



STRETCHING LIMITS • SINCE 1979

Safety Data Sheet

Section 1 : Identification

Product

Powder Free Polymer Coated NR Latex Surgical Gloves, Sterile

Identifier

DD-SPBPYF/S/T

Intended use

Surgical gloves are intended to be used once in an invasive procedure involving a single patient and permanently discarded after use. These gloves are worn on the hands of surgeon's and/or operating room personnel to provide barrier protection of surgical wound from contamination.

Manufacturer : Wear Safe (Malaysia) Sdn Bhd

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41050 Klang, Selangor Darul Ehsan, Malaysia.

Tel : +603-3392 1388

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Recommended use

For use in 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 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

Natural Rubber Latex, Cross Linking Agent, Accelerator, Activator, Titanium Dioxide

Section 4 : First-Aid Measures

None, as glove is non-hazardous.



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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

Storage – Single use only, sterile in unopened, undamaged package. Keep away from sunlight, heat and petroleum products. Store at room temperature.

Section 8 : Exposure Controls/Personal Protection

None.

Section 9 : Physical and Chemical Properties

- 1) Feature
These rubber gloves meet the ASTM D 3577 standard and EN 455 standard
- 2) Form
Soft solid form
- 3) Color
Natural 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



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Section 13 : Disposal Considerations* (non-mandatory)

- a) Product – Dispose off in accordance with local regulation
- b) Packaging - Contaminated packaging must be disposed off in the same manner as the product.
 - Non-contaminated packaging may be recycled. Contact your local service providers for more information.

Section 14 : Transport Information* (non-mandatory)

No special transportation requirements.

Section 15 : Regulatory Information* (non-mandatory)

- FDA Establishment Registration No. : 3010602489
- FDA 510(k) Notification No. : K090066
- FDA Device Listing No. : D076873

Section 16 : Other Information

Date of preparation: 27th March 2017

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