

Recombivax®



SAFETY DATA SHEET

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IMPORTANT NOTICE This Safety Data Sheet (SDS) is prepared by Seqirus Pty. Ltd. in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (February 2016). 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 Recombivax®

Other Names H-B Vax II

Manufacturer's Product Code 4980 – Pediatric/Adolescent Formulation 0.5ml single dose vial (NDC 006-4980-00)
4981 - Paediatric/Adolescent Formulation 0.5 mL single-dose in box of 10 single-dose vials (NDC 0006-4981-00)
4995 - Adult Formulation 1 mL single-dose vial (NDC 0006-4995-00) and 1 mL single-dose vial in box of 10 single-dose vials (NDC 0006-4995-41)
4992 - Dialysis Formulation 1 mL single-dose vial (NDC 0006-4992-00)

Use Vaccine indicated for immunization against infection caused by all known subtypes of hepatitis B virus.

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

Address 63 Poplar Road, Parkville, Victoria 3052, Australia

Telephone +61 03 9389 2000

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 the Australian WHS Regulations

GHS Classification(s) None Allocated

Signal Word No signal word

Pictogram(s) No Pictogram(s)

Hazard Statement(s) None Allocated

Prevention statement(s) None Allocated

Response None Allocated

Storage None Allocated

Disposal None Allocated

3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Chemical name:</i>	<i>CAS Number:</i>	<i>Proportion:</i>
Hepatitis B surface antigen (HBsAg)	-	< 1%
Other non-hazardous ingredients	-	Up to 100%

4. FIRST AID MEASURES

- Eye** In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.
- Ingestion** Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.
- Skin** In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse.
- Inhaled** If inhaled, remove to fresh air. If breathing is difficult, give oxygen. Get medical attention if symptoms occur. If not breathing, give artificial respiration.
- 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** Not applicable.
- Fire Extinguishing Media** In case of fire, use water spray (fog), foam, dry chemical, or CO₂
- Hazchem Code** Not applicable.

6. ACCIDENTAL RELEASE MEASURES

- Minor Spills** Wear protective gloves and safety glasses. 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. Wash area with copious amounts of water.
- 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. Wash area with copious amounts of water.

7. HANDLING AND STORAGE

Transport and Store vials at 2-8°C (do not freeze).
Protect from light.
Store as per Schedule 4 pharmaceutical.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards No exposure limits set by SWA or ACGIH.

Engineering Controls None required when handling sealed vials. Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections). Laboratory operations do not require special containment.

Personal Protection None required with the normal handling of the finished product.

For good infection control, gloves and safety glasses with side shields should be worn when administering an injection. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with liquids, mists, or aerosols.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance Clear or opaque liquid

Odour Not available

pH Not available

Boiling Point/Melting Point 100°C

Vapour Pressure Not available

Vapour Density Not available

Specific Gravity Not available

Flashpoint Not applicable

Flammability Limits Not applicable

Solubility in Water Soluble in water in any proportion.

10. STABILITY AND REACTIVITY

Reactivity Not available

Stability Not available

Decomposition Products Not known

11. TOXICOLOGICAL INFORMATION

Skin Non-irritating to the skin.

Eye Non-irritating to the eyes.

Inhalation Not available.

Ingestion Not available.

Chronic Health Effects This compound is a vaccine indicated for immunization against infection caused by all known subtypes of hepatitis B virus. RECOMBIVAX HB Hepatitis B Vaccine is a non-infectious subunit viral vaccine consisting of surface antigen of hepatitis B virus produced yeast cells.

In a group of studies involving healthy adults, the most frequent complains (>1% of injections) in individuals receiving RECOMBIVAX HB included injection-site reactions, fatigue/weakness, headache, fever (>100° F), malaise, nausea, diarrhoea, pharyngitis, and upper respiratory infection.

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

12. ECOLOGICAL INFORMATION

Not available

13. DISPOSAL CONSIDERATIONS

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

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

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 March 2017**Reason for Revision** Update SDS to GHS
Update business contact details**Abbreviations**

SWA	Safe Work Australia
WHS	Work, Health and Safety
ACGIH	American Conference of Governmental Industrial Hygienists
GHS	Globally Harmonised System
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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