MATERIAL SAFETY DATA SHEET

Product Name: THAM Solution Tromethamine Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
THAM Solution Tromethamine Injection

Synonyms
2-Amino-2-(hydroxymethyl)-1,3-propanediol; THAM; Tromethamine (USP); TRIS (Base); Trisamine; TRIS

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Tris (hydroxymethyl)aminomethane

Chemical Formula
C₄H₁₁NO₃

Preparation
Non-hazardous ingredients include Water for Injection. Glacial acetic acid is added to adjust the pH.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tris (hydroxymethyl)aminomethane</td>
<td>3.6</td>
<td>77-86-1</td>
<td>TY2900000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tris (hydroxymethyl)aminomethane</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
THAM Solution Tromethamine Injection is a solution containing tromethamine, a hydroxy aminomethane buffer used clinically to correct metabolic acidosis and promote diuresis. It is given intravenously as a systemic alkaliizer and fluid replenisher. In the workplace, this material should be considered potentially irritating to the eyes, and respiratory tract. Based on clinical use, possible target organs include the eyes, liver, and lungs.

Occupational Exposure Potential
Information on the absorption of this material via inhalation or skin contact is not available. Avoid aerosol generation and skin contact.

Signs and Symptoms
None known from workplace exposures. Ingestion may produce nausea, vomiting and diarrhea. In clinical use, tromethamine is generally well-tolerated. Adverse effects may include hypoglycemia, respiratory depression, and infusion site reactions (phlebitis). In infants, clinical use of tromethamine has been associated with hepatic necrosis.

Medical Conditions
Pre-existing hypersensitivity to tromethamine; pre-existing ocular, liver, or lung ailments.
Product Name: THAM Solution Tromethamine Injection

4. FIRST AID MEASURES

**Eye contact**
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin contact**
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation**
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion**
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

**Flammability**
None anticipated for this aqueous product.

**Fire & Explosion Hazard**
None anticipated for this aqueous product.

**Extinguishing media**
As with any fire, use extinguishing media appropriate for primary cause of fire.

**Special Fire Fighting Procedures**
No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

**Spill Cleanup and Disposal**
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

**Handling**
No special handling required for hazard control under conditions of normal product use.

**Storage**
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions**
No special precautions required for hazard control.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure Guidelines**

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m3</th>
<th>ppm</th>
<th>µg/m3</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tris (hydroxymethyl)aminomethane</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
</tbody>
</table>

**Respiratory protection**  
Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**  
If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**  
Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**  
Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Non-pyrogenic solution</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>8.6 (8.4-8.7)</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point</td>
<td>NA</td>
</tr>
<tr>
<td>Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Water</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: THAM Solution Tromethamine Injection

10. STABILITY AND REACTIVITY

Reactivity Not determined.
Chemical Stability Stable under standard use and storage conditions.
Hazardous Reactions Not determined.
Conditions to avoid Heat
Incompatibilities Copper, brass, aluminum, and oxidizing agents.
Hazardous decomposition products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
Hazardous Polymerization Not anticipated to occur with this material.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tromethamine</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>5900</td>
<td>mg/kg</td>
<td>Rat</td>
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<td>Tromethamine</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>1800</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2300</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1210</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3500</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard None anticipated from normal handling of this material.
Dermal Irritation/Corrosion None anticipated from normal handling of this product.
Ocular Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation.
Dermal or Respiratory Sensitization None anticipated from normal handling of this product.
Reproductive Effects Animal fertility or developmental toxicity studies have not been conducted with tromethamine.
Mutagenicity Studies have not been conducted with tromethamine to evaluate the mutagenic potential.
Carcinogenicity Studies have not been conducted with tromethamine to evaluate carcinogenic potential.
Target Organ Effects Based on clinical use, possible target organs include the eyes, liver, and lungs.
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12. ECOLOGICAL INFORMATION

Aquatic Toxicity  Not determined.
Persistence/Biodegradability  Not determined.
Bioaccumulation  Not determined.
Mobility in Soil  Not determined.

13. DISPOSAL CONSIDERATIONS

Waste Disposal  All waste materials must be properly characterized by the waste generator. Further, disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal  Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:  Not regulated
IMDG STATUS:  Not regulated
ICAO/IATA STATUS:  Not regulated
Transport Comments:  None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tris (hydroxymethyl)aminomethane</td>
<td>Listed</td>
<td>Not Listed</td>
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</table>

RCRA Status  Not Listed
U.S. OSHA Classification  Target Organ Toxin
GHS Classification  Possible Irritant

Hazard Class  Not Applicable
Hazard Category  Not Applicable
Signal Word  Not Applicable

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:
Product Name: THAM Solution Tromethamine Injection

Symbol: Not Applicable
Hazard Statement: Not Applicable
Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Tris (hydroxymethyl)aminomethane.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases: S23 - Do not breathe vapor.
S24 - Avoid contact with skin.
S25 - Avoid contact with eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS: Chemical Abstracts Service Number
CERCLA: US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT: US Department of Transportation Regulations
EEL: Employee Exposure Limit
IATA: International Air Transport Association
LD50: Dosage producing 50% mortality
NA: Not applicable/Not available
NE: Not established
NIOSH: National Institute for Occupational Safety and Health
OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65: California Proposition 65
RCRA: US EPA, Resource Conservation and Recovery Act
RTECS: Registry of Toxic Effects of Chemical Substances
SARA: Superfund Amendments and Reauthorization Act
STEL: 15-minute Short Term Exposure Limit
TSCA: Toxic Substance Control Act
TWA: 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 11/07/2011
Obsolete Date: 10/21/2008
Product Name: THAM Solution Tromethamine Injection

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