

Safety Data Sheet

Section 1 : Identification

Product

Non-Sterile , Ambidextrous, Single Use, On-line Chlorinated, Powder Free Nitrile Examination Gloves. White Colored, Low Dermatitis and Accelerator-Free.

Identifier

PFN-W LD (NS)

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. Nitrile rubber examination gloves are usually used for conducting medical examination and also performing laboratory works.

Manufacturer : Wear Safe (Malaysia) Sdn Bhd

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Recommended use

For use in medical, healthcare and electronic clean room 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, Titanium Dioxide, Potassium Hydroxide

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 : Not applicable

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 are tested according to ASTM D 6319 standard and EN 455 standard
- 2) Form**
Soft solid form.
- 3) Color**
White

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)

Not applicable

Section 13 : Disposal Considerations* (non-mandatory)

The gloves are non-biodegradable product where special decommissioning or disposal is required. Dispose according to your local regulation or contact your local service providers for more information.

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) BS EN ISO 13485
- 3) CAN/CSA ISO 13485
- 4) ISO 9001
- 5) US FDA QSR

Section 16 : Other Information

Date of preparation: 15 August 2018

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