



Antihemophilic Products

Preparation Date 17-Oct-2006

Revision Date 05-Sep-2008

Revision Number 4

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Antihemophilic Products
Common Name Anti-Hemophil FACTOR VIII
Chemical Name Not applicable
Synonyms ReFacto, XYNTHA, Antihemophil Factor (Recombinant) Factor VIII
Product Use Biopharmaceutical product
Classification Blood Formation and Coagulation 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 biopharmaceutical ingredient that can affect body functions; handle with caution..

Appearance Biopharmaceutical 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 Not available
Other The most common effects may include hypersensitivity reactions including anaphylaxis (hives, urticaria, difficulty breathing, wheezing, tightness in chest, hypotension). 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
Inactive Ingredients	Not applicable	Remainder

Common Name	CAS-No	Composition
Antihemophil Factor VIII	284036-24-4	100%

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	Presumed to be a combustible particulate solid.
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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Biopharmaceutical powder	Physical State	Solid
Color	White	Odor	Not available
Odor Threshold	Not available		
Molecular Formula	Not applicable	Molecular Weight	Not applicable
pH	Not applicable		
Specific Gravity	Not applicable	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not applicable
Boiling Point	Not applicable	Autoignition Temperature	Not applicable
Flash Point	Not available	Method	None
Melting Point	Not available		
Flammability Limits in Air	Upper Not applicable	Lower Not applicable	
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	Incompatible with strong acids and bases.
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

Antihemophil Factor VIII

LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Multiple Dose Toxicity

Antihemophil Factor VIII

No Toxicologic Effect Dose/Species/Study Length:	No data available
---	-------------------

Maximum Tolerated Dose (MTD), Oral

Antihemophil Factor VIII

Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Antihemophil Factor VIII

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)	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	Product Package Insert
Revision Summary	Changes to Section 1

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