



Material Safety Data Sheet

ANSI Format

HibTITER

Revision Date 23-Jan-2008

Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	HibTITER
Common Name	Haemophilus b Conjugate
Chemical Name	Not applicable
Synonyms	Haemophilus b Conjugate, Diphteria CRM197 Protein Conjugate
Product Use	Biopharmaceutical product
Classification	Serums, Toxoids, and Vaccines
Supplier	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
Emergency Telephone Number	Chemtrec USA, Puerto Rico, Canada 1-800-424-9300 Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active biopharmaceutical ingredient that can affect body functions; handle with caution..

Appearance Biopharmaceutical liquid	Physical State Liquid	Odor Not available
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Potential Physical Hazards	None known
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Potential Health Effects	
Eyes	Not available
Skin	Not available
Inhalation	Not available
Ingestion	Not available
Other	The most common effects may include immune response, allergic or hypersensitivity reactions including anaphylaxis and shock (hives, urticaria, difficulty breathing, wheezing, tightness in chest, hypotension), edema, fatigue, headache, drowsiness, rash, convulsions, erythema multiforme, lethargy, and Guillain Barre syndrome. Please see Product Insert for further information.
Therapeutic Target Organ(s)	Immune system
—	Not listed by OSHA, NTP or IARC..
Potential Environmental Effects	There is no known ecological information for this product..

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Haemophilus b Conjugate	None assigned	70 mcg/ml
Inactive Ingredients	Not applicable	Remainder

4. FIRST AID MEASURES

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable.
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide..***
Unsuitable Extinguishing Media	
Fire Fighting	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
Hazardous Combustion Products	Carbon oxides, nitrogen oxides.
Protective Equipment and Precautions for Firefighters	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters..

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in Sections 7 and 8..
Environmental Precautions	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling	For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Risk Based Exposure Control Classification	2
Engineering Controls	No special precautions required.
Personal Protective Equipment	
Eye/face Protection	Avoid contact with skin and eyes.
Skin Protection	For prolonged or repeated exposure use protective gloves. No special protective clothing required under typical conditions of use.
Respiratory Protection	No personal respiratory protective equipment normally required..
General Hygiene Considerations	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
Other	Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Biopharmaceutical liquid	Physical State	Liquid
Color	Colorless	Odor	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	Water Solubility	Not applicable
Solubility	Not applicable	Evaporation Rate	Not available
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not available
Boiling Point	Not available	Autoignition Temperature	Not applicable
Flash Point	Not applicable	Method	None
Melting Point	Not applicable		
Flammability Limits in Air	Upper Not applicable	Lower Not applicable	
Explosion Limits	Upper Not applicable	Lower Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature..
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned..
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Haemophilus b Conjugate

LD50 Oral	Not applicable
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Multiple Dose Toxicity

Haemophilus b Conjugate

No Toxicologic Effect	In a 4-week IV study in rats, no adverse effects were observed. In a repeated-dose toxicity study in monkeys, this product was well tolerated prior to the formation of antibodies.
Dose/Species/Study Length:	

Maximum Tolerated Dose (MTD), Oral

Haemophilus b Conjugate

Carcinogenicity	No carcinogenicity studies have been performed.
Genetic Toxicity	Non-mutagenic in the mouse micronucleus assay.
Reproductive Toxicity	Animal studies to evaluate effects on fertility have not been conducted.
Developmental Toxicity	Animal reproduction studies have not been conducted.

Haemophilus b Conjugate

Target Organ(s) of Toxicity	No data available
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12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Not available

Ecotoxicity

Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations..

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport..

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

15. REGULATORY INFORMATION**USA****Federal Regulations****OSHA Regulatory Status**

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs..

State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

Canada

Not classified

WHMIS Hazard Class

Non-controlled

European Union

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled..

16. OTHER INFORMATION**Prepared By**

Wyeth Department of Environment, Health & Safety

Format

This MSDS was prepared in accordance with ANSI Z400.1-2004.

List of References

Email L Wylie to DVonKaenel June 11, 2007

Revision Summary

Administrative

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End of MSDS