



# SAFETY DATA SHEET

Revision date 18-Jun-2025

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** TRUMENBA (Meningococcal Group B Vaccine) Suspension for intramuscular injection

**Product Code(s)** WR00037

**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

**Trade Name:** TRUMENBA

**Compound Number** PF-05212366

**Chemical Family:** Not determined

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Vaccine

### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

#### OSHA Classification

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements

**Signal word** Not classified

**Hazard statements** Not classified in accordance with international standards for workplace safety.

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**Supplemental Hazard** Compound, not fully tested, additional hazards may exist.

## 2.3. Other hazards

**Other hazards** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**PBT & vPvB** The product does not contain any substance(s) classified as PBT or vPvB.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

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

## **Section 3: COMPOSITION/INFORMATION ON INGREDIENTS**

### 3.1 Substances

**Substances** Not applicable

### 3.2 Mixtures

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available
MnB Bivalent rLP2086 (CAS #: PROPRIETARY)	*		Not Listed	Not classified	Not classified	No data available	No data available
L-Histidine (CAS #: 71-00-1)	*	-	200-745-3	Not classified	Not classified	No data available	No data available
Polysorbate 80 (CAS #: 9005-65-6)	*	-	500-019-9	Not classified	Not classified	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
L-Histidine 71-00-1	5110	No data available	No data available	No data available	No data available
Polysorbate 80 9005-65-6	34.5 mL/kg	No data available	No data available	No data available	No data available

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This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## Additional information

\* Proprietary

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.

### 4.2. Most important symptoms and effects, both acute and delayed

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO<sub>2</sub>, alcohol-resistant foam or water spray.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Fine particles (such as mists) may fuel fires/explosions.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

#### Explosion data

**Sensitivity to mechanical impact** No information available.

**Sensitivity to static discharge** No information available.

### 5.3. Advice for firefighters

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

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## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.  
**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.  
**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.  
**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

**Advice on safe handling** Restrict access to work area. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Additional controls (based on risk assessment) should be implemented where open handling is required. Use enclosed manufacturing processing strategies. 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.  
**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Vaccine.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

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

#### SODIUM CHLORIDE

Latvia

TWA: 5 mg/m<sup>3</sup>;

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Russia  
**L-Histidine**  
Latvia

MAC: 5 mg/m<sup>3</sup>

TWA: 5 mg/m<sup>3</sup>;

**Pfizer Occupational Exposure Band (OEB) Statement:** The Vaccines Occupational Exposure Band (V-OEB) is a classification that has been assigned to biotechnology-based vaccines and antigen components. Risk assessments should be performed to assess potential exposures and determine appropriate controls.

## SODIUM CHLORIDE

Pfizer Occupational Exposure  
Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

## 8.2. Exposure controls

### Engineering controls

Release prevention and exposure protection measures should be established for any activities involving this material, as determined by a risk assessment conducted using appropriate Occupational Hygiene Risk Assessment tools. The containment level required for the activity should be based on the conclusions of the risk assessment. Where warranted, engineering controls, such as biosafety cabinets, should be applied as the primary means to control exposures.

### Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

### Eye/face protection

Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

### Hand protection

Wear impervious gloves, (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

### Skin and body protection

Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

### Respiratory protection

If operating and handling conditions result in airborne exposure, wear an appropriate respirator with a protection factor sufficient to control exposures (e.g. particulate cartridge with a full face respirator, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

### Thermal hazards

No information available.

### Environmental exposure controls

No information available.

## **Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

### 9.1. Information on basic physical and chemical properties

Physical state

Liquid

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**Color** Clear  
**Odor** No information available.  
**Odor threshold** No information available

<u>Property</u>	<u>Values</u>
<b>Melting point / freezing point</b>	No data available
<b>Boiling point or initial boiling point and boiling range</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Lower and upper explosion limit/flammability limit</b>	
<b>Lower explosion limit</b>	No data available
<b>Upper explosion limit</b>	No data available
<b>Flash point</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	
<b>SADT (°C)</b>	No data available
<b>pH</b>	6.5 - 8.5
<b>pH (as aqueous solution)</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Solubility</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Density and/or relative density</b>	No data available
<b>Bulk density</b>	No data available
<b>Liquid Density</b>	No data available
<b>Vapor density</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available

## 9.2. Other information

**Molecular formula** Mixture  
**Molecular weight** Mixture

### 9.2.1. Information with regard to physical hazard classes

No information available

### 9.2.2. Other safety characteristics

No information available

## **Section 10: STABILITY AND REACTIVITY**

### 10.1. Reactivity

**Reactivity** No information available.

### 10.2. Chemical stability

**Stability** Stable under normal conditions.

#### **Explosion data**

**Sensitivity to mechanical impact** No information available.

**Sensitivity to static discharge** No information available.

### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** No information available.

### 10.4. Conditions to avoid

**Conditions to avoid** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

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## 10.5. Incompatible materials

### Incompatible materials

As a precautionary measure, keep away from strong oxidizers.

## 10.6. Hazardous decomposition products

**Hazardous decomposition products** No data available.

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### 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: drowsiness, headache, diarrhea, vomiting, muscle pain, joint pain, fever, injection site pain.

#### Acute toxicity

Based on available data, the classification criteria are not met.

#### Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

#### Skin corrosion/irritation

Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitization

Based on available data, the classification criteria are not met.

#### STOT - single exposure

Based on available data, the classification criteria are not met.

#### STOT - repeated exposure

Based on available data, the classification criteria are not met.

#### Reproductive toxicity

Based on available data, the classification criteria are not met.

#### Germ cell mutagenicity

Based on available data, the classification criteria are not met.

#### Carcinogenicity

Based on available data, the classification criteria are not met.

#### Aspiration hazard

Based on available data, the classification criteria are not met.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

#### L-Histidine

Rat Oral LD 50 > 15 g/kg

Rat Para-periosteal LD 50 > 2 g/kg

Mouse Oral LD 50 > 15 g/kg

Mouse Intravenous LD 50 > 2 g/kg

#### Polysorbate 80

Rat Intravenous LD 50 1790 mg/kg

Mouse Oral LD 50 25 g/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
SODIUM CHLORIDE	= 3550 mg/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
L-Histidine	> 5110 mg/kg ( Rat )	-	-
Polysorbate 80	= 34.5mL/kg ( Rat )	-	-

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## 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)

### MnB Bivalent rLP2086

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

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

### MnB Bivalent rLP2086

Fertility and Embryonic Development Rabbit Intramuscular \* 200 ug/dose NOAEL No effects at maximum dose,  
Reproductive toxicity, Developmental toxicity

### Reproductive & Development

#### Toxicity Comments:

**MnBrLP2086: \* NOTE:** 4 doses -17 and 4 days prior to mating, gestation days 10 and 24.

## Carcinogenicity

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### 11.2.2. Other information

#### Other adverse effects

No information available.

## Section 12: ECOLOGICAL INFORMATION

### Environmental Overview:

Releases to the environment should be avoided. Environmental properties of the formulation have not been investigated.

### 12.1. Toxicity

No information available

### 12.2. Persistence and degradability

#### Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

#### Bioaccumulation

No information available.

### 12.4. Mobility in soil

#### Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

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## PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
L-Histidine	Not PBT/vPvB

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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 wastewater 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.

## Section 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.**

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

SODIUM CHLORIDE  
**CERCLA/SARA Section 313 de minimus %** Not Listed  
**California Proposition 65** Not Listed

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<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present
MnB Bivalent rLP2086	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
L-Histidine	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-745-3
<b>AICS</b>	Present
Polysorbate 80	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present

## National regulations

### France

#### **Occupational Illnesses (R-463-3, France)**

Chemical name	French RG number
SODIUM CHLORIDE 7647-14-5	RG 78

### Germany

#### **Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

### **TRGS 905**

Not applicable

### Switzerland

**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable

**Storage of Hazardous Material** Not applicable

**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20** Not applicable

**Major Accidents Ordinance SR 814.012** Not applicable

### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### **Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### **Persistent Organic Pollutants**

Not applicable

#### **Ozone-depleting substances (ODS) Regulation (EU) 2024/590**

Not applicable.

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## EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE 7647-14-5	Plant protection agent

  

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene

## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

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

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**Revision date** 18-Jun-2025

**Prepared By** Pfizer Global Environment, Health, and Safety

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