



A Pfizer Company

SAFETY DATA SHEET

Revision date: 29-May-2018

Version: 1.1

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

Product Identifier

Material Name: Aminocaproic Acid Injection (Hospira Inc.)

Trade Name: Not established

Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified

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

Other Hazards

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

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

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3. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|-------------------|------------|-----------------------|---|-----|
| HYDROCHLORIC ACID | 7647-01-0 | 231-595-7 | Skin Corr.1B (H314) STOT SE 3 (H335) | *** |

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|---------------------|------------|-----------------------|--------------------|----|
| Aminocaproic Acid | 60-32-2 | 200-469-3 | Not Listed | 25 |
| Water for Injection | 7732-18-5 | 231-791-2 | Not Listed | * |

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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and plenty of water. Remove contaminated clothing and shoes. Wash clothing and thoroughly clean shoes before reuse. If irritation occurs or persists, get 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: Move to fresh air If discomfort persists, get medical attention.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and 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.

Conditions for Safe Storage, Including any Incompatibilities

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

Specific end use(s): Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

HYDROCHLORIC ACID

| | |
|--------------------------------|-----------------------|
| ACGIH Ceiling Threshold Limit: | 2 ppm |
| Australia PEAK | 5 ppm |
| | 7.5 mg/m ³ |
| Austria OEL - MAKs | 5 ppm |
| | 8 mg/m ³ |
| Belgium OEL - TWA | 5 ppm |
| | 8 mg/m ³ |
| Bulgaria OEL - TWA | 5 ppm |
| | 8.0 mg/m ³ |
| Cyprus OEL - TWA | 5 ppm |
| | 8 mg/m ³ |
| Czech Republic OEL - TWA | 8 mg/m ³ |
| Estonia OEL - TWA | 5 ppm |
| | 8 mg/m ³ |
| Germany - TRGS 900 - TWAs | 2 ppm |
| | 3 mg/m ³ |
| Germany (DFG) - MAK | 2 ppm |
| | 3.0 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|-------------------------|--------------------------------|
| Greece OEL - TWA | 5 ppm 7 mg/m ³ |
| Hungary OEL - TWA | 8 mg/m ³ |
| Ireland OEL - TWAs | 5 ppm 8 mg/m ³ |
| Italy OEL - TWA | 5 ppm 8 mg/m ³ |
| Japan - OELs - Ceilings | 2 ppm 3.0 mg/m ³ |
| Latvia OEL - TWA | 5 ppm 8 mg/m ³ |
| Lithuania OEL - TWA | 5 ppm 8 mg/m ³ |
| Luxembourg OEL - TWA | 5 ppm 8 mg/m ³ |
| Malta OEL - TWA | 5 ppm 8 mg/m ³ |
| Netherlands OEL - TWA | 8 mg/m ³ |
| Poland OEL - TWA | 5 mg/m ³ |
| Portugal OEL - TWA | 5 ppm 8 mg/m ³ |
| Romania OEL - TWA | 5 ppm 8 mg/m ³ |
| Slovakia OEL - TWA | 5 ppm 8.0 mg/m ³ |
| Slovenia OEL - TWA | 5 ppm 8 mg/m ³ |
| Spain OEL - TWA | 5 ppm 7.6 mg/m ³ |
| Switzerland OEL -TWAs | 2 ppm 3.0 mg/m ³ |
| Vietnam OEL - TWAs | 5 mg/m ³ |

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Aminocaproic Acid

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

Exposure Controls

| | |
|---------------------------------------|--|
| 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. |
| Personal Protective Equipment: | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). |
| Hands: | Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.) |
| Eyes: | 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.) |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (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 Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---------------------------|--------------------|--------------------------|--------------------|
| Physical State: | Liquid | Color: | Colourless |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |

Solvent Solubility: No data available
Water Solubility: Soluble
Solubility: **Slightly Soluble:** methanol
pH: 6.8

Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Aminocaproic Acid

No data available

Water for Injection

No data available

HYDROCHLORIC ACID

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

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

Hazardous Decomposition Products: No data available

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11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

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

Short Term:

Not acutely toxic (based on animal data) . Accidental ingestion may cause effects similar to 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: (Species, Route, End Point, Dose)

Aminocaproic Acid

Rat Oral LD50 > 10,000 mg/kg

Mouse Oral LD50 12,000mg/kg

Dog Oral LD50 > 7000mg/kg

Rat Intravenous LD50 3200mg/kg

Mouse Intravenous LD50 3000mg/kg

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 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)

Aminocaproic Acid

Eye Irritation Mild Moderate

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Aminocaproic Acid

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

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Micronucleus Rat Negative

Carcinogen Status:

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)

12. ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties have not been investigated.

Toxicity:

No data available

Persistence and Degradability:

No data available

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Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Aminocaproic Acid

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 200-469-3 |

HYDROCHLORIC ACID

| | |
|--|--------------------|
| CERCLA/SARA 313 Emission reporting | 1.0 % |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 5000 lb 2270 kg |
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs | 500 lb |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 5000 lb |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |

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15. REGULATORY INFORMATION

| | |
|--|------------|
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| EU EINECS/ELINCS List | Schedule 6 |
| | 231-595-7 |

Water for Injection

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| 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 | 231-791-2 |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information.

Revision date: 29-May-2018
Product Stewardship Hazard Communication

Prepared by: 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