



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)).