

**European Format** 

**Meningitec Injection** 

#### Preparation Date 09-Jan-2007

Revision Date 09-Sep-2008

**Revision Number** 2

# **1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**

Product Name Common Name Chemical Name Synonyms Product Use Classification	Meningitec Injection Not available Meningococcal group C conjugate vaccine Meningitec Biopharmaceutical product 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. COMPOSITION/INFORMATION ON INGREDIENTS**

Common Name	CAS-No	EC No.	Composition	Classification
Conjugated antigens of N. meningitides	Not applicable	Not applicable	<44 mcg/m <sup>3</sup>	R36/37/38, S13/37/39
Water	7732-18-5	231-791-2	>99%	None assigned

# 3. HAZARDS IDENTIFICATION

This contains an active	Emergency Overview biopharmaceutical ingredient that can affect body functions; handle	e with caution
Appearance Biopharmaceutical liquid	Physical State Liquid	Odor Odorless
Potential Physical Hazards	None known	
Potential Health Effects Eyes Skin Inhalation Ingestion Other	May cause irritation. May cause irritation. May cause irritation of respiratory tract. Not available The most common effects may include immunosuppression, aller fever, headache, and general feeling of discomfort or illness.	rgic reactions, chills, fatigue,
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.
	4. FIRST AID MEASURES
Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes 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 Unsuitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide. 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

<b>Common Name</b> Conjugated antigens of N. meningitides	Exposure Guideline None assigned
Risk Based Exposure Control Classification Engineering Controls	3 Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.
Personal Protective Equipment	
Eye/face Protection Skin Protection	Provide eye protection based on risk assessment. For prolonged or repeated exposure use protective gloves. No special protective clothing required under typical conditions of use.
<b>Respiratory Protection</b>	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. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

# 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance Color Odor Threshold	Biopharmaceutical liquid Hazy Not available	Physical State Odor	Liquid Odorless
рН	5 -7		
Specific Gravity Solubility Partition Coefficient (n-octanol/water) Vapor Pressure	Not available Not applicable Not available Not available	Water Solubility Evaporation Rate Vapor Density	Soluble in water Not available Not available
Boiling Point Flash Point Flammability Limits in Air Explosion Limits	Not available Not applicable <b>Upper</b> Not applicable <b>Upper</b> Not applicable	Autoignition Temperature Melting Point Lower Not applicable Lower Not applicable	Not applicable 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

Conjugated antigens of N. meningitides			
LD50 Oral	No data available		
Acute Dermal Irritation	No data available		
Primary Eye Irritation	No data available		
Sensitization	No data available		

### Multiple Dose Toxicity

Conjugated antigens of N. meningitic	des
No Toxicologic Effect	No data available
Dose/Species/Study Length:	

### Maximum Tolerated Dose (MTD), Oral

Conjugated antigens of N. meningitides			
Carcinogenicity	No data available		
Genetic Toxicity	No data available		
Reproductive Toxicity	No data available		
<b>Developmental Toxicity</b>	No data available		

### Conjugated antigens of N. meningitides Target Organ(s) of Toxicity No data available

## **12. ECOLOGICAL INFORMATION**

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.

## **15. REGULATORY INFORMATION**

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

## **16. OTHER INFORMATION**

Prepared By	
Format	
List of References	
Revision Summary	

Wyeth Department of Environment, Health & Safety This MSDS was prepared in accordance with Directive 2001/58/EC. See Patient Package Insert for more information. Administrative

#### Disclaimer:

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End of MSDS