MATERIAL SAFETY DATA SHEET

Product Name: Promethazine Hydrochloride Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

<table>
<thead>
<tr>
<th>Manufacturer Name And Address</th>
<th>Hospira Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>275 North Field Drive</td>
</tr>
<tr>
<td></td>
<td>Lake Forest, Illinois USA</td>
</tr>
<tr>
<td></td>
<td>60045</td>
</tr>
<tr>
<td>Emergency Telephone</td>
<td>CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880</td>
</tr>
<tr>
<td>Hospira, Inc., Non-Emergency</td>
<td>224-212-2000</td>
</tr>
<tr>
<td>Product Name</td>
<td>Promethazine Hydrochloride Injection</td>
</tr>
<tr>
<td>Synonyms</td>
<td>(10H-Phenothiazine-10-ethanamine, N,Nα-trimethyl-, monohydrochloride, (±)-)</td>
</tr>
</tbody>
</table>

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Active Ingredient Name</th>
<th>Promethazine Hydrochloride</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Formula</td>
<td>C₁₇H₂₀N₂S • HCl</td>
</tr>
<tr>
<td>Preparation</td>
<td>Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include 0.1 mg edetate disodium, 0.04 mg calcium chloride, and not more than 5 mg monothioglycerol and 5 mg phenol. Sodium acetate-acetic acid buffer added to adjust the pH.</td>
</tr>
</tbody>
</table>

<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>Promethazine Hydrochloride</td>
<td>2.5</td>
<td>58-33-3</td>
<td>SO6825000</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>Promethazine Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview

Promethazine Hydrochloride Injection is a solution containing promethazine hydrochloride, a sedating anti-histamine with anti-muscarinic properties. Clinically, it is used for symptomatic relief of hypersensitivity reactions (allergic rhinitis, cold and allergy symptoms, conjunctivitis, pruritic skin disorders or anaphylactic reactions), as an antiemetic, for motion sickness, for anti-cholinergic and local anesthetic effects. In the workplace, this product should be considered severely irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the skin, eyes, respiratory tract, central nervous system, cardiovascular system and blood.

Occupational Exposure Potential

Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms

None known from occupational exposures. In the workplace, this material should be considered
severely irritating to the eyes and respiratory tract. In clinical use, adverse effects may include drowsiness and sedation, or stimulation. Other effects may include dryness of mouth, blurring of vision, dizziness or lassitude, gastrointestinal effects such as epigastric distress, nausea, diarrhea or constipation, elevated body temperature, muscle rigidity, and autonomic instability. Cardiovascular side effects are occasionally seen after injection and can include tachycardia, bradycardia, mild transient hypertension and hypotension. Effects on the skin may include dermatitis, photosensitivity, and urticaria. Hematological effects may include leukopenia, thrombocytopenia, thrombocytopenic purpura, or agranulocytosis.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to this material; pre-existing central nervous system, cardiovascular, or hematological ailments.

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 firefighting 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. The product is light sensitive. For product protection, follow storage recommendations noted on the product
Product Name: Promethazine Hydrochloride Injection

case label, the primary container label, or the product insert.

Special Precautions
No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Exposure Guidelines</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Component</strong></td>
<td><strong>Type</strong></td>
</tr>
<tr>
<td>Promethazine Hydrochloride</td>
<td>Not Applicable</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>Appearance/Physical State</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Clear, Colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>4.9 (4.0 to 5.5)</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>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>NA</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: Promethazine Hydrochloride Injection

10. STABILITY AND REACTIVITY

Reactivity
Not determined

Chemical Stability
Not determined

Hazardous Reactions
Not determined

Conditions to avoid
Not determined

Incompatibilities
Not determined

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), sulfur oxides (SOx), and hydrogen chloride.

Hazardous Polymerization
Not anticipated to occur with this product.

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>
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</thead>
<tbody>
<tr>
<td>Promethazine</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>326</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>580</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>640</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
<tr>
<td>Promethazine</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>45</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>40</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>27</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
<tr>
<td>Promethazine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>255</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Promethazine Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>15</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>42.5</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation. Promethazine is reported to be a severe eye irritant in rabbits; however, it was not irritating in skin irritation test in rabbits.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
Studies in animals to evaluate the affect on fertility have not been conducted. Teratogenic effects have not been demonstrated in rat-feeding studies at dosages of 6.25 and 12.5 mg/kg. Daily dosages of 25 mg/kg intraperitoneally have been found to produce fetal mortality in rats.

Mutagenicity
Promethazine HCl Injection was nonmutagenic in the Salmonella test system.
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of Ames, and negative in an in vitro chromosomal aberration assay in CHO cells.

Carcinogenicity
In 2-year (gavage) carcinogenicity studies, there was no evidence of carcinogenic activity of promethazine hydrochloride in male or female F344/N rats receiving 8.3, 16.6, or 33.3 mg/kg. There was no evidence of carcinogenic activity of promethazine hydrochloride in male B6C3F mice receiving 11.25, 22.5, or 45 mg/kg. There was no evidence of carcinogenic activity of promethazine hydrochloride in female B6C3F mice receiving 3.75, 7.5, or 15 mg/kg.

Target Organ Effects
Based on clinical use, possible target organs include the skin, eyes, respiratory tract, central nervous system, cardiovascular system and blood.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product

Persistence/Biodegradability
Not determined for product

Bioaccumulation
Not determined for product

Mobility in Soil
Not determined for product

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized. Further, disposal 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>Promethazine Hydrochloride</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>
Product Name: Promethazine Hydrochloride Injection

RCRA Status: Not Listed

U.S. OSHA Classification:
- Target Organ Toxin
- Possible Irritant

GHS Classification:
*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:

Hazard Class: Not Applicable
Hazard Category: Not Applicable
Signal Word: Not Applicable
Symbol: Not Applicable

Prevention:
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

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 Promethazine Hydrochloride.

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


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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:  11/02/2011  
Obsolete Date:  10/21/2008  

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