SAFETY DATA SHEET

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

1.1. Product identifier

Product Name Aminophylline Injection, USP (Hospira Inc.)

Product Code(s) PZ03246
Trade Name: Aminophylline Injection, USP
Chemical Family: Mixture

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

Recommended Use Pharmaceutical product for the treatment of asthma

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).

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)
Aminophylline Dihydrate (CAS #: 5897-66-5)	2.5		Not Listed	Acute Tox 3 (H301)	Not classified	No data available	No data available
1,2-DIAMINOETHANE (CAS #: 107-15-3)	**		203-468-6 (612-006-00-6) (615-034-00-7)	Flam. Liq. 3 (H226) Acute Tox. 4 (H302) Acute Tox. 4 (H312) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Resp. Sens. 1 (H334)	Not classified	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)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate No information available

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
1,2-DIAMINOETHANE 107-15-3	866	560	14.7	No data available	No data available
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available

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

Chemical name	CAS No.	SVHC candidates
1,2-DIAMINOETHANE	107-15-3	X

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 Remove to fresh air. If not breathing, give artificial respiration.

Eye contact If symptoms persist, call a physician.

Skin contact Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion Get medical attention. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

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 Not applicable.

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 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 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.

Aminophylline Dihydrate
Pfizer OEL TWA-8 Hr: 800 µg/m³

1,2-DIAMINOETHANE

ACGIH - Skin Absorbers	Skin - potential significant contribution to overall exposure by the cutaneous route
ACGIH TLV	TWA: 10 ppm pSk
Austria	TWA-TMW: 10 ppm; TWA-TMW: 25 mg/m³; STEL-KZGW: 40 ppm (4 X 15 min); STEL-KZGW: 100 mg/m³ (4 X 15 min); Sk DS
Bulgaria	TWA: 25 mg/m³;
Czech Republic	25 mg/m³ Ceiling: 50 mg/m³ D*
Denmark	TWA: 10 ppm; TWA: 25 mg/m³; STEL: 20 ppm; STEL: 50 mg/m³;
Estonia	TWA: 10 ppm; TWA: 25 mg/m³; STEL: 15 ppm; STEL: 35 mg/m³; S
Finland	TWA: 10 ppm; TWA: 25 mg/m³; STEL: 20 ppm; STEL: 50 mg/m³; pSk
France	25 mg/m³
Germany DFG	DS RS
Ireland	TWA: 10 ppm; TWA: 25 mg/m³; STEL: 30 ppm (calculated); STEL: 75 mg/m³ (calculated);
Latvia	TWA: 2 mg/m³; TWA: 0.5 mg/m³;
Poland	TWA-NDS: 20 mg/m³; STEL-NDSCh: 50 mg/m³; Sk
Romania	TWA: 8 ppm; TWA: 20 mg/m³; STEL: 12 ppm; STEL: 30 mg/m³;
Russia	MAC: 2 mg/m³ MAC: 5 mg/m³
Slovakia	TWA: 10 ppm; TWA: 25 mg/m³; S
Spain	TWA-(VLA-ED): 10 ppm; TWA-(VLA-ED): 25 mg/m³; pSk S

Switzerland	TWA-MAK: 10 ppm; TWA-MAK: 25 mg/m^3; STEL-KZGW: 20 ppm; STEL-KZGW: 50 mg/m^3; S
OSHA PEL	TWA: 10 ppm TWA: 25 mg/m^3 (vacated) TWA: 10 ppm (vacated) TWA: 25 mg/m^3

8.2. 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 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 or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection 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.).

Skin and body protection 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.).

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

Appearance	Solution
Physical state	Liquid
Color	No information available
Odor	Not applicable.

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	8.8 (8.6-9)
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available Soluble
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

Oxidizing properties	None

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.

10.4. Conditions to avoid

Conditions to avoid	Not determined.

10.5. Incompatible materials

Incompatible materials	None.

10.6. Hazardous decomposition products
Hazardous decomposition products Nitrogen oxides (nox). Oxides of carbon.

Section 11: TOXICOLOGICAL INFORMATION

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

General Information: There are no data for this formulation. The information in this section includes the potential hazards of the individual ingredients and/or of a chemically-related material.

Short term May cause eye and skin irritation
Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include nausea, vomiting, headache, insomnia, diarrhea, irritability, restlessness, tremors, irregular heartbeat (cardiac arrhythmia), seizure.

Acute toxicity Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation Based on available data, the classification criteria are not met.
Skin corrosion/irritation Based on available data, the classification criteria are not met.
Respiratory or skin sensitization Based on available data, the classification criteria are not met.
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)
Aminophylline Dihydrate
Mouse Oral LD50 250 mg/kg
Mouse IV LD50 150 mg/kg
Aminophylline
Rat Oral LD50 243 mg/kg
Mouse Oral LD50 150 mg/kg
Rat IV LD50 104 mg/kg
Theophylline, anhydrous
Mouse Oral LD50 235 mg/kg
Rat Oral LD50 225 mg/kg
Rabbit Oral LD50 350 mg/kg
Guinea Pig Oral LD50 183 mg/kg
Rat IP LD50 188 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
1,2-DIAMINOETHANE	= 866 mg/kg (Rat)	= 560 mg/kg (Rabbit)	= 14.7 mg/L (Rat) 4 h
Water	> 90 mL/kg (Rat)	-	-

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.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
Theophylline, anhydrous
75 Week(s) Rat Oral 300 mg/kg/day LOEL Male reproductive system
13 Week(s) Mouse Oral 300 mg/kg/day LOEL Male reproductive system
13 Week(s) Rat Oral 150 mg/kg/day LOEL Male reproductive system

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

Theophylline, anhydrous
Reproductive & Fertility Mouse Oral 125 mg/kg/day NOEL Embryotoxicity
Embryo / Fetal Development Mouse Intraperitoneal 100 mg/kg LOEL Teratogenic
Embryo / Fetal Development Mouse Oral 396 mg/kg/day NOEL Fetotoxicity, Not Teratogenic
Embryo / Fetal Development Rat Oral 259 mg/kg/day NOEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Theophylline, anhydrous
In Vivo Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive
In Vitro Chromosome Aberration Rat liver Negative
In Vitro Sister Chromatid Exchange Human Positive
In Vitro Chromosome Aberration Human Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Theophylline, anhydrous
2 Year(s) Rat Oral 75 mg/kg/day NOEL Not carcinogenic
2 Year(s) Female Mouse Oral 75 mg/kg/day NOEL Not carcinogenic
2 Year(s) Male Mouse Oral 150 mg/kg/day NOEL Not carcinogenic

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

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: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

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

Mobility in soil No information available.

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
1,2-DIAMINOETHANE	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

Aminophylline Dihydrate
CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
EINECS Not Listed
1,2-DIAMINOETHANE
CERCLA/SARA Section 313 de minimus % Not Listed
Hazardous Substances RQs 5000 lb
California Proposition 65 Not Listed

TSCA	Present
EINECS	203-468-6
AICS	Present

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

National regulations

Chemical name	French RG number
1,2-DIAMINOETHANE 107-15-3	RG 49,RG 49bis

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

Chemical name	Number	Class
1,2-DIAMINOETHANE 107-15-3	5.2.5	Class I

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)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
1,2-DIAMINOETHANE 107-15-3	75	-

Persistent Organic Pollutants

Not applicable

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

Not applicable.

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
H226 - Flammable liquid and vapor H301 - Toxic if swallowed H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H317 - May cause an allergic skin reaction H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled H312 - Harmful in contact with skin

Data Sources:	The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.
Reason for revision	Updated Section 7 - Handling and Storage. 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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