



MATERIAL SAFETY DATA SHEET

Revision date: 04-Dec-2012

Version: 2.0

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

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Material Name: Thrombin-JMI

Trade Name:	THROMBIN-JMI
Synonyms:	THROMBIN, TOPICAL U.S.P. (BOVINE ORIGIN)
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as blood clotting agent

2. HAZARDS IDENTIFICATION

Appearance: Tan powder
Signal Word: WARNING

Statement of Hazard: Can cause allergic reaction
Pharmaceutical blood clotting agent: may be fatal if injected or enters bloodstream

Additional Hazard Information:

Short Term: May cause allergic skin reaction . Dust may cause irritation
Known Clinical Effects: This product contains protein of bovine origin. Those with known sensitivity should avoid contact. Serious allergic reactions, including anaphylaxis, have been reported. Extensive intravascular clotting and death may result if injected or allowed to enter large blood vessels.
EU Indication of danger: Irritant

EU Hazard Symbols:

Xi



EU Risk Phrases:

Australian Hazard Classification (NOHSC): R43 - May cause sensitization by skin contact.
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 product or its ingredients 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.

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2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Thrombin	9002-04-4	232-648-7	Xi;R43	15

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

Additional Information:

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

For the full text of the R phrases mentioned in this Section, see Section 16

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.

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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)

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Sodium chloride

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

Thrombin

Rat Subcutaneous LD50 > 40 mg/kg
Rat IP LD50 > 40 mg/kg
Mouse Subcutaneous LD50 > 50 mg/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

Skin Irritation / Sensitization

Thrombin is an antigenic substance of bovine origin and has caused sensitivity and allergic reactions including anaphylaxis. Not a significant irritant in clinical use

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

Thrombin

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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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 Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S24 - Avoid contact with skin.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Can cause allergic reaction
Pharmaceutical blood clotting agent: may be fatal if injected or enters bloodstream

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B



Thrombin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-648-7

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15. REGULATORY INFORMATION

Mannitol

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	200-711-8

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R43 - May cause sensitization by skin contact.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 7 - Handling and Storage.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet