

Revision date 13-Jun-2025 Version 3 Page 1/12

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

1.1. Product identifier

Product Name Aminocaproic Acid Injection (Hospira Inc.)

Product Code(s) PZ03068
Trade Name: Not applicable
Chemical Family: Not determined

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

Recommended Use Pharmaceutical product

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company 275 North Field Drive Lake Forest, Illinois 60045 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

Not classified as hazardous.

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 Not classified

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients

(see Section 8).

M-Factor

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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.

Specific

M-Factor

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

REACH

3.1 Substances

Chemical name

Substances Not applicable

Weight-%

3.2 Mixtures

Haz<u>ardous</u>

Onemical name	Weight-70	registration number	Index No)	according to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)	W-I actor	(long-term)
+ Hydrochloric Acid	***	-	231-595-7	Press. Gas	Eye Irrit. 2 ::	No data	No data
(CAS #: 7647-01-0)			(017-002-00-2)	Skin Corr. 1A	10%<=C<25%	available	available
			(017-002-01-X)	,	Skin Corr. 1B ::		
				Acute Tox. 3	C>=25%		
				(H331)	Skin Irrit. 2 ::		
					10%<=C<25%		
					STOT SE 3 :: C>=10%		
NonHazardous I					C>=10%		
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)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Aminocaproic Acid (CAS #: 60-32-2)	25		200-469-3	Not classified	Not classified	No data available	No data available

EC No (EU Classification

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

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Aminocaproic Acid 60-32-2	>10000	No data available	No data available	No data available	No data available

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Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
+ 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

- * Proprietary
- ** to adjust pH

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Move victim to fresh air.

Eve contact If symptoms persist, call 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.

Formation of toxic gases is possible during heating or fire. **Hazardous combustion products**

Explosion data

Sensitivity to mechanical impact No information available. Sensitivity to static discharge No information available.

5.3. Advice for firefighters

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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.

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 spill if it is safe to do so. Collect spill with absorbent material. Clean

spill area 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

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 Handle and store per label and other instructions to maintain product integrity.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical 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.

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Pfizer OEL TWA-8 Hr: 3000 µg/m³

Aminocaproic Acid

Finland

Russia MAC: 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: 10 ppm (8 X 5 min); STEL-KZGW: 15 mg/m³ (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: 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: 10 ppm; STEL: 15 mg/m³; STEL: 5 ppm; STEL: 7.6 mg/m³;

Germany DFG STEL: 7.6 mg/m³;
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: 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; TWA: 5 ppm;

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; TWA: 5 ppm;

Netherlands TWA: 5 ppm; TWA: 8 mg/m³;

STEL: 10 ppm; STEL: 15 mg/m³; TWA-NDS: 5 mg/m³; STEL-NDSCh: 10 mg/m³;

Poland

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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;

TWA-(VLA-ED): 5 ppm; Spain 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 ma/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

8.2. Exposure controls

Personal protective equipment

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. 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). Tape gloves to coveralls or suit.

Eye/face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the

standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is Hand protection

possible and for bulk processing operations. (Protective gloves must meet the standards in

accordance with EN374, ASTM F1001 or international equivalent.).

Impervious protective clothing is recommended if skin contact with drug product is possible Skin and body protection

and for bulk processing operations. (Protective clothing must meet the standards in

accordance with EN13982, ANSI 103 or international equivalent.).

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is Respiratory protection

exceeded, wear an appropriate respirator with a protection factor sufficient to control

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exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter).

No data available

(Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10

or international equivalent.).

Thermal hazards No information available.

No information available. **Environmental exposure controls**

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state Liquid Color Colourless

Odor No information available. **Odor threshold** No information available

Values Property

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

No data available **Autoignition temperature Decomposition temperature**

SADT (°C)

No data available pН 68

pH (as aqueous solution)

Kinematic viscosity No data available **Dynamic viscosity** No data available

Solubility Slightly Soluble: methanol Soluble

No data available Vapor pressure

Density and/or relative density No data available **Bulk density** No data available No data available **Liquid Density**

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

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10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stable under normal conditions. Stability

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.

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

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

ingredients

Not acutely toxic (based on animal data). Accidental ingestion may cause effects similar to Short term

those seen in clinical use.

Known Clinical Effects: Effects reported during clinical use include headache, dizziness, nausea, diarrhea,

gastrointestinal disturbances, decrease in blood pressure (hypotension), ringing of the ears,

nasal congestion, skin rash, changes in blood chemistry.

Acute toxicity Serious eye damage/eye irritation

Skin corrosion/irritation

Respiratory or skin sensitization STOT - single exposure STOT - repeated exposure Reproductive toxicity Germ cell mutagenicity Carcinogenicity **Aspiration hazard**

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

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

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

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

Aminocaproic Acid

Rat Oral LD50 > 10,000 mg/kg Mouse Oral LD50 12,000 mg/kg Dog Oral LD50 > 7000 mg/kg Rat Intravenous LD50 3200 mg/kg Mouse Intravenous LD50 3000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
+ 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

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achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Aminocaproic Acid Eye Irritation Mild Moderate + Hydrochloric Acid Skin irritation Severe

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Aminocaproic Acid

Eye irritation Severe

Reproductive & Fertility Rat Oral ~ 500 mg/kg/day LOAEL Fertility

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

+ 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

Group 3 IARC

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

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

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

The environmental impact of this product has not been fully investigated.

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

No information available. Mobility in soil

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12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment	
Aminocaproic Acid	PBT assessment does not apply	
+ Hydrochloric Acid	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.

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

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.

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

Section 15: REGULATORY INFORMATION

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

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **TSCA** Present

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EINECS 231-791-2 **AICS** Present

Aminocaproic Acid

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed Present **TSCA EINECS** 200-469-3 **AICS** Present

+ Hydrochloric Acid

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

National regulations

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 does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

1	(-9 (-)	
Chemical name	Restricted substance per REACH	Substance subject to authorization per
	Annex XVII	REACH Annex XIV
Aminocaproic Acid	75	-
60-32-2		
+ Hydrochloric Acid	75	-
7647-01-0		

Persistent Organic Pollutants

Not applicable

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

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

Not applicable.

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Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
+ Hydrochloric Acid	Product-type 2: Disinfectants and algaecides not intended
7647-01-0	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

H314 - Causes severe skin burns and eye damage H331 - Toxic if inhaled

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Updated Section 3 - Composition / Information on Ingredients, Added Pfizer OEL (Section Reason for revision

8). Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology

Information.

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Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this 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.