MATERIAL SAFETY DATA SHEET

Product Name: Isoproterenol Hydrochloride Injection (Isuprel)

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
Isoproterenol Hydrochloride Injection (Isuprel)

Synonyms
3,4-Dihydroxy-α-[(isopropylamino)methyl] benzyl alcohol hydrochloride.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Isoproterenol Hydrochloride

Chemical Formula
C_{11}H_{17}NO_{3} \cdot \text{HCl}

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include edetate disodium (EDTA), sodium citrate dihydrate, anhydrous citric acid, and sodium chloride. Hydrochloric acid is added to adjust the pH of the solution.

<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>Isoproterenol Hydrochloride</td>
<td>0.02</td>
<td>51-30-9</td>
<td>DO1925000</td>
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</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>Isoproterenol Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview

Isoproterenol Hydrochloride Injection (Isuprel) is a solution containing isoproterenol hydrochloride, a sympathomimetic amine that acts on beta-adrenergic receptors. It stimulates the central nervous system and has stimulating action on the heart, resulting in increased cardiac output, excitability, and heart rate. It also causes peripheral vasodilatation and produces a fall in diastolic blood pressure; systolic blood pressure is usually maintained or slightly increased. In addition, isoproterenol has bronchodilating properties. Therapeutically, isoproterenol has been used to treat a variety of cardiac disorders, asthma, bronchospasm, carotid sinus hypersensitivity and shock. In the workplace, this material should be considered a potent drug, and potentially irritating to the skin, eyes, and respiratory tract. Based on clinical use, possible target organs include the central nervous system, respiratory system, cardiovascular system, and smooth muscle.
Product Name: Isoproterenol Hydrochloride Injection (Isuprel)

Occupational Exposure Potential
Clinically, isoproterenol hydrochloride is available as an inhalation medication for the treatment of asthma. It is systemically bioavailable via the pulmonary route. Other studies suggest that isoproterenol has some potential to be absorbed through the skin. Avoid dust or aerosol generation and avoid skin contact.

Signs and Symptoms
None known from workplace exposures. In clinical use, adverse reactions may include nervousness, increased heart rate, palpitations, flushing, chest pain, restlessness, insomnia, anxiety, tension, fear and excitement. Manifestations of acute over dosage include chest pain, dizziness, headache, irregular heartbeat, fast or pounding heartbeat, nausea or vomiting, restlessness, weakness, flushing, or decreased diastolic pressure. Direct application of isoproterenol to the eye can cause a decrease in intraocular pressure and even an increase in heart rate.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to sympathomimetic amines; pre-existing central nervous system, respiratory system, or cardiovascular system disorders such as cardiac arrhythmias associated with tachycardia.

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. Notes to physician: Blood pressure and ECG may be monitored and the following treatment used, as appropriate: tachycardia in asthmatic patients may be treated with cardio-selective beta-blockers (metoprolol or atenolol, but used cautiously since cardio-selectivity may not be absolute). Non-asthmatics may be treated with propranolol; blood pressure may be regulated with rapid-acting vasodilators (nitrites, sodium nitroprusside) or alpha-blocking agents (quinidine, phentolamine).

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. Do not breathe aerosol; avoid contact with skin and eyes.

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

Special Precautions  Protect from light, oxidizing materials, and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mg/m3 ppm µg/m3</td>
</tr>
<tr>
<td>Isoproterenol Hydrochloride</td>
<td>N/A</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 this material is likely, the use of latex or nitrile gloves is recommended.

Eye protection  Eye protection is normally not required during intended 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>
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</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid, aqueous</td>
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<tr>
<td>Color</td>
<td>Clear, Colorless</td>
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<tr>
<td>Odor</td>
<td>Odorless</td>
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<tr>
<td>Odor Threshold:</td>
<td>NA</td>
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<tr>
<td>pH</td>
<td>2.5 - 4.5</td>
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<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
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</table>
Product Name: Isoproterenol Hydrochloride Injection (Isuprel)

Initial Boiling Point/Boiling Point Range: NA
Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: Soluble in water and alcohol mixture; less soluble in absolute ethanol and practically insoluble in chloroform, ether, benzene.
Partition coefficient: n-octanol/water: -2.69
Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.
Chemical Stability Stable under standard use and storage conditions. Solutions become pink to brownish-pink on standing exposed to air and almost immediately when made alkaline.
Hazardous Reactions Not determined.
Conditions to avoid To minimize decomposition, protect from light.
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 chloride.
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>
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<tbody>
<tr>
<td>Isoproterenol Hydrochloride</td>
<td>100%</td>
<td>LD50</td>
<td>Oral</td>
<td>2221</td>
<td>mg/kg</td>
<td>Rat</td>
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<td>600</td>
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<td>LD50</td>
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<td>50</td>
<td>mg/kg</td>
<td>Dog</td>
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</tbody>
</table>
Product Name: Isoproterenol Hydrochloride Injection (Isuprel)

**Aspiration Hazard**
None anticipated from normal handling of this material.

**Dermal Irritation/Corrosion**
Inadvertent contact with skin may produce irritation with redness and discomfort. This material has some potential to be absorbed through skin and mucus membranes.

**Ocular Irritation/Corrosion**
Inadvertent contact with the eyes may produce irritation with redness, tearing and pain.

**Dermal or Respiratory Sensitization**
Not anticipated from normal handling of this product.

**Reproductive Effects**
Reproduction studies have been performed in rats and rabbits with isoproterenol at aerosol doses (30 minutes per day for 12 days) up to 15 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to isoproterenol. In another study, pregnant rats were given isoproterenol hydrochloride intraperitoneally at dosages of 0, 20, 40 or 80 mg/kg/day in sterile 0.9% saline on gestational days 6 through 15. Although these dosages produced some evidence of fetal and maternal toxicity, there was no evidence for teratogenicity in this study.

**Mutagenicity**
Isoproterenol was negative in the Ames test for mutagenicity in the presence and absence of metabolic activation. In an in vitro chromosomal aberration assay, isoproterenol hydrochloride was negative in the absence of metabolic activation but positive in the presence of metabolic activation.

**Carcinogenicity**
Long-term studies in animals to evaluate the carcinogenic potential of isoproterenol hydrochloride have not been conducted.

**Target Organ Effects**
Based on clinical use, possible target organs include the central nervous system, respiratory system, cardiovascular system, and smooth muscle.

### 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. 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

DOT STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

IMDG STATUS: Not regulated

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>
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<tr>
<td>Isoproterenol Hydrochloride</td>
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</table>

**US 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**
- HNA - 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 Isoproterenol Hydrochloride.*

**Classification(s):**
- Not Applicable

**Symbol:**
- Not Applicable

**Indication of Danger:**
- Not Applicable
Product Name: Isoproterenol Hydrochloride Injection (Isuprel)

Risk Phrases: Not Applicable


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: 12/10/2010
Obsolete Date: 10/21/2008

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