

Safety Data Sheet

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.

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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 user.

2) 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

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 gloves.
- 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) Medical Device Single Audit Program (MDSAP)
- 3) ISO 9001
- 4) US FDA QSR

Section 16: Other Information

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