

Material Safety Data Sheet

ANSI Format

Prevnar

| Preparation Date 27-Jun-2007 | Revision Date 09-Sep-2008 | Revision Number 3 |
|------------------------------|---|--------------------------|
| 1. | PRODUCT AND COMPANY IDENTIFICATION | |
| Product Name | Prevnar | |
| Common Name | Not available | |
| Chemical Name | Not applicable | |
| Synonyms | Pneumococcal 7-Valent Conjugate Vaccine | |
| | Prevenar | |
| Product Use | Biopharmaceutical product | |
| Classification | Vaccine | |
| 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 pharmaceutical 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 Skin Inhalation Ingestion Other | Not available Not available Not available Not available The most common effects may include antibody response, all including anaphylaxis and shock (hives, urticaria, difficulty bre- chest, hypotension), facial edema, rash, fever, loss of appetite vomiting, diarrhea, dermatitis, pruritus, edema, crying and irrita | athing, wheezing, tightness in e, drowsiness, restless sleep, |
| Therapeutic Target Organ(s) | Please see Patient Package Insert for further information. 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 |
|---|--|--|---|
| Pneumococcal 7-valent conju | gate | Not assigned | 72 mcg/ml |
| Inactive Ingredients | | Not applicable | Remainder |
| | 4. F | IRST AID MEASURES | |
| Eye Contact | In the case of advice. | contact with eyes, rinse immediately wit | th plenty of water and seek medical |
| 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 | | ersist, call a physician. Do not induce vo by mouth to an unconscious person. | omiting without medical advice. Never |
| | 5. FIRE | -FIGHTING MEASURES | |
| Flammable Properties | Presumed to b | e a combustible particulate solid. | |
| Extinguishing Media | | | |
| Suitable Extinguishing Media Unsuitable Extinguishing Media | | ay, alcohol-resistant foam, dry chemical olid water stream as it may scatter and | |
| Fire Fighting | | and fight fire from a safe distance. Coo the event of fire and/or explosion do n | ol closed containers exposed to fire with ot breathe fumes. |
| Hazardous Combustion Products | Carbon oxides | , nitrogen oxides. | |
| Protective Equipment and Precautions for Firefighters | | wear self-contained breathing apparatu quivalent) and full protective gear | s pressure-demand, MSHA/NIOSH |
| 6. ACCIDENTAL RELEASE MEASURES | | | |
| Personal Precautions | Safety glasses | or goggles when splash potential exist | s |
| Environmental Precautions | Prevent produc | | s should be advised if a significant spill |
| Methods for Containment | Not available | | |
| Methods for Cleaning up | | anically and collect in suitable containe ghly. Avoid formation of dust and aeros | |

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

| Common Name Pneumococcal 7-valent conjugate | Exposure Guideline 3000 mcg/m ³ |
|---|---|
| Engineering Controls | No special precautions required. |
| Personal Protective Equipment Eye/face Protection Skin Protection Respiratory Protection | Avoid contact with skin and eyes. For prolonged or repeated exposure use protective gloves. No special protective clothing required under typical conditions of use. Base respirator selection on a risk assessment. |
| 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 |

9. PHYSICAL AND CHEMICAL PROPERTIES

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

| 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

| Pneumococcal 7-valent conjugate LD50 Oral Acute Dermal Irritation Primary Eye Irritation Sensitization | No toxicological effects noted in monkeys or rabbits. Not applicable Not applicable Not applicable |
|---|---|
| Multiple Dose Toxicity | |
| Pneumococcal 7-valent conjugate No Toxicologic Effect Dose/Species/Study Length: | Not applicable |
| Maximum Tolerated Dose (MTD), Ora | |
| Pneumococcal 7-valent conjugate Carcinogenicity Genetic Toxicity Reproductive Toxicity Developmental Toxicity | No studies to assess the carcinogenic potential have been performed. No studies to assess the mutagenic potential have been performed. Animal studies to evaluate effects on fertility have not been conducted. Animal reproduction studies have not been conducted. |
| Pneumococcal 7-valent conjugate Target Organ(s) of Toxicity | No data available |

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) Canadian Transport of Dangerous Goods (TDG) | Not regulated Not regulated |
|---|-----------------------------|
| International Civil Aviation Organization (ICAO) | Not regulated |
| International Air Transport Association (IATA) | Not regulated |
| International Maritime Dangerous Goods (IMDG)/International | Not regulated |
| Maritime Organization (IMO) | |
| 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 Format List of References Revision Summary Wyeth Department of Environment, Health & Safety This MSDS was prepared in accordance with ANSI Z400.1-2004. See Patient Package Insert for more information. Revised Product Insert - changes to Section 2.

Disclaimer:

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS