



SAFETY DATA SHEET

Revision date 27-Feb-2025

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name	Thrombin-JMI
Product Code(s)	PZ01453
Synonyms	THROMBIN, TOPICAL U.S.P. (BOVINE ORIGIN)
Trade Name:	THROMBIN-JMI
Item Code	H000009846, H000009847, H000012853, H000012854, H000010202, H000010204, H000010206: H000012974
Chemical Family:	Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use	Pharmaceutical product used as blood clotting agent
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1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address	pfizer-MSDS@pfizer.com
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1.4. Emergency telephone number

Emergency Telephone	Chemtrec 1-800-424-9300 International Chemtrec (24 hours): +1-703-527-3887
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Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Respiratory sensitization	Category 1 - (H334)
Skin sensitization	Category 1 - (H317)

2.2. Label elements



Signal word	Danger
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Hazard statements

H315 - Causes skin irritation
H319 - Causes serious eye irritation
H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
P363 - Wash contaminated clothing before reuse
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB

Endocrine Disruptor Information

The product does not contain any substance(s) classified as PBT or vPvB.
This product does not contain any known or suspected endocrine disruptors.

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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Thrombin (CAS #: 9002-04-4)	15		232-648-7	Eye Irrit.2 (H319) Skin Irrit.2 (H315) Skin Sens.1 (H317) Resp.Sens.1 (H334) STOT SE.3	Not classified	No data available	No data available

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				(H335)			
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%≤C<2% Skin Corr. 1A :: C≥5% Skin Corr. 1B :: 2%≤C<5% Skin Irrit. 2 :: 0.5%≤C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%≤C<25% Skin Corr. 1B :: C≥25% Skin Irrit. 2 :: 10%≤C<25% STOT SE 3 :: C≥10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available
Mannitol (CAS #: 69-65-8)	*	-	200-711-8	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Mannitol 69-65-8	13500	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

Additional information

+ Substance with a Union workplace exposure limit

* Proprietary

** to adjust pH

Non-hazardous ingredients provided for completeness. 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.

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Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products	Formation of toxic gases is possible during heating or fire.
Explosion data	
Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment

Prevent further leakage or spillage if safe to do so.

Methods for cleaning up

Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.

Prevention of secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections

See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Restrict access to work area. Minimize dust generation and accumulation. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. 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 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.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s)

Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

SODIUM CHLORIDE

Latvia

5 mg/m³

Russia

MAC: 5 mg/m³

Mannitol

Russia

MAC: 10 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)

2 mg/m³

ACGIH TLV

Ceiling: 2 mg/m³

Austria

2 mg/m³

STEL 4 mg/m³

Bulgaria

2.0 mg/m³

Czech Republic

1 mg/m³

Ceiling: 2 mg/m³

Denmark

Ceiling: 2 mg/m³

Estonia

1 mg/m³

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Finland	STEL: 2 mg/m ³
France	Ceiling: 2 mg/m ³
Hungary	2 mg/m ³
	1 mg/m ³
Ireland	STEL: 2 mg/m ³
Ceiling Limit Value	STEL: 2 mg/m ³
Latvia	2 mg/m ³
Poland	0.5 mg/m ³
	STEL: 1 mg/m ³
Romania	0.5 mg/m ³
	1 mg/m ³
Slovakia	STEL: 3 mg/m ³
Spain	2 mg/m ³
Switzerland	STEL: 2 mg/m ³
	2 mg/m ³
OSHA PEL	STEL: 2 mg/m ³
	2 mg/m ³
United Kingdom	(vacated) Ceiling: 2 mg/m ³
+ Hydrochloric Acid	STEL: 2 mg/m ³
ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	5 ppm
	8 mg/m ³
	STEL 10 ppm
Bulgaria	STEL 15 mg/m ³
	STEL: 10 ppm
	STEL: 15.0 mg/m ³
	5 ppm
Czech Republic	8.0 mg/m ³
	8 mg/m ³
Estonia	Ceiling: 15 mg/m ³
	5 ppm
	8 mg/m ³
European Union	STEL: 10 ppm
	STEL: 15 mg/m ³
	TWA: 5 ppm
	TWA: 8 mg/m ³
	STEL: 10 ppm
	STEL: 15 mg/m ³
Finland	STEL: 5 ppm
	STEL: 7.6 mg/m ³
Germany DFG	2 ppm I(2)
	3.0 mg/m ³ I(2)
	Ceiling / Peak: 4 ppm
	Ceiling / Peak: 6 mg/m ³
Germany TRGS	2 ppm
	3 mg/m ³
Hungary	8 mg/m ³
	5 ppm
	STEL: 165 mg/m ³
	STEL: 10 ppm
Ireland	8 mg/m ³
	5 ppm
	STEL: 10 ppm
	STEL: 15 mg/m ³
Italy MDLPS	5 ppm
	8 mg/m ³

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	STEL: 10 ppm
	STEL: 15 mg/m ³
Ceiling Limit Value	2 ppm
	3.0 mg/m ³
Latvia	5 ppm
	8 mg/m ³
	STEL: 10 ppm
	STEL: 15 mg/m ³
Netherlands	5 ppm
	8 mg/m ³
	STEL: 10 ppm
	STEL: 15 mg/m ³
Poland	STEL: 10 mg/m ³
	5 mg/m ³
Romania	5 ppm
	8 mg/m ³
	STEL: 10 ppm
	STEL: 15 mg/m ³
Russia	MAC: 5 mg/m ³
Slovakia	5 ppm
	8.0 mg/m ³
Spain	5 ppm
	7.6 mg/m ³
	STEL: 10 ppm
	STEL: 15 mg/m ³
Switzerland	2 ppm
	3 mg/m ³
	STEL: 4 ppm
	STEL: 6 mg/m ³
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm
	7 mg/m ³
OSHA PEL	(vacated) Ceiling: 5 ppm
	(vacated) Ceiling: 7 mg/m ³
	Ceiling: 5 ppm
	Ceiling: 7 mg/m ³
United Kingdom	TWA: 1 ppm
	TWA: 2 mg/m ³
	STEL: 5 ppm
	STEL: 8 mg/m ³

Pfizer Occupational Exposure Band (OEB) Statement: The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

Thrombin

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

SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

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8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range. All operations should be fully enclosed. No air recirculation permitted.

Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

Thermal hazards

No information available.

Environmental exposure controls

No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Powder

Color

tan

Odor

No information available.

Odor threshold

No information available

Property

Values

Melting point / freezing point

No data available

Boiling point or initial boiling point and boiling range

No data available

Flammability (solid, gas)

No data available

Lower and upper explosion limit/flammability limit

Lower explosion limit

No data available

Upper explosion limit

No data available

Flash point

No data available

Autoignition temperature

No data available

Decomposition temperature

SADT (°C)

No data available

pH

No data available

pH (as aqueous solution)

No data available

Kinematic viscosity

No data available

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Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

Hazardous polymerization

Will not occur.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

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Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Causes serious eye irritation. Classification is based on mixture calculation methods based on component data.
Skin corrosion/irritation	Causes skin irritation. Classification is based on mixture calculation methods based on component data.
Respiratory or skin sensitization	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Classification is based on mixture calculation methods based on component data.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

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

Thrombin

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

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³
Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 4 g/kg
Rabbit Dermal LD 50 > 10 g/kg

Mannitol

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
SODIUM CHLORIDE	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Mannitol	= 13500 mg/kg (Rat)	-	-
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

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

Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

+ Hydrochloric Acid

Skin irritation Severe
Eye irritation Severe

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

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

Thrombin

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Micronucleus Rat Negative

Carcinogenicity

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

+ Hydrochloric Acid

IARC

Group 3 (Not Classifiable)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects

No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability

No information available.

12.3. Bioaccumulative potential

Bioaccumulation

No information available.

12.4. Mobility in soil

Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply

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12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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 wastewater 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.

Section 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.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Thrombin

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	232-648-7
AICS	Present

SODIUM CHLORIDE

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present

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Mannitol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-711-8
AICS	Present

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5
	Schedule 6

+ Hydrochloric Acid

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5
	Schedule 6

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
SODIUM CHLORIDE 7647-14-5	RG 78

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide 1310-73-2	Use restricted. See entry 75.	-
+ Hydrochloric Acid 7647-01-0	Use restricted. See entry 75.	-

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Persistent Organic Pollutants

Not applicable

Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid 7647-01-0	25	250

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE 7647-14-5	Plant protection agent

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H319 - Causes serious eye irritation. H317 - May cause an allergic skin reaction. H315 - Causes skin irritation. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 - May cause respiratory irritation. H314 - Causes severe skin burns and eye damage. H331 - Toxic if inhaled.

Data Sources:

Publicly available toxicity information. Safety data sheets for individual ingredients.

SAFETY DATA SHEET

Product Name Thrombin-JMI
Revision date 27-Feb-2025

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Reason for revision

Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

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Prepared By

Pfizer Global Environment, Health, and Safety

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