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 60045
USA

Emergency Telephone
CHEMTREC: North America: 800-424-9300; International: 1-703-527-3887
Hospira, Inc., Non-Emergency
224 212-2055

Product Name
Scopolamine Hydrobromide Injection, USP

Synonyms
Hyoscin 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
C_{17}H_{21}NO_{4}·HBr·3H_{2}O

<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</td>
<td>&lt;0.1</td>
<td>6533-68-2</td>
<td>YM4730000</td>
</tr>
</tbody>
</table>

Non-hazardous ingredients include water for injection. Hydrobromic acid is added for pH adjustment.

3. HAZARD INFORMATION

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 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.

Carcinogen Lists:
IARC: Not listed
NTP: Not listed
OSHA: Not listed
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 product.

Fire & Explosion Hazard
None anticipated for this 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 under conditions of normal product use. Protect from light by retaining in carton until contents have been used.

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

Special Precautions
Protect from freezing, light, and extreme heat.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</th>
<th>Hospira EEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scopolamine Hydrobromide</td>
<td>8-hr TWA: Not</td>
<td>8-hr TWA: Not</td>
<td>8-hr TWA: Not</td>
<td>8-hr TWA: Not</td>
</tr>
<tr>
<td></td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
</tr>
</tbody>
</table>


Respiratory Protection
Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or 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 (N99 or equivalent) is recommended under conditions where airborne dust or 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>Sterile solution in water for injection</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 (Air =1)</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate</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>
<tr>
<td>Decomposition 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</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>
</tr>
<tr>
<td>Scopolamine Hydrobromide</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>203</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

LD 50: Dosage that produces 50% mortality.

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 normochromic 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.

Notes:
1. LC50: Concentration in water that produces 50% mortality in fish.
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.

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.
Product Name: Scopolamine Hydrobromide Injection, USP

14. TRANSPORTATION INFORMATION

<table>
<thead>
<tr>
<th>DOT STATUS:</th>
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<tbody>
<tr>
<td>Proper Shipping Name:</td>
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<td>Hazard Class:</td>
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<td>UN Number:</td>
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<tr>
<td>Packing Group:</td>
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</tr>
<tr>
<td>Reportable Quantity:</td>
<td>NA</td>
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</tbody>
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<table>
<thead>
<tr>
<th>ICAO/IATA STATUS</th>
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<tbody>
<tr>
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<td>Hazard Class:</td>
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<td>Packing Group:</td>
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<td>Reportable Quantity:</td>
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<table>
<thead>
<tr>
<th>IMDG STATUS</th>
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<td>Hazard Class:</td>
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<td>Packing Group:</td>
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<tr>
<td>Reportable Quantity:</td>
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</tr>
</tbody>
</table>

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

| U.S. TSCA Status | Exempt. |
| U.S. CERCLA Status | Not listed |
| U.S. SARA 302 Status | Not listed |
| U.S. SARA 313 Status | Not listed |
| U.S. RCRA Status | Not listed |
| U.S. PROP 65 (Calif.) | Not listed |


**U.S. OSHA Classification**

Possible Irritant

Target Organ Toxin
Product Name: Scopolamine Hydrobromide Injection, USP

15. REGULATORY INFORMATION: continued

GHS Classification *Where medicinal products are not exempt, the recommended GHS workplace classification is as follows:

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Acute Oral Toxicity</th>
<th>Eye Irritation</th>
<th>Target Organ Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Category</td>
<td>Not Classified</td>
<td>Eye Irritant 2</td>
<td></td>
</tr>
<tr>
<td>Symbol</td>
<td>NA</td>
<td>2B</td>
<td></td>
</tr>
</tbody>
</table>

Signal Word NA Warning Warning

Hazard Statement NA Causes eye irritation May cause damage to the central nervous system and eyes through prolonged or repeated exposure.

Prevention:
Wear protective gloves and eye/face protection
Avoid breathing dust/vapors/spray.

Response:
IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or doctor/physician.
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical advice/attention. Wash contaminated clothing before reuse.
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. If skin irritation occurs, get medical advice/attention. 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.

Classification(s): Harmful Irritant
Symbol: Xn Xi

Indication of Danger: Xn Xi

Risk Phrases: R22/23 - Harmful if swallowed or inhaled
R36/37 - Irritating to eyes and respiratory system

Safety Phrases: S22 - Do not breathe dust
S23 - Do not breathe vapor/spray
S24 - Avoid contact with the 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:  Global Occupational Toxicology
Date Prepared:  July 17, 2009

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