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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:



EU Risk Phrases:

R43 - May cause sensitization by skin contact. **Australian Hazard Classification**Hazardous Substance. Non-Dangerous Goods.

(NOHSC):

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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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.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid

breathing dust, vapor or mist. Use only in a well-ventilated area. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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 appropriate to the protection of procedural values of procedural values of procedural values.

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.

Storage Temperature: 2°-25°C (36°-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium chloride

Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

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: Wear impervious gloves if skin contact is possible. **Eyes:** Wear safety goggles if eye contact is possible.

Skin: This product contains protein of bovine origin. Those with known sensitivity should avoid

contact. Protective coveralls should be worn. The sleeves should either be taped or have

gloves worn over them to prevent material from contacting the skin.

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 in vialColor:TanMolecular Formula:MixtureMolecular Weight:Mixture

Polymerization: Will not occur

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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)

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)

Australia (AICS):

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)PresentAustralia (AICS):PresentEU EINECS/ELINCS List231-598-3

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

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