

Revision date 13-Nov-2023

Version 2.02

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

1.1. Product identifier

Product NameMeningococcal Vaccine PentavalentProduct Code(s)PF00225SynonymsPenta (PF-06886992)Trade Name:PENBRAYAChemical 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
E-mail address	pfizer-MSDS@pfizer.com	+353 21 4378701

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: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

<u>2.2. Label elements</u> Signal word	Not classified
Hazard statements	Not classified in accordance with international standards for workplace safety.
2.3. Other hazards Other hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
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	EC No	Classification	Specific	M-Factor	M-Factor
Onemical name	Weight-70	Registration	LONO	according to	concentration		(long-term)
		Number		Regulation	limit (SCL)		(iong-term)
		Number		(EC) No.			
				1272/2008			
				[CLP]			
Water	93.2042	-	231-791-2	Not classified	Not Listed	No data	No data
(CAS #: 7732-18-5)				as hazardous		available	available
Sucrose	*	-	200-334-9	Not classified	Not Listed	No data	No data
(CAS #: 57-50-1)				as hazardous		available	available
SODIUM CHLORIDE	*	-	231-598-3	Not classified	Not Listed	No data	No data
(CAS #: 7647-14-5)				as hazardous		available	available
L-Histidine	*	-	200-745-3	Not classified	Not Listed	No data	No data
(CAS #: 71-00-1)				as hazardous		available	available
Aluminum phosphate	*	-	232-056-9	Not classified	Not Listed	No data	No data
(CAS #: 7784-30-7)				as hazardous		available	available
VinB Bivalent rLP2086	< 1		Not Listed	Not classified	Not Listed	No data	No data
(CAS #:				as hazardous		available	available
PROPRIETARY)							
Tromethamine	*	-	201-064-4	Not classified	Not Listed	No data	No data
(CAS #: 77-86-1)				as hazardous		available	available
Tetanus toxoid	< 1		297-262-3	Not classified	Not Listed	No data	No data
(CAS #:				as hazardous		available	available
93384-51-1)							
MenACWY-TT	< 1		Not Listed	Not classified	Not Listed	No data	No data
(CAS #: -)				as hazardous		available	available
Polysorbate 80	*	-	500-019-9	Not classified	Not Listed	No data	No data
(CAS #: 9005-65-6)				as hazardous		available	available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Sucrose 57-50-1	29700	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
L-Histidine 71-00-1	15000	No data available	No data available	No data available	No data available
Tromethamine 77-86-1	5900	5000	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

Additional information

- Not Assigned * Proprietary

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

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.			
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.			
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.			
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 N	IEASURES			
5.1. Extinguishing media				
Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.			
5.2. Special hazards arising from the	ne 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.			
5.3. Advice for firefighters				
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.			
Section 6: ACCIDENTAL RE	LEASE 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 conta	inment 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 S	TORAGE

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 at 2 to 8 °C in properly labeled containers. Keep away from heat, sparks, and flames.

7.3. Specific end use(s)

Specific use(s)

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Vaccine.

8.1. Control parameters

Exposure Limits

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

Sucrose

ACGIH TLV	10 mg/m ³
Bulgaria	10.0 mg/m ³
Estonia	10 mg/m ³
France	10 mg/m ³
Ireland	10 mg/m ³
	STEL: 20 mg/m ³
Latvia	5 mg/m ³
Spain	10 mg/m ³
OSHA PEL	15 mg/m ³
	5 mg/m ³
	(vacated) TWA: 15 mg/m ³ total dust
	(vacated) TWA: 5 mg/m ³ respirable fraction
United Kingdom	TWA: 10 mg/m ³
	STEL: 20 mg/m ³

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SODIUM CHLORIDE Latvia Russia L-Histidine Latvia Aluminum phosphate ACGIH TLV Spain Pfizer Occupational Exposure Bane (OEB) Statement:	5 mg/m ³ MAC: 5 mg/m ³ 5 mg/m ³ 1 mg/m ³ 1 mg/m ³ d 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): MnB Bivalent rLP2086	OEB 1 (control exposure to the range of 1000ug/m ³ to 3000ug/m ³)
Pfizer Occupational Exposure Band (OEB): Tromethamine	V-OEB
Pfizer Occupational Exposure Band (OEB): PF-06886992 Pfizer Occupational Exposure	OEB 1 (control exposure to the range of 1000ug/m ³ to 3000ug/m ³) V-OEB
Band (OEB): 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.
Environmental exposure controls	No information available.
Personal protective equipment	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. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
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 disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (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.)

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state Color Odor Odor threshold Molecular formula Molecular weight

Property pH Melting point / freezing point Boiling point / boiling range Flash point Evaporation rate Flammability (solid, gas) Flammability Limit in Air Upper flammability limit:

Lower flammability limit:

Vapor pressure Vapor density Relative density Water solubility Solubility(ies) Partition coefficient Autoignition temperature Decomposition temperature Kinematic viscosity Dynamic viscosity Particle characteristics Particle Size Particle Size Particle Size Distribution Explosive properties

Partition Coefficient: (Method, pH, Endpoint, Value) Tromethamine Predicted 7.4 Log D -4.668

<u>9.2. Other information</u> No information available

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 10.2. Chemical stability Stability

No data available.

Stable under normal conditions.

Sterile solution Clear No information available. No information available Mixture Mixture Values

No data available No data available

No information available No data available No data available

No data available

No data available

No data available No data available No data available No data available No data available No data available No data available No data available No data available No data available No data available

No information available No information available No information available Product Name Meningococcal Vaccine Pentavalent Revision date 13-Nov-2023

Explosion data

Sensitivity to Mechanical Impact No data available. Sensitivity to Static Discharge No data 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 dust and mists) may fuel fires/explosions.		

10.5. 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:	The following information is available for the individual ingredients. Toxicological properties of the formulation have not been investigated.
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: injection site pain, swelling, tiredness, headache, muscle 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) Sucrose Rat Oral LD 50 29,700 mg/kg

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³ 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

Aluminum phosphate

Mouse Oral LD 50 > 5000 mg/kg Rat Oral LD 50 > 2000 mg/kg Rabbit Dermal LD 50 > 4640 mg/kg Tromethamine Rat Oral LD50 5900 mg/kg Rat Dermal LD 50 > 5000 mg/kg MenACWY-TT Rabbit Intramuscular NOEL 0.5 mL Polysorbate 80 Rat Intravenous LD 50 1790 mg/kg Mouse Oral LD 50 25 g/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Sucrose	= 29700 mg/kg (Rat)	-	-
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h
L-Histidine	> 15 g/kg (Rat)	-	-
Tromethamine	= 5900 mg/kg (Rat)	> 5000 mg/kg (Rat)	-
Polysorbate 80	= 34.5mL/kg (Rat)	-	-

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

SODIUM CHLORIDE Skin irritation Rabbit Mild Eye irritation Rabbit Mild Tromethamine Eye Irritation Rabbit Slight Skin Irritation Rabbit Slight

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

 MenACWY-TT

 9 Week(s) Rabbit Intramuscular
 0.5 mL/dose/2weeks NOAEL None identified

 Repeated Dose Toxicity Comments:
 MnB Bivalent rLP2086: * 5 doses were administered.

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

MenACWY-TT

Prenatal & Postnatal Development Rat Intramuscular 0.5 mL NOAEL No effects at maximum dose: Maternal toxicity, Fertility, Fetotoxicity

<u>Genetic Toxicity: (Study Type, Cell Type/Organism, Result)</u> <u>Tromethamine</u> Bacterial Mutagenicity (Ames) *E. coli* Negative

Carcinogenicity

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

11.2. Information on other hazards11.2.1. Endocrine disrupting propertiesEndocrine disrupting propertiesNo information available.

11.2.2. Other information Other adverse effects

No information available.

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Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

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

12.1. Toxicity

 No information available

 Tromethamine

 Daphnia magna (Water Flea) OECD EC50 48 hours > 980 mg/L

 Pseudokirchneriella subcapitata (Green Alga) OECD EC50 48 Hours 473 mg/L

 Tromethamine

 Activated sludge OECD EC50 > 1000 mg/L

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value) Tromethamine Predicted 7.4 Log D -4.668

12.4. Mobility in soil

Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does
	not apply
L-Histidine	The substance is not PBT / vPvB
Aluminum phosphate	The substance is not PBT / vPvB PBT assessment does
	not apply
Tromethamine	The substance is not PBT / vPvB PBT assessment does
	not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific

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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 transport under USDOT, EUADR, IATA, or IMDG regulations.

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
Special precautions for user:	Not applicable

Section 15: REGULATORY INFORMATION

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

Water CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS Sucrose	Not Listed Not Listed Present 231-791-2 Present
CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS	Not Listed Not Listed Present 200-334-9 Present
SODIUM CHLORIDE CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS L-Histidine	Not Listed Not Listed Present 231-598-3 Present
CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS Aluminum phosphate	Not Listed Not Listed Present 200-745-3 Present
CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS MnB Bivalent rLP2086	Not Listed Not Listed Present 232-056-9 Present

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CERCLA/SARA Section 313 de minimus % California Proposition 65 EINECS Tromethamine	Not Listed Not Listed Not Listed
CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS	Not Listed Not Listed Present 201-064-4 Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4
Tetanus toxoid CERCLA/SARA Section 313 de minimus % California Proposition 65 EINECS Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Not Listed Not Listed 297-262-3 Schedule 4
MenACWY-TT CERCLA/SARA Section 313 de minimus % California Proposition 65 EINECS Polysorbate 80	Not Listed Not Listed Not Listed
CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS	Not Listed Not Listed Present Not Listed Present

France

Occupational Illnesses (R-463-3, France)

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

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 (EC) 1005/2009

Not applicable

Plant protection products directive (91/414/EEC)

	Chemical name		Plant protection products directive (91/414/EEC)
S	ucrose - 57-50-1		Plant protection agent
SODIUM	CHLORIDE - 7647-14	-5	Plant protection agent

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances **AICS** - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section	16:	OTHER	INFORMATION
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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.
Revision date	13-Nov-2023
Prepared By	Pfizer Global Environment, Health, and Safety

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