



## 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)).