

# SAFETY DATA SHEET

**PRODUCT NAME: RECOMBIVAX®****Page: 1/6****Revision 25-Sep-2008**

## 1. Product and Company Identification

Manufactured/Supplied by MERCK & CO., INC.  
One Merck Drive  
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(908) 423-1000

Emergency Telephone Number: 1-732-594-5555

Label Name RECOMBIVAX®  
Chemical Name hepatitis B vaccine (recombinant)  
Synonyms H-B VAX II  
Material Product Number 4980 - Pediatric/Adolescent Formulation 0.5 mL single-dose vial (**NDC 006-4980-00**)  
4981 - Pediatric/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**)

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

## 2. Composition/Information on Ingredients

<u>Component</u>	<u>Molecular Formula</u>	<u>Molecular weight</u>	<u>CAS Number</u>	<u>Percent (%)</u>
Hepatitis B surface antigen (HBsAg)	Not available	Not available	Not available	<1
Aluminum hydroxide	Not available	Not available	20257-20-9	<1
Water	H <sub>2</sub> O	18.02	7732-18-5	>95

EC Label Not classified as Dangerous according to the Dangerous Substances Directive (DSD).

### 3. Hazards Identification

<u>Appearance</u>	Clear or opaque liquid
<u>Label Text</u>	CAUTION! VACCINE
<u>Emergency Overview</u>	No specific hazard with intact vials.  Avoid direct contact with skin and eyes. Wash thoroughly after handling.
<u>Potential Health Effects</u>	See Section 11 for detailed information.

### 4. First Aid Measures

<u>Eye Contact</u>	In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.
<u>Skin Contact</u>	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.
<u>Inhalation</u>	If inhaled, remove to fresh air. If breathing is difficult, give oxygen. Get medical attention if symptoms occur. If not breathing, give artificial respiration.
<u>Ingestion</u>	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.
<u>Notes to physician</u>	Treat supportively and symptomatically.  For additional guidance refer to the current prescribing information or the local poison control center.

### 5. Fire Fighting Measures

<u>Flash Point</u>	Not applicable
<u>Flammable Limits (% in air)</u>	Not applicable
<u>Autoignition Temperature</u>	Not available
<u>Oxidizing Properties</u>	Not available
<u>Combustibility Information</u>	Not available
<u>Dust Explosivity Information</u>	Not applicable
<u>Shock Sensitivity</u>	Not applicable
<u>Fire/Explosion Hazards</u>	None known.
<u>Special Fire Procedures</u>	No special procedures.
<u>Extinguishing Media</u>	In case of fire, use water spray (fog), foam, dry chemical, or CO <sub>2</sub> .
<u>Hazardous Decomposition Products</u>	None known.

## 6. Accidental Release Measures

### Personal Precautions

**See Section 8 for Personal Protective Equipment** Contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures (Section 5).

### Methods for cleaning up

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. 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. **See Section 13 for Waste Disposal Information**

## 7. Handling and Storage

### Handling

Avoid direct contact with skin and eyes. Wash thoroughly after handling.

### Storage

Keep container tightly closed. Store vials at 2-8°C (36-46.4°F)

## 8. Exposure Controls/Personal Protection

### Exposure Guidelines

<u>Component</u>	<u>OSHA Permissible Exposure Limit (PEL)</u>	<u>ACGIH Threshold Limit Value (TLV)</u>	<u>Merck Exposure Control Limit (ECL) or PB-ECL Category</u>
Hepatitis B surface antigen (HBsAg)	Not established	Not established	Not established
Aluminum hydroxide	Not established	Not established	Not established
Water	Not established	Not established	Not established

### 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 Protective Equipment

#### Eye/Face Protection

None required with normal handling of finished product.

Safety glasses with side shields. Wear appropriate splash goggles if there is a potential for direct contact with liquid splash, mists or aerosols. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with liquids, mists, or aerosols.

#### Skin Protection

None required with normal handling of finished product.

Disposable chemical resistant gloves.

Respiratory Protection

None required with normal handling of finished product.

Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. When handling a compound in solution, a cartridge/canister appropriate for the solution may also be needed.

Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.

Additional Protective Equipment

None required with normal handling of finished product.

Work uniform or laboratory coat.

## 9. Physical and Chemical Properties

Appearance

Clear or opaque liquid

Odor/Threshold Limit

Not available

pH

Not available

Boiling Point

**Water:** 100°C (212°F)

Melting Point

**Water:** 0°C (32°F)

Flash point

Not applicable

Flammable Limits (% in air)

Not applicable

Autoignition Temperature

Not available

Solubility

**Water:** Soluble in water in any proportion.

Partition Coefficient

Not available

Specific Gravity

Not available

Vapor Density

Not available

Vapor Pressure

Not available

Volatility Component

Not available

## 10. Stability and Reactivity

Stability

Not available

Conditions to Avoid

Not available

Incompatibility

Not available

Hazardous Polymerization

Not available

Hazardous Decomposition Products

None known.



### 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

Shipping DescriptionU.S. DOT

Not regulated.

IATA/ICAO

Not regulated.

IMO

Not regulated.

ADR/RID

Not regulated.

### 15. Regulatory Information

U.S. Federal Regulations

Hazardous per OSHA Hazard Communication Standard criteria (29 CFR 1910.1200).

State Regulations

Not available

International Regulations

Not classified as Dangerous according to the Dangerous Substances Directive (DSD).

### 16. Other Information

Revisions: Exposure Guidelines, Engineering Controls

Revision:

9/25/2008.

Date of Preparation

6/7/2007

Date of Previous Issue

18-Apr-2008

Validation Date

9/25/2008.

MSDS Coordinator:

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Disclaimer:

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