



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

**Address** : Lot 5068 & 5069, Batu 4½, Jalan Meru,  
41050 Klang, Selangor Darul Ehsan, Malaysia.

**Tel** : +603-3392 1388

**Fax** : +603-3392 2733

**Emergency Phone number**

**Tel** : +603-3392 1388

**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: 27<sup>th</sup> March 2017**

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