

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

Product identifier

Product Name Menactra®

Other means of identification

Product Information Single-dose vial, supplied as a package of 5 vials.

Synonyms

Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine Solution for Intramuscular Injection

Recommended use of the chemical and restrictions on use

Recommended Use Active immunization to prevent invasive meningococcal disease caused by *N meningitides* serogroups A, C, Y and W-135.

Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address

Sanofi Pasteur
Discovery Drive
Swiftwater, PA 18370
Phone: 1-800-822-2463 (1-800-VACCINE)

Emergency telephone number

24 Hour Emergency Phone 1-703-741-5970 / 1-800-424-9300 CCN # 2118 (CHEMTREC)

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Not classified.

Physical hazards

Not classified.

OSHA Regulatory Status

This product is a vaccine that is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows throughout the sheet.

Label elements

Emergency Overview

Normal precautions common to safe manufacturing practice should be followed in handling and storage.

Appearance Clear to slightly turbid solution.	Physical state Liquid	Odor Not available.
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Hazards not otherwise classified (HNOC)

Not classified as a hazardous substance.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine Solution for Intramuscular Injection

Chemical Name	CAS No.	Weight-%
Meningococcal (Serogroup A) Polysaccharide (Monovalent Conjugate)	N/A	0.008
Meningococcal (Serogroup C) Polysaccharide (Monovalent Conjugate)	N/A	0.008
Meningococcal (Serogroup Y) Polysaccharide (Monovalent Conjugate)	N/A	0.008
Meningococcal (Serogroup W135) Polysaccharide (Monovalent Conjugate)	N/A	0.008
Diphtheria Toxoid Protein	N/A	0.0096
Sodium Chloride	7647-14-5	0.87
Water	7732-18-5	q.s. to 100

Note: Ingredients below reportable levels are not listed.

4. FIRST AID MEASURES

First aid measures

Eye contact

In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact

In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation

In case of inhalation, remove to fresh air. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion

In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention if needed. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-protection of the first aider

Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms

Common effects of vaccine for infants and toddlers 9 and 12 months of age were injection site tenderness, erythema, and swelling; irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever.

Common effects of the vaccine for individuals 2 through 55 years of age were injection site pain, redness, induration and swelling; anorexia, diarrhea, irritability, drowsiness, headache, fatigue, malaise, and arthralgia.

Indication of any immediate medical attention and special treatment needed

Note to physicians

Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical

Not available.

Hazardous combustion products Not available.**Explosion data****Sensitivity to Mechanical Impact** Not available.**Sensitivity to Static Discharge** None known.**Protective equipment and precautions for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures****Personal precautions** Wear appropriate personal protective equipment (see Section 8).**Environmental precautions****Environmental precautions** See Section 12 for additional ecological information.**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**

Wipe up with absorbent material (e.g. cloth) for disposal. Area where spill occurred can be cleaned with the regular cleaning materials designated for the area.

7. HANDLING AND STORAGE**Precautions for safe handling****Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.**Conditions for safe storage, including any incompatibilities****Storage Conditions** Store at 2° to 8°C (35° to 46°F). Do not freeze.**Incompatible materials**

Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Control parameters****Exposure Guidelines**

This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Appropriate engineering controls**Engineering Controls**

Used as supplied, no special engineering controls are needed when administering the vaccine.

Individual protection measures, such as personal protective equipment**Eye/face protection**

In laboratory or industrial settings, safety glasses with side shields are recommended.

Skin and body protection

In laboratory or industrial settings, gloves and lab coats are recommended.

Respiratory protection

Used as supplied, general room ventilation is acceptable and no special respiratory protection is needed when administering the vaccine.

General Hygiene Considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid	Odor	Not available.
Appearance	Clear to slightly turbid solution.	Odor threshold	Not available.
Color	Clear		

<u>Property</u>	<u>Values</u>	<u>Remarks</u>
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	Not available.	
Decomposition temperature	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive properties	Not available.	
Oxidizing properties	Not available.	

Other Information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal handling.

Hazardous polymerization	Hazardous polymerization does not occur.
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Conditions to avoid

Not available.

Incompatible materials

Not available.

Hazardous Decomposition Products

None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	No data available.
Inhalation	No impact known or expected under normal use.
Eye contact	No impact known or expected under normal use.
Skin Contact	No impact known or expected under normal use.
Ingestion	No impact known or expected under normal use.

Information on toxicological effects

Symptoms	Common effects of vaccine for infants and toddlers 9 and 12 months of age were injection site tenderness, erythema, and swelling; irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever.
	Common effects of the vaccine for individuals 2 through 55 years of age were injection site pain, redness, induration and swelling; anorexia, diarrhea, irritability, drowsiness, headache, fatigue, malaise, and arthralgia.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Not available.
Serious eye damage/eye irritation	Not available.
Irritation	Not available.
Corrosivity	Not available.
Sensitization	Not available.
Germ cell mutagenicity	Menactra vaccine has not been evaluated for mutagenic potential.
Carcinogenicity	Menactra vaccine has not been evaluated for carcinogenic potential.
Reproductive toxicity	There are no adequate and well-controlled studies of Menactra administration in pregnant women in the US. Available data suggest that rates of major birth defects and miscarriage in women who received Menactra 30 days prior to pregnancy or during pregnancy are consistent with estimated background rates.
Developmental Toxicity	A developmental toxicity study was performed in female mice. The animals were administered 0.1 mL of Menactra (in divided doses) at each of the following time points: 14 days prior to mating, and on Days 6 and 18 of gestation (a single human dose is 0.5 mL). There were no vaccine-related fetal malformations or variations, and no adverse effects on pre-weaning development observed in the study.
Teratogenicity	Not available.
STOT - single exposure	Not classified.
STOT - repeated exposure	Not classified.
Chronic toxicity	Not available.
Subchronic toxicity	Not available.
Target Organ Effects	Not available.
Neurological effects	Not available.
Other adverse effects	Not available.
Aspiration hazard	Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Not available.

Persistence and degradability

Not available.

Bioaccumulation

Not available.

Mobility

Not available.

Other adverse effects

Not available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods****Disposal of wastes**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging

Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number

Not applicable.

California Hazardous Waste Codes

Not applicable.

14. TRANSPORT INFORMATION**DOT**

Not regulated.

TDG

Not regulated.

MEX

Not regulated.

ICAO (air)

Not regulated.

IATA

Not regulated.

IMDG

Not regulated.

RID

Not regulated.

ADR

Not regulated.

ADN

Not regulated.

15. REGULATORY INFORMATION**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355).

US State Regulations**California Proposition 65**

No component is on the Proposition 65 list.

U.S. State Right-to-Know Regulations

This drug is regulated by the Food and Drug Administration and is therefore exempt from State Right-to-Know Regulations.

16. OTHER INFORMATION

Prepared By	IES Engineers
Issue Date	16-Apr-2015
Revision Date	22-Jan-2019
Revision Note	Updated Sanofi Pasteur address. Revised by Sanofi Pasteur.

Disclaimer

Sanofi Pasteur considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. Sanofi Pasteur cannot be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet