



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, Diphtheria 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 |
|--|------------------------------|---------------------------|

Potential Physical Hazards None known

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 | Do NOT use water jet.. |
| 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 |
|------------------------------------|-------------------|

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

| | |
|---|---------------|
| <u>Chemical Fate Information</u> | Not available |
|---|---------------|

| | |
|---------------------------|---------------|
| <u>Ecotoxicity</u> | 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

Disclaimer:

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End of MSDS