



# Material Safety Data Sheet

ANSI Format

## Blood Coagulation Factor IX

Preparation Date 07-Dec-2006

Revision Date 23-Jan-2008

Revision Number 1

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name** Blood Coagulation Factor IX  
**Common Name** Coagulation Factor IX  
**Chemical Name** Not applicable  
**Synonyms** BeneFIX, Christmas Factor, Factor IX, Antihemophilic Factor B  
**Product Use** Pharmaceutical product  
**Classification** Blood Formation, Coagulation, Thrombosis Agent  
  
**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** Pharmaceutical powder      **Physical State** Solid      **Odor** Not available

#### Potential Physical Hazards

Powders and solids are presumed to be combustible.

#### Potential Health Effects

**Eyes**

May cause mechanical eye irritation.

**Skin**

Not available

**Inhalation**

Not available

**Ingestion**

See Other

**Other**

The most common effects may include allergic or hypersensitivity reactions including anaphylaxis and shock (hives, urticaria, difficulty breathing, wheezing, tightness in chest, hypotension), fatigue, nausea, vomiting, headache, flushing, lethargy, fever, chills, and venous thromboembolic events.

Please see Patient Package Insert for further information.

**Therapeutic Target Organ(s)**

Blood 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
Coagulation Factor IX	9001-28-9	100%

**4. FIRST AID MEASURES**

<b>Eye Contact</b>	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
<b>Skin Contact</b>	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
<b>Inhalation</b>	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
<b>Ingestion</b>	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**

<b>Flammable Properties</b>	Presumed to be a combustible particulate solid.
<b>Extinguishing Media</b>	
<b>Suitable Extinguishing Media</b>	Use water spray, foam, dry chemical or carbon dioxide.
<b>Unsuitable Extinguishing Media</b>	Do NOT use water jet.
<b>Fire Fighting</b>	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.
<b>Hazardous Combustion Products</b>	Carbon oxides, nitrogen oxides.
<b>Protective Equipment and Precautions for Firefighters</b>	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

**6. ACCIDENTAL RELEASE MEASURES**

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

## 7. HANDLING AND STORAGE

<b>Handling</b>	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.
<b>Storage</b>	No special safety precautions required. Keep container tightly closed.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Risk Based Exposure Control Classification</b>	3
<b>Engineering Controls</b>	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.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Avoid contact with skin and eyes. Provide eye protection based on risk assessment..
<b>Skin Protection</b>	Wear nitrile or latex gloves. Wear protective garment.
<b>Respiratory Protection</b>	Base respirator selection on a risk assessment..
<b>General Hygiene Considerations</b>	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
<b>Other</b>	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

<b>Appearance</b>	Pharmaceutical powder	<b>Physical State</b>	Solid
<b>Color</b>	White	<b>Odor</b>	Not available
<b>Odor Threshold</b>	Not available		
<b>pH</b>	Not applicable		
<b>Specific Gravity</b>	Not applicable	<b>Water Solubility</b>	Not available
<b>Solubility</b>	Not applicable	<b>Evaporation Rate</b>	Not applicable
<b>Partition Coefficient (n-octanol/water)</b>	Not available	<b>Vapor Pressure</b>	Not applicable
<b>Boiling Point</b>	Not applicable	<b>Autoignition Temperature</b>	Not applicable
<b>Flash Point</b>	Not available	<b>Method</b>	None
<b>Melting Point</b>	Not available		
<b>Flammability Limits in Air</b>	<b>Upper</b> Not applicable	<b>Lower</b> Not applicable	
<b>Explosion Limits</b>	<b>Upper</b> Not applicable	<b>Lower</b> 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**Acute Toxicity

## Coagulation Factor IX

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

Multiple Dose ToxicityMaximum Tolerated Dose (MTD), Oral**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.
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**14. TRANSPORT INFORMATION**

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

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**16. OTHER INFORMATION****Prepared By**

Wyeth Department of Environment, Health &amp; Safety

**Format**

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

**List of References**

See Patient Package Insert for more information.

**Revision Summary**

Administrative

## Disclaimer:

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**End of MSDS**