



# MATERIAL SAFETY DATA SHEET

Revision date: 03-Feb-2012

Version: 1.1

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

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

Trade Name: XYNTHA  
Synonyms: ReFacto AF  
Chemical Family: Not determined  
Intended Use: Pharmaceutical product used as coagulant

## 2. HAZARDS IDENTIFICATION

**Appearance:** White powder

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Additional Hazard Information:**  
**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.

**EU Classification**  
**EU Indication of danger:** Not classified

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
L-Histidine	71-00-1	200-745-3	Not Listed	*
Moroctocog alfa	284036-24-4	Not Listed	Not Listed	0.5

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Calcium chloride USP	10035-04-8	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

### 4. 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.

**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.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

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

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**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.

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

**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.

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### 7. HANDLING AND STORAGE

**General 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.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### L-Histidine

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

#### Sodium chloride

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

#### 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>

#### Moroctocog alfa

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

**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.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**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.

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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

<b>Physical State:</b>	Powder	<b>Color:</b>	White
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.

**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

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

### 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 1940 mg/kg

#### **Polysorbate 80**

Rat Oral LD50 25 g/kg

#### **Sodium chloride**

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD50 4000 mg/kg

#### **L-Histidine**

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

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## 11. TOXICOLOGICAL INFORMATION

### 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 NOEL None identified  
4 Week(s) Monkey Intravenous 3.6 µg/kg/day NOEL

### 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.

## 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

EU Indication of danger: Not classified

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## 15. REGULATORY INFORMATION

### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

None required

#### Calcium chloride USP

Australia (AICS): Present

#### L-Histidine

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS/ELINCS List 200-745-3

#### Polysorbate 80

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

#### Sodium chloride

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS/ELINCS List 231-598-3

#### Sucrose

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

## 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 8 - Exposure Controls / Personal Protection.

**Prepared by:** Product Stewardship Hazard Communication  
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.

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**End of Safety Data Sheet**