

Preparation Date 17-Oct-2006

Revision Date Not applicable

Revision Number Not applicable

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name BeneFIX
Common Name Coagulation Factor IX
Chemical Name Not applicable
Synonyms Benefix
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** Odorless

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes May cause mechanical eye irritation.
Skin None known
Inhalation See Ingestion and/or Other
Ingestion Not available
Other The most common effects may include allergic reactions including anaphylaxis (hives, urticaria, difficulty breathing, wheezing, tightness in chest, hypotension), fatigue, nausea, vomiting, headache, flushing, lethargy fever, chills, and venous thromboembolic events. Please see Product Insert for further information.
Target Organ(s) Blood system

Carcinogenicity 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	250 - 1000 IU/Vial
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 Clean-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

Common Name	Exposure Guideline
Coagulation Factor IX	100 mcg/m ³

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

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

Coagulation Factor IX	
LD50 Oral	Not applicable
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable

Sensitization Not applicable

Multiple Dose Toxicity

Coagulation Factor IX

No Toxicologic Effect Dose/Species/Study Length: Subacute toxicity studies in mice, rats, and dogs revealed no evidence of systemic toxicity.

Genetic, Reproductive, Developmental Toxicity

Coagulation Factor IX

Carcinogenicity No carcinogenicity studies have been performed.
Genetic Toxicity Non-mutagenic in Ames test; non-clastogenic in chromosomal aberrations assay.
Reproductive Toxicity Animal studies to evaluate effects on fertility have not been conducted.
Developmental Toxicity Animal reproduction studies have not been conducted.

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.

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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and 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

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)

This product does not contain any HAPs.

State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

State Right-to-Know

Not applicable

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

See Product Insert for more information

Revision Summary

Not applicable

Disclaimer:

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End of MSDS