

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

Product identifier

Product Name Pentacel®

Other means of identification

Product Code 5 Dose Package (NDC 49281-510-05) containing 5 vials of DTaP-IPV component (NDC 49281-560-05) to be used to reconstitute 5 single dose vials of lyophilized ActHIB vaccine (NDC 49281-545-15)

Synonyms Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine

Recommended use of the chemical and restrictions on use

Recommended Use Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenza type b.

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 Cloudy, uniform, white to off-white (yellow tinge) after reconstitution. **Physical state** Powder and liquid diluent **Odor** Not available.

Hazards not otherwise classified (HNOC)

Not classified as a hazardous substance.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine

Chemical Name	CAS No.	Weight-%
Diphtheria Toxoid Adsorbed	N/A	N/A
Tetanus Toxoid Adsorbed	N/A	N/A
Pertussis Adsorbed	N/A	0.004
Filamentous Haemagglutinin Adsorbed (FHA)	N/A	0.004
Fimbriae Types 2 and 3 Adsorbed (FIM)	N/A	0.001
Pertactin Adsorbed	N/A	0.0006
Haemophilus influenzae type b polysaccharide (polyribosylribitol phosphate)	N/A	0.002
Concentrated trivalent of inactivated poliomyelitis virus: Type 1, 2, 3	N/A	N/A
conjugated to Tetanus protein	N/A	0.0048
Sucrose NF	57-50-1	8.5
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 effect of the vaccine include the following: tenderness and increased circumference of the injection site; fussiness/irritability; inconsolable crying.

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 other hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH
Sucrose NF 57-50-1	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust

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	Powder and liquid diluent	Odor	Not available.
Appearance	Cloudy, uniform, white to off-white (yellow tinge) after reconstitution.	Odor threshold	Not available.
Color	White to off-white.		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</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.

Acute Effects

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Sucrose NF 57-50-1	= 29700 mg/kg (Rat)	-	-	-

Information on toxicological effects

Symptoms Common effects of the vaccine include the following: tenderness and increased circumference of the injection site; fussiness/irritability; inconsolable crying.

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	Not available.
Carcinogenicity	Not available.
Reproductive toxicity	Pregnancy Category C: Animal reproduction studies have not been conducted with Pentacel vaccine. It is also not known whether Pentacel vaccine can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.
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 may contain substances regulated by state right-to-know regulations.

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Sucrose NF 57-50-1	-	X	X

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