benicia, CA 94510
USA

Phone: 800-277-0994

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
 1. loss of product lot traceability,
 2. risk of contamination and infection increases due to improper cleaning process,
 3. damages / weakening by the cleaning process 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, Black 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 glove.
- 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 standard.

2) Form

Soft solid form

3) Color

Black

Section 10: Stability and Reactivity

Stability : Stable

Condition 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 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 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: July 8, 2019

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