



# SAFETY DATA SHEET

Revision date 13-May-2020

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

### 1.1. Product identifier

**Product Name** Tromethamine Injection (Hospira Inc.)  
**Product Code(s)** PZ03044  
**Synonyms** THAM; Tromethamine (USP); TRIS (Base); Trisamine; TRIS  
**Trade Name:** THAM Solution  
**Chemical Family:** Not determined

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

**Recommended Use** Pharmaceutical product used as systemic alkalizer and fluid replenisher

### 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

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887  
**E-mail address** pfizer-MSDS@pfizer.com

## 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

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(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.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Hazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
ACETIC ACID	200-580-7	64-19-7	**	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	

#### NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Water	231-791-2	7732-18-5	*	Not Listed	
Tromethamine	201-064-4	77-86-1	1-5	Not Listed	

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

#### 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.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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** For information on potential signs and symptoms of exposure, See Section 2 - Hazards

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**effects** 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, CO<sub>2</sub>, 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 mists) may fuel fires/explosions.

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

#### **5.3. Advice for firefighters**

**Special protective equipment 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 if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. 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). 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.

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## 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 product used as. systemic alkalizer and fluid replenisher.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

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

#### ACETIC ACID

ACGIH TLV	STEL: 15 ppm
Austria	10 ppm 10 ppm 25 mg/m <sup>3</sup>
Bulgaria	STEL 20 ppm STEL 50 mg/m <sup>3</sup> STEL: 50 mg/m <sup>3</sup> STEL: 20 ppm 25 mg/m <sup>3</sup>
Czech Republic	10 ppm 25 mg/m <sup>3</sup>
Denmark	Ceiling: 50 mg/m <sup>3</sup> 10 ppm
Estonia	25 mg/m <sup>3</sup> 10 ppm 25 mg/m <sup>3</sup>
Finland	STEL: 10 ppm STEL: 25 mg/m <sup>3</sup> 5 ppm 13 mg/m <sup>3</sup>
Germany	STEL: 10 ppm STEL: 25 mg/m <sup>3</sup> 10 ppm 25 mg/m <sup>3</sup> Ceiling / Peak: 20 ppm Ceiling / Peak: 50 mg/m <sup>3</sup>
Germany	10 ppm 25 mg/m <sup>3</sup>
Hungary	25 mg/m <sup>3</sup>
Ireland	STEL: 50 mg/m <sup>3</sup> 10 ppm 25 mg/m <sup>3</sup>
Latvia	STEL: 20 ppm STEL: 50 mg/m <sup>3</sup> 10 ppm 25 mg/m <sup>3</sup>
Netherlands	STEL: 50 mg/m <sup>3</sup> STEL: 20 ppm 25 mg/m <sup>3</sup>
Poland	STEL: 50 mg/m <sup>3</sup> STEL: 50 mg/m <sup>3</sup>
Romania	25 mg/m <sup>3</sup> 10 ppm

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	25 mg/m <sup>3</sup> STEL: 20 ppm STEL: 50 mg/m <sup>3</sup> MAC: 5 mg/m <sup>3</sup> Skin
Russia	10 ppm
Slovakia	25 mg/m <sup>3</sup>
Spain	10 ppm
	25 mg/m <sup>3</sup> STEL: 20 ppm STEL: 50 mg/m <sup>3</sup>
Switzerland	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>
United Kingdom	TWA: 10 ppm TWA: 25 mg/m <sup>3</sup> STEL: 20 ppm STEL: 50 mg/m <sup>3</sup>

## Tromethamine

Pfizer Occupational Exposure  
Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/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 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.).

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**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
Molecular formula (MF):	Mixture
Molecular weight	Mixture
Odor	No data available.
Odor threshold	No data available

#### Property

#### Values

pH	
Melting point / freezing point	No data available
Boiling point / boiling range	No data available
Flash point	No data 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	No data available
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available
Partition Coefficient: (Method, pH, Endpoint, Value)	
<u>Tromethamine</u>	
Predicted 7.4 Log D -4.668	

### 9.2. Other information

Liquid Density	No data available
Bulk density	No data available

## Section 10: STABILITY AND REACTIVITY

### 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

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**Conditions to avoid** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

**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 toxicological effects

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include infusion site reactions (phlebitis), low blood sugar and respiratory depression

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

##### **Tromethamine**

Rat Oral LD50 5900 mg/kg  
Rat Dermal LD 50 > 5000 mg/kg

##### **ACETIC ACID**

Mouse Sub-tenon injection (eye) LC 50 5620 ppm/1H  
Rat Oral LD 50 3310 mg/kg  
Rabbit Dermal LD 50 1060 uL/kg

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Tromethamine	= 5900 mg/kg ( Rat )	-	-
ACETIC ACID	= 3310 mg/kg ( Rat )	= 1060 mg/kg ( Rabbit )	= 11.4 mg/L ( Rat ) 4 h

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

##### **Tromethamine**

Eye Irritation Rabbit Slight  
Skin Irritation Rabbit Slight

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

##### **Tromethamine**

Bacterial Mutagenicity (Ames) *E. coli* Negative

**Carcinogenicity** Not listed as a carcinogen by IARC, NTP or US OSHA.

## Section 12: ECOLOGICAL INFORMATION

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

### 12.1. Toxicity

#### **Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

##### **Tromethamine**

*Daphnia magna* (Water Flea) OECD EC50 48 hours > 980 mg/l  
*Pseudokirchneriella subcapitata* (Green Alga) OECD EC50 48 Hours 473 mg/L

##### **ACETIC ACID**

Fathead Minnow NPDES LC-50 96 hours 88 mg/l

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Bluegill Sunfish NPDES LC-50 96 hours 75 mg/L  
Goldfish NPDES LC-50 24 hours 423 mg/l

## **Bacterial Inhibition: (Inoculum, Method, End Point, Result)**

### **Tromethamine**

Activated sludge OECD EC50 > 1000 mg/l

## **12.2. Persistence and degradability**

**Persistence and degradability** No information available.

## **12.3. Bioaccumulative potential**

### **Bioaccumulation**

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

### **Tromethamine**

Predicted 7.4 Log D -4.668

## **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
Tromethamine	The substance is not PBT / vPvB PBT assessment does not apply
ACETIC ACID	The substance is not PBT / vPvB PBT assessment does not apply

## **12.6. Other adverse effects**

**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 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.

## **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.



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## Section 15: REGULATORY INFORMATION

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

Water

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

Tromethamine

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	201-064-4
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

ACETIC ACID

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-580-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6 Schedule 2

### 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

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage. Flammable liquids-Cat.3; H226 - Flammable liquid and vapor

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

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**Prepared By** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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