



Liquid PedvaxHIB™

SAFETY DATA SHEET

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IMPORTANT NOTICE This Safety Data Sheet (SDS) is prepared by CSL Limited in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (December 2011). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product Name Liquid PedvaxHIB™

Other Names Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)

Manufacturer's Product Code No. 4897 — A box of 10 single-dose vials of liquid vaccine
NDC 0006-4897-00

Use Vaccine indicated for routine vaccination against invasive disease caused by *Haemophilus influenzae* type b in infants and children 2 to 71 months of age.

Supplier's Name CSL Limited (ABN 99 051 588 348)

Address 45 Poplar Road, Parkville, Victoria 3052, Australia

Telephone +61 03 9389 1911

Emergency Telephone +61 03 9389 1984 (24hr)

Manufacturer MERCK & CO., INC

Address One Merck Drive, Whitehouse Station, NJ 08889-0100

Telephone (908) 423-1000

Emergency Telephone 1-732-594-5555

2. HAZARDS IDENTIFICATION

Not classified as hazardous according to the criteria of SWA

Not classified as a dangerous good by the criteria of the ADG Code

3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Chemical name:</i>	<i>CAS Number:</i>	<i>Proportion:</i>
Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)	-	< 0.1%
Aluminum Hydroxyphosphate Sulphate	20257-20-9	< 0.1%
Inactive Ingredients	-	>99.9%

4. FIRST AID MEASURES

- Eye** In case of contact, flush eyes with plenty of water. Get medical attention if symptoms occur.
- Ingestion** Do NOT induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms appear.
- Skin** Wash with soap and water. Get medical attention if irritation develops.
- Inhaled** If inhaled, remove to fresh air. Get medical attention if symptoms appear.
- Advice to Doctor** Treat supportively and symptomatically. For additional guidance refer to the current prescribing information or the local poison control centre.

5. FIRE FIGHTING MEASURES

- Fire/Explosion Hazard** None known.
- Fire Extinguishing Media** In case of fire, use water spray (fog), foam, dry chemical, or CO₂
- Hazchem Code** None known.

6. ACCIDENTAL RELEASE MEASURES

- Minor Spills** Wear protective gloves and safety glasses. Contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal.
- Major Spills** Wear protective gloves and safety glasses. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways.

7. HANDLING AND STORAGE

Avoid direct contact with skin and eyes. Wash thoroughly after handling.
In the absence of specific storage recommendations, keep container in a cool, well-ventilated area.
Keep container tightly closed.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- Exposure Standards** No exposure limits set by SWA or ACGIH.
- Engineering Controls** Adequate ventilation should be provided if there is risk of aerosol formation. None required when handling sealed vials.

Personal Protection For good infection control, gloves and safety glasses with side shields should be worn when administering an injection.

Additional body garments should be used based upon the task being performed (e.g. sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

No respiratory protection is required when handling bulk liquid formulation or sealed vials. As an adjunct to engineering controls, use an approved, properly fitted, powered air purifying respirator, or respirator of equivalent or greater protection if the potential exists for exposure to airborne aerosols.

Work uniform or laboratory coat.

No PPE is required when handling sealed vials.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance Slightly opaque white liquid

Odour Not available

pH Not available

Boiling Point Not available

Melting Point Not available

Flash Point Not applicable

Flammability Limits Not applicable

Autoignition Temperature Not applicable.

Solubility Not available.

Partition Coefficient Not available.

Specific Gravity Not available.

Vapour Density Not available.

Vapour Pressure Not available.

Volatility Component Not available.

10. STABILITY AND REACTIVITY

Reactivity Not available

Stability Not available

Decomposition Products Not known

11. TOXICOLOGICAL INFORMATION

Routes of Entry Ingestion: No
Inhalation: Yes
Skin Contact: No

Toxicity Data Haemophilus b Conjugate Vaccine Not available
Aluminium hydroxyphosphate sulphate Not available

Effects of Acute Exposure

Eye Contact Not available

Skin Contact Not available

Inhalation Not available

Ingestion Not available

Effects of Chronic Health Exposure This compound is a vaccine indicated for routine vaccination against invasive disease caused by *Haemophilus influenzae* type b in infants and children 2 to 71 months of age. PedvaxHIB showed no adverse effects in general safety testing conducted in guinea pigs and mice. Because the lipopolysaccharide (LPS) contained by OMPC has the capacity to elicit a pyrogenic response when the LPS is biologically accessible, pyrogenicity tests through intramuscular and intravenous routes were developed and are conducted in rabbits. Release criteria require that no significant temperature rise is observed in these tests. PedvaxHIB has not been evaluated for its carcinogenic, mutagenic potential, or the potential to impair fertility.

The most frequently reported (>1%) adverse reactions, without regard to causality, were fever (>101°F), irritability, sleepiness, injection-site pain/soreness, injection-site erythema (<2.5 cm diameter), injection-site swelling/induration (<2.5 cm diameter), unusual high-pitched crying, prolonged crying (>4 hours), diarrhoea, vomiting, crying, pain, otitis media, rash, and upper respiratory infection.

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

Medical Conditions Aggravated by Overexposure Not available

12. ECOLOGICAL INFORMATION

Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Information Avoid contact of spilled material and runoff with soil and surface waterways. Dispose of or treat all spill residues including contaminated soils following all applicable regulations.

14. TRANSPORT INFORMATION

UN Number	Not regulated
Proper Shipping Name	Not regulated
Transport Hazard Class	Not regulated
Packing Group	Not regulated
Hazchem Code	Not regulated

15. REGULATORY INFORMATION

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

16. OTHER INFORMATION

Last Revised 20 April 2013

Reason for Revision New Product

Abbreviations

SWA	Safe Work Australia
ACGIH	American Conference of Governmental Industrial Hygienists
ADG Code	Australian Dangerous Goods Code
UN Number	United Nations Number
CAS Number	Chemical Abstract Service Number

Contact Point

Company Contact:	+61 3 9389 1984 (24hr)
Australian Poisons Information Centre, 24 hour service:	13 11 26
Australian Police, Fire Brigade or Ambulance:	000

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