



# SAFETY DATA SHEET

Revision date 22-Mar-2022

Version 1.01

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## 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

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

**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

### 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).

**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.

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## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC 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 Listed	No data available	No data available
1,2-DIAMINOETHAN E (CAS #: 107-15-3)	**		203-468-6	Acute Tox. 4 (H302) Acute Tox. 4 (H312) Skin Corr. 1B (H314) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) Flam. Liq. 3 (H226)	Not Listed	No data available	No data available

#### NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC 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 as hazardous	Not Listed	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	Dermal LD50	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	637	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

### 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

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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

<b>Inhalation</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
<b>Eye contact</b>	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
<b>Skin contact</b>	Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.
<b>Ingestion</b>	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

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

<b>Most important symptoms and effects</b>	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

<b>Note to physicians</b>	None.
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## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

<b>Suitable Extinguishing Media</b>	As for primary cause of fire.
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### 5.2. Special hazards arising from the substance or mixture

<b>Specific hazards arising from the chemical</b>	Not applicable.
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<b>Hazardous combustion products</b>	Formation of toxic gases is possible during heating or fire.
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### 5.3. Advice for firefighters

<b>Special protective equipment for fire-fighters</b>	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

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

### 6.2. Environmental precautions

<b>Environmental precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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### 6.3. Methods and material for containment and cleaning up

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**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 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.

**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/m<sup>3</sup>

#### 1,2-DIAMINOETHANE

ACGIH - Skin Absorbers

Skin - potential significant contribution to overall exposure by the cutaneous route

ACGIH TLV

10 ppm

Austria

S\*

10 ppm

25 mg/m<sup>3</sup>

STEL 40 ppm

STEL 100 mg/m<sup>3</sup>

H\*

Bulgaria

25 mg/m<sup>3</sup>

Czech Republic

25 mg/m<sup>3</sup>

Ceiling: 50 mg/m<sup>3</sup>

D\*

Denmark

10 ppm

25 mg/m<sup>3</sup>

Estonia

10 ppm

25 mg/m<sup>3</sup>

STEL: 15 ppm

STEL: 35 mg/m<sup>3</sup>

Finland

10 ppm

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	25 mg/m <sup>3</sup> STEL: 20 ppm STEL: 50 mg/m <sup>3</sup> iho*
France	25 mg/m <sup>3</sup>
Ireland	10 ppm 25 mg/m <sup>3</sup> STEL: 30 ppm STEL: 75 mg/m <sup>3</sup>
Latvia	2 mg/m <sup>3</sup>
Poland	0.5 mg/m <sup>3</sup> STEL: 50 mg/m <sup>3</sup>
Romania	20 mg/m <sup>3</sup> 8 ppm 20 mg/m <sup>3</sup> STEL: 12 ppm STEL: 30 mg/m <sup>3</sup>
Russia	MAC: 2 mg/m <sup>3</sup> MAC: 5 mg/m <sup>3</sup>
Slovakia	10 ppm 25 mg/m <sup>3</sup>
Spain	10 ppm 25 mg/m <sup>3</sup>
Switzerland	via dérmica* 10 ppm 25 mg/m <sup>3</sup> STEL: 20 ppm STEL: 50 mg/m <sup>3</sup>
OSHA PEL	10 ppm 25 mg/m <sup>3</sup> (vacated) TWA: 10 ppm (vacated) TWA: 25 mg/m <sup>3</sup>

## 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.

### Environmental exposure controls

No information available.

### 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

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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.)

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Physical state	Solution
Color	No information available
Odor	Not applicable.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

<u>Property</u>	<u>Values</u>
pH	8.8 (8.6-9)
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Soluble
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

### 9.2. Other information

No information available

#### 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

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## 10.1. Reactivity

Reactivity No data available.

## 10.2. Chemical stability

Stability Stable under normal conditions.

## Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data 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	= 637 mg/kg ( Rat )	= 560 mg/kg ( Rabbit )	= 14.7 mg/L ( Rat ) 4 h
Water	> 90 mL/kg ( Rat )	-	-

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**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 Bone Marrow 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** No information available.

### **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.



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## 12.4. Mobility in soil

**Mobility in soil** No information available.

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

Chemical name	PBT and vPvB assessment
1,2-DIAMINOETHANE	The substance is not PBT / vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. 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 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

**Special precautions for user:** 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

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<b>EINECS</b>	Not Listed
1,2-DIAMINOETHANE	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	203-468-6
<b>AICS</b>	Present
Water	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

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

## 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	Use restricted. See item 75.	

## Persistent Organic Pollutants

Not applicable

## Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

## Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 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 H-Statements referred to under section 3

Flammable liquids-Cat.3; H226 - Flammable liquid and vapor Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction Sensitization, respiratory-Cat.1; H334 - May cause allergy or

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asthma symptoms or breathing difficulties if inhaled Acute toxicity, dermal-Cat.4; 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.

**Revision date** 22-Mar-2022

**Prepared By** Pfizer Global Environment, Health, and Safety

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