



Xyntha (Antihemophilic Factor VIII)

Preparation Date 07-Dec-2006

Revision Date 10-Jul-2008

Revision Number 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Xyntha (Antihemophilic Factor VIII)
Common Name Anti-Hemophil FACTOR VIII
Chemical Name Not applicable
Synonyms Antihemophil Factor (Recombinant), Factor VIII, Coagulation Factor VIII, ReFacto
Product Use Pharmaceutical Treatment for Hemophilia A
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 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 Not available
Other The most common effects may include hypersensitivity reactions including anaphylaxis (hives, urticaria, difficulty breathing, wheezing, tightness in chest, hypotension), headache, nausea, fever, lethargy, chills, vomiting, and flushing.

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
Antihemophil Factor VIII	None assigned	100%

4. FIRST AID MEASURES

Eye Contact	In case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice
Skin Contact	Wash off immediately with soap and plenty of water
Inhalation	Artificial respiration and/or oxygen may be necessary
Ingestion	Immediate medical attention is not required

5. FIRE-FIGHTING MEASURES

Flammable Properties	Presumed to be a combustible particulate solid.
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
Unsuitable Extinguishing Media	Do not use a solid water stream as it may scatter and spread fire
Fire Fighting	Evacuate area and fight fire from a safe distance
Hazardous Combustion Products	Hazardous Combustion Products
Protective Equipment and Precautions for Firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Safety glasses or goggles when splash potential exists
Environmental Precautions	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

7. HANDLING AND STORAGE

Handling	Handle in accordance with good industrial hygiene and safety practice
Storage	Keep container tightly closed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name	Exposure Guideline
Antihemophil Factor VIII	0.5 mcg/m ³

Risk Based Exposure Control Classification	2
Engineering Controls	Apply technical measures to comply with the occupational exposure guideline. Fully contained systems with no open handling.
Personal Protective Equipment	
Eye/face Protection	Avoid contact with skin and eyes. Provide eye protection based on risk assessment..
Skin Protection	Wear nitrile or latex gloves. Wear protective garment.
Respiratory Protection	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	Pharmaceutical powder	Physical State	Solid
Color	White	Odor	Not available
Odor Threshold	Not available		
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

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	IV rats up to 10,000 IU/kg (714ug/kg): No adverse effect (NOEL) was noted
Dose/Species/Study Length:	IV monkey up to 1600 IU/kg (114ug/kg): No adverse effect (NOEL) was noted

Maximum Tolerated Dose (MTD), Oral**Antihemophil Factor VIII**

Carcinogenicity	Not applicable
Genetic Toxicity	Mouse micronucleus assay: Negative
Reproductive Toxicity	Not applicable
Developmental Toxicity	Not applicable

Antihemophil Factor VIII

Target Organ(s) of Toxicity	No data available
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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	See Patient Package Insert for more information.
Revision Summary	Administrative

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