1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product identifier

Material Name: TRUMENBA (Meningococcal Group B Vaccine) Suspension for intramuscular injection

Trade Name: TRUMENBA

Compound Number: PF-05212366

Synonyms: TRUMENBA- neisseria meningitidis serogroup b recombinant lp2086 a05 protein variant antigen and neisseria meningitidis serogroup b recombinant lp2086 b01 protein variant antigen injection, suspension ; PF-05212366 (Neisseria meningitidis Serogroup B Bivalent Recombinant Lipoprotein [rLP2086; subfamily A and B; E coli] Vaccine); rLP2086; MnBvLP2086

Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Vaccine

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Other Hazards: No data available

Australian Hazard Classification (NOHSC):


Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
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<tr>
<td>L-Histidine</td>
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<td>200-745-3</td>
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<td>Not Listed</td>
<td>*</td>
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<tr>
<td>MnBrLP2086</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
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<td>231-598-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Description of First Aid Measures
- **Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- **Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- **Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- **Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed
- **Symptoms and Effects of Exposure:** No data available
- **Medical Conditions Aggravated by Exposure:** None known

Indication of the Immediate Medical Attention and Special Treatment Needed
- **Notes to Physician:** None

5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**
- **Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- **Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Environmental Precautions**
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Restrict access to work area. Avoid open handling. Minimize generating airborne mists and vapors. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): Vaccine

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

L-Histidine
Latvia OEL - TWA 5 mg/m³

SODIUM CHLORIDE
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures.
Personal Protective Equipment:
Hands: Wear impervious gloves if skin contact is possible.
Eyes: Wear safety glasses as minimum protection.
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available

Color: Clear
Odor Threshold: No data available.
Molecular Weight: Mixture
9. PHYSICAL AND CHEMICAL PROPERTIES

- **Water Solubility:** No data available
- **pH:** 6.5 - 8.5
- **Melting/Freezing Point (°C):** No data available
- **Boiling Point (°C):** No data available
- **Partition Coefficient:** No data available
- **Decomposition Temperature (°C):** No data available
- **Evaporation Rate (Gram/s):** No data available
- **Vapor Pressure (kPa):** No data available
- **Vapor Density (g/ml):** No data available
- **Relative Density:** No data available
- **Viscosity:** No data available
- **Flammability:** No data available
  - **Autoignition Temperature (Solid) (°C):** No data available
  - **Flammability (Solids):** No data available
  - **Flash Point (Liquid) (°C):** No data available
  - **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
  - **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

- **Reactivity:** No data available
- **Chemical Stability:** Stable under normal conditions of use.
- **Possibility of Hazardous Reactions**
  - **Oxidizing Properties:** No data available
  - **Conditions to Avoid:** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
  - **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
  - **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

- **Information on Toxicological Effects**
  - **General Information:** Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients.
  - **Short Term:** In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.
  - **Known Clinical Effects:** Based on clinical trials in humans, possible adverse effects following exposure to this compound may include:

**Acute Toxicity: (Species, Route, End Point, Dose)**
11. TOXICOLOGICAL INFORMATION

L-Histidine
Rat Oral LD 50 > 15 g/kg
Rat Para-periosteal LD 50 > 2g/kg
Mouse Oral LD 50 > 15g/kg
Mouse Intravenous LD 50 > 2g/kg

SODIUM CHLORIDE
Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³
Rat Oral LD 50 3g/kg
Mouse Oral LD 50 4g/kg
Rabbit Dermal LD 50 > 10g/kg

Polysorbate 80
Rat Intravenous LD 50 1790 mg/kg
Mouse Oral LD 50 25g/kg

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

MnBrLP2086
9 Week(s) Rabbit Intramuscular 400 ug/dose/2weeks NOAEL None identified

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

MnBrLP2086
Fertility and Embryonic Development Rabbit Intramuscular * 200 ug/dose NOAEL Reproductive toxicity, Developmental toxicity
Reproductive & Development Toxicity Comments: MnBrLP2086: * NOTE: 4 doses -17 and 4 days prior to mating, gestation days 10 and 24.

Carcinogen Status:
Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:
Environmental properties have not been investigated.

Toxicity:
No data available

Persistence and Degradability:
No data available

Bio-accumulative Potential:
No data available

Mobility in Soil:
No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transportation as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Additional Information: This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

Canada - WHMIS: Classifications
WHMIS hazard class: None required

Polysorbate 80
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: Not Listed

L-Histidine
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-745-3

MnBrLP2086
CERCLA/SARA 313 Emission reporting: Not Listed
SAFETY DATA SHEET

Material Name: TRUMENBA (Meningococcal Group B Vaccine) Suspension for intramuscular injection
Revision date: 19-Nov-2014

15. REGULATORY INFORMATION

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<thead>
<tr>
<th>Data Source</th>
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<td>California Proposition 65</td>
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SODIUM CHLORIDE

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16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 19-Nov-2014

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet