SAFETY DATA SHEET

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

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

1.4. Emergency telephone number

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

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)

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
Not applicable

2.2. Label elements

Signal word Danger

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
The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information
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	15		232-648-7	Eye Irrit.2	Not classified	No data	No data

(CAS #: 9002-04-4)				(H319) Skin Irrit.2 (H315) Skin Sens.1 (H317) Resp.Sens.1 (H334) STOT SE.3 (H335)		available	available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	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 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	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

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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.

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.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

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.

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 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	TWA: 5 mg/m^3;
Russia	MAC: 5 mg/m^3

Mannitol

Russia	MAC: 10 mg/m^3

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m³
ACGIH TLV	Ceiling: 2 mg/m³
Austria	TWA-TMW: 2 mg/m³; inhalable fraction
	STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction
Bulgaria	TWA: 2.0 mg/m³; alkaline aerosols
Czech Republic	1 mg/m³
	Ceiling: 2 mg/m³
Denmark	Ceiling: 2 mg/m³;
Estonia	TWA: 1 mg/m³;
	STEL: 2 mg/m³;
Finland	Ceiling: 2 mg/m³;
France	2 mg/m³
Hungary	TWA-AK: 1 mg/m³;
	STEL-CK: 2 mg/m³;
Ireland	STEL: 2 mg/m³;
Ceiling Limit Value	2 mg/m³
Latvia	TWA: 0.5 mg/m³;
Poland	TWA-NDS: 0.5 mg/m³;
	STEL-NDSCh: 1 mg/m³;
Romania	TWA: 1 mg/m³;
	STEL: 3 mg/m³;
Slovakia	TWA: 2 mg/m³;
Spain	STEL (VLA-EC): 2 mg/m³;
Switzerland	TWA-MAK: 2 mg/m³; inhalable dust
	STEL-KZGW: 2 mg/m³; inhalable dust
OSHA PEL	TWA: 2 mg/m³
	(vacated) Ceiling: 2 mg/m³
United Kingdom	STEL: 2 mg/m³;

+ Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	TWA-TMW: 5 ppm;
	TWA-TMW: 8 mg/m³;
	STEL-KZGW: 10 ppm (8 X 5 min);
	STEL-KZGW: 15 mg/m³ (8 X 5 min);
Bulgaria	TWA: 5 ppm;
	TWA: 8.0 mg/m³;
	STEL: 10 ppm;
	STEL: 15.0 mg/m³;
Czech Republic	8 mg/m³
	Ceiling: 15 mg/m³
Denmark	STEL: 5 ppm;
	STEL: 8 mg/m³;
Estonia	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
European Union	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Finland	STEL: 5 ppm;
	STEL: 7.6 mg/m³;
Germany DFG	TWA-MAK: 2 ppm; I(2);
	TWA-MAK: 3.0 mg/m³; I(2);
	Peak: 4 ppm;
	Peak: 6 mg/m³;
Germany TRGS	TWA-AGW; 2 ppm (exposure factor 2);

	TWA-AGW; 3 mg/m³ (exposure factor 2);
Hungary	TWA-AK: 8 mg/m³; TWA-AK: 5 ppm; STEL-CK: 165 mg/m³; STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m³; TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m³;
Italy MDLPS	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Ceiling Limit Value	2 ppm 3.0 mg/m³
Latvia	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Poland	TWA-NDS: 5 mg/m³; STEL-NDSCh: 10 mg/m³;
Romania	TWA: 5 ppm; TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;
Russia	MAC: 5 mg/m³
Slovakia	TWA: 5 ppm; TWA: 8.0 mg/m³; Ceiling: 15 mg/m³;
Spain	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m³; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m³;
Switzerland	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m³; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m³;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m³
OSHA PEL	Ceiling: 5 ppm Ceiling: 7 mg/m³ (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m³
United Kingdom	TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m³; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m³; gas and aerosol mist

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)

Chemical name	Oral	Dermal	Inhalation
SODIUM CHLORIDE 7647-14-5	-	295.52 mg/kg bw/day [4] [6] 295.52 mg/kg bw/day [4] [7]	2068.62 mg/m³ [4] [6] 2068.62 mg/m³ [4] [7]
+ Hydrochloric Acid 7647-01-0	-	-	8 mg/m³ [5] [6] 15 mg/m³ [5] [7]

Chemical name	Oral	Dermal	Inhalation
SODIUM CHLORIDE 7647-14-5	126.65 mg/kg bw/day [4] [6] 126.65 mg/kg bw/day [4] [7]	126.65 mg/kg bw/day [4] [6] 126.65 mg/kg bw/day [4] [7]	443.28 mg/m³ [4] [6] 443.28 mg/m³ [4] [7]
+ Hydrochloric Acid 7647-01-0	-	-	8 mg/m³ [5] [6] 15 mg/m³ [5] [7]

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
SODIUM CHLORIDE 7647-14-5	5 mg/L	-	-	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
SODIUM CHLORIDE 7647-14-5	-	-	500 mg/L	4.86 mg/kg soil dw	-

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
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.

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

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

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
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply

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

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	75	-
+ Hydrochloric Acid 7647-01-0	75	-

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	Plant protection agent

7647-14-5	

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

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algaecides 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/NDSL - 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.

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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