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 (NDC 49281-589-58)
Supplied as a package of 5 vials (NDC 49281-589-05)

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

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
1 Discovery Drive
Swiftwater, PA 18370

Emergency telephone number

Company Phone Number 1-800-VACCINE (1-800-822-2463)
24 Hour Emergency Phone Number 1-570-957-4400
Emergency Telephone 1-570-957-4400

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.

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

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 (SerogroupW135) 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		
Appearance	Clear to slightly turbid solution.	**Odor**	Not available.
Color	Clear	**Odor threshold**	Not available.

Property	**Values**	**Remarks**
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.

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 ager 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 Pregnancy Category C
Animal reproduction studies have not been conducted with Menactra vaccine. It is also not known whether Menactra vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. There are no adequate and well controlled studies in pregnant women. Menactra vaccine should only be given to a pregnant woman if clearly needed. Assessment of the effects on animal reproduction has not been fully conducted with Menactra vaccine as effects on male fertility in animals as not been evaluated. The effect of Menactra vaccine on embryo-fetal and pre-weaning development was evaluated in one developmental toxicity study in mice. Animals were administered Menactra vaccine on Day 14 prior to gestation and during the period of organogenesis (gestation Day 6). The total dose given per time point was 0.1 mL/mouse via intramuscular injection (900 times the human dose, adjusted by body weight). There were no adverse effects on pregnancy, parturition, lactation or pre-weaning development noted in this study. Skeletal examinations revealed one fetus (1 of 234 examined) in the vaccine group with a cleft palate. None were observed in the concurrent control group (0 of 174 examined). There are no data that suggest that this isolated finding is vaccine-related, and there were no vaccine-related fetal malformations or other evidence of teratogenesis observed in this study.

It is not known whether Menactra vaccine is excreted in human milk.

Developmental Toxicity Not available.
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
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations
This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information
EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Revision Date
Revision Note
Not available.

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