MATERIAL SAFETY DATA SHEET

Product Name: Scopolamine Hydrobromide Injection, USP

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 Scopolamine Hydrobromide Injection, USP

Synonyms Hyoscine hydrobromide trihydrate; (·)-(1S,3s,5R,6R,7S)-6,7-Epoxytropan-3-yl (S)-tropate hydrobromide trihydrate.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Scopolamine Hydrobromide Trihydrate

Chemical Formula C₁₇H₂₁NO₄ • HBr • 3H₂O

Preparation Non-hazardous ingredients include Water for Injection. Hydrobromic acid is added for pH adjustment.

<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>Scopolamine Hydrobromide Trihydrate</td>
<td>&lt;0.1</td>
<td>6533-68-2</td>
<td>YM4730000</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>Scopolamine Hydrobromide Trihydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview Scopolamine Hydrobromide Injection, USP, contains scopolamine hydrobromide, an antimuscarinic material used to treat nausea and vomiting induced by motion. Clinically, it is also used as a sedative and as a tranquilizing depressant to the central nervous system. In the workplace, this material should be considered a potent drug and potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the central nervous system and eyes.

Occupational Exposure Potential Information on the absorption of this product via inhalation or skin contact is not available. Commercial patch formulations containing scopolamine are available, suggesting some potential for dermal absorption. In the workplace, avoid liquid aerosol generation and skin contact.

Signs and Symptoms None known from workplace exposures. In clinical use, adverse effects include dry mouth, dry skin, thirst and difficulty swallowing. Scopolamine also suppresses sweating and can cause
Product Name: Scopolamine Hydrobromide Injection, USP

flushing and heat intolerance. At higher doses, additional adverse effects may include drowsiness or euphoria, tachycardia, fatigue and dreamless sleep. Scopolamine can also dilate the pupils of the eyes (mydriasis) resulting in transient impairment of ocular accommodation and blurred vision. Less frequently, other adverse effects may include disorientation, memory disturbances, dizziness, restlessness, giddiness, hallucinations, delirium, and confusion.

Medical Conditions Aggravated by Exposure
Pre-existing narrow angle glaucoma or other ocular disorders; pre-existing hypersensitivity to atropine-like compounds.

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 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>Scopolamine Hydrobromide Trihydrate</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>Appearance/Physical State</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Sterile solution in water</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>3.5 to 6.5</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point 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>Soluble in 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>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

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) and hydrogen bromide.

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>
</tr>
</thead>
<tbody>
<tr>
<td>Scopolamine Hydrobromide Trihydrate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>1270</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>1880</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Scopolamine Hydrobromide Trihydrate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>203</td>
<td>mg/kg</td>
<td>Mouse</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.

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

Reproductive Effects
Fertility studies conducted in female rats indicated no evidence of impaired fertility or harm to the fetus due to scopolamine hydrobromide administered by daily subcutaneous injection. Maternal body weights were reduced in the highest-dosage group. Teratology studies were performed in pregnant rats and rabbits with scopolamine hydrobromide administered by daily intravenous injection. No adverse effects were noted in rats. Scopolamine hydrobromide has been shown to have a marginal embryotoxic effect in rabbits when given by daily intravenous injection.

Mutagenicity
Scopolamine hydrobromide trihydrate did not induce mutations in any of five strains of Salmonella typhimurium, with or without S9 metabolic activation enzymes, nor did it induce sister chromatid exchanges in cultured Chinese hamster ovary cells, with or without S9. A weakly positive response was
obtained, however, in a chromosomal aberrations test conducted in cultured Chinese hamster ovary cells with very high doses of scopolamine hydrobromide trihydrate in the presence of S9; without S9, no increase in aberrations was noted. Despite the evidence for chromosomal damage observed in vitro, no increase in the frequencies of micronucleated normochromatic erythrocytes was observed in peripheral blood samples of male or female mice exposed to scopolamine hydrobromide trihydrate for 14 weeks by gavage.

Carcinogenicity

Groups of male and female rats were given scopolamine hydrobromide trihydrate (in distilled water) by gavage at dosages of 0, 1, 5, or 25 mg/kg for 104 weeks. Similarly, groups of male and female mice were given scopolamine hydrobromide trihydrate (in distilled water) by gavage at dosages of 0, 1, 5, or 25 mg/kg for 104 to 105 weeks. Under the conditions of these 2-year gavage studies, there was no evidence of carcinogenic activity of scopolamine hydrobromide trihydrate in male or female F344IN rats or B6C3F, mice administered 1, 5, or 25 mg/kg.

Target Organ Effects

Based on clinical use, possible target organs include the central nervous system and eyes.

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
Product Name: Scopolamine Hydrobromide Injection, USP

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>Scopolamine Hydrobromide Trihydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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.

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 Scopolamine Hydrobromide Trihydrate.

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:**

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

**MSDS Coordinator:** Hospira GEHS  
**Date Prepared:** 11/03/2011  
**Obsolete Date:** 07/17/2009

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