



# SAFETY DATA SHEET

Revision date: 01-Apr-2015

Version: 2.0

Page 1 of 8

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Xyntha (Moroctocog alfa; Antihemophilic Factor VIII)

**Trade Name:** XYNTHA  
**Synonyms:** ReFacto AF  
**Chemical Family:** Not determined

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use:** Pharmaceutical product used as coagulant

### Details of the Supplier of the Safety Data Sheet

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Warning  
**Hazard Statements:** May form combustible dust concentrations in air

### Other Hazards

**Australian Hazard Classification (NOHSC):**

No data available  
Non-Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## SAFETY DATA SHEET

Material Name: Xyntha (Moroctocog alfa; Antihemophilic Factor VIII)  
Revision date: 01-Apr-2015

Page 2 of 8

Version: 2.0

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Moroctocog alfa	284036-24-4	Not Listed	Not Listed	Not Listed	0.5
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
L-Histidine	71-00-1	200-745-3	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Calcium chloride USP	10035-04-8	Not Listed	Not Listed	Eye Irrit. 2 (H319)	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*

**Additional Information:**

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

## SAFETY DATA SHEET

Material Name: Xyntha (Moroctocog alfa; Antihemophilic Factor VIII)  
Revision date: 01-Apr-2015

Page 3 of 8

Version: 2.0

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

### Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

## SAFETY DATA SHEET

Material Name: Xyntha (Moroctocog alfa; Antihemophilic Factor VIII)  
Revision date: 01-Apr-2015

Page 4 of 8

Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Sodium chloride

Latvia OEL - TWA 5 mg/m<sup>3</sup>  
Lithuania OEL - TWA 5 mg/m<sup>3</sup>

#### L-Histidine

Latvia OEL - TWA 5 mg/m<sup>3</sup>

#### Moroctocog alfa

Pfizer Occupational Exposure Band (OEB): B-OEB 5 (control exposure to <10 µg/day)

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

##### Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

##### Eyes:

Wear safety glasses or goggles if eye contact is possible.

##### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

##### Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Powder

#### Color:

White

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

No data available

#### pH:

No data available.

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

#### Partition Coefficient: (Method, pH, Endpoint, Value)

#### Moroctocog alfa

No data available

#### Calcium chloride USP

No data available

#### Polysorbate 80

No data available

#### Sodium chloride

No data available

#### L-Histidine

No data available

#### Sucrose

No data available

#### Decomposition Temperature (°C):

No data available.

## SAFETY DATA SHEET

Material Name: Xyntha (Moroctocog alfa; Antihemophilic Factor VIII)  
Revision date: 01-Apr-2015

Page 5 of 8

Version: 2.0

Evaporation Rate (Gram/s): No data available  
Vapor Pressure (kPa): No data available  
Vapor Density (g/ml): No data available  
Relative Density: No data available  
Viscosity: No data available

### Flammability:

Autoignition Temperature (Solid) (°C): No data available  
Flammability (Solids): No data available  
Flash Point (Liquid) (°C): No data available  
Upper Explosive Limits (Liquid) (% by Vol.): No data available  
Lower Explosive Limits (Liquid) (% by Vol.): No data available

## 10. STABILITY AND REACTIVITY

Reactivity: No data available  
Chemical Stability: Stable under normal conditions of use.  
Possibility of Hazardous Reactions  
Oxidizing Properties: No data available  
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.  
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers  
Hazardous Decomposition Products: No data available

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.  
**Short Term:** As with any protein, the possibility of allergic reactions exists.  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on blood, cardiovascular system.  
**Known Clinical Effects:** Adverse effects associated with therapeutic use include allergic reaction, hives, redness and swelling of the skin (urticaria), tightness of chest, wheezing, nausea, headache, decrease in blood pressure (hypotension), restlessness.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Moroctocog alfa

Rat Intravenous Minimum Lethal Dose > 12 mL/kg

#### Calcium chloride USP

Rat Oral LD50 1000 mg/kg  
Mouse Oral LD50 1940mg/kg

#### Polysorbate 80

Rat Oral LD50 25 g/kg

#### Sodium chloride

Rat Oral LD50 3000 mg/kg

## SAFETY DATA SHEET

Material Name: Xyntha (Moroctocog alfa; Antihemophilic Factor VIII)  
Revision date: 01-Apr-2015

Page 6 of 8

Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

Mouse Oral LD50 4000 mg/kg

#### L-Histidine

Rat Oral LD 50 > 15 g/kg  
Rat Para-periosteal LD 50 > 2g/kg  
Mouse Oral LD 50 > 15g/kg  
Mouse Intravenous LD 50 > 2g/kg

#### Sucrose

Rat Oral LD50 29.7 g/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Sodium chloride

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Moroctocog alfa

4 Week(s) Rat Intravenous 89 µg/kg/day NOAEL None identified  
4 Week(s) Monkey Intravenous 3.6 µg/kg/day NOAEL

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Moroctocog alfa

Micronucleus Mouse Negative

##### Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## SAFETY DATA SHEET

Material Name: Xyntha (Moroctocog alfa; Antihemophilic Factor VIII)  
Revision date: 01-Apr-2015

Page 7 of 8

Version: 2.0

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

None required

**Sucrose**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

**Moroctocog alfa**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

**Calcium chloride USP**

CERCLA/SARA 313 Emission reporting	Not Listed
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## SAFETY DATA SHEET

Material Name: Xyntha (Moroctocog alfa; Antihemophilic Factor VIII)  
Revision date: 01-Apr-2015

Page 8 of 8

Version: 2.0

### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Polysorbate 80

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

#### L-Histidine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-745-3

### 16. OTHER INFORMATION

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 7 - Handling and Storage. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

**Revision date:** 01-Apr-2015

Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**