



## SAFETY DATA SHEET

**Product Name: Isuprel (Isoproterenol Hydrochloride Injection, USP)**

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
<b>Emergency Telephone</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
<b>Hospira, Inc., Non-Emergency</b>	224 212-2000
<b>Product Name</b>	Isuprel (Isoproterenol Hydrochloride Injection, USP)
<b>Synonyms</b>	3,4-Dihydroxy- $\alpha$ -[(isopropylamino)methyl] benzyl alcohol hydrochloride.

### 2. HAZARD(S) IDENTIFICATION

<b>Emergency Overview</b>	Isuprel (Isoproterenol Hydrochloride Injection, USP) is a solution containing isoproterenol, a sympatho-mimetic amine that acts almost exclusively on beta-adrenergic receptors. Therapeutically, isoproterenol is used to treat a variety of cardiac disorders, asthma, bronchospasm, carotid sinus hypersensitivity and shock. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potent drug. Based on clinical use, possible target organs include the nervous system, respiratory system, cardiovascular system, and smooth muscle.
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#### U.S. OSHA GHS Classification

<b>Physical Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Not Classified	Not Classified
<b>Health Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Not Classified	Not Classified

#### Label Element(s)

**Pictogram** NA

**Signal Word** NA

**Hazard Statement(s)** NA

#### Precautionary Statement(s)

**Prevention** Do not breathe vapor or spray.  
Wash hands thoroughly after handling.

**Response** Get medical attention if you feel unwell.

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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name** Isoproterenol Hydrochloride  
**Chemical Formula** C<sub>11</sub>H<sub>17</sub>NO<sub>3</sub> • HCl

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Isoproterenol Hydrochloride	0.02	51-30-9	DO1925000

Non-hazardous ingredients include Water for Injection and sodium lactate. Hazardous ingredients present at less than 1% include lactic acid, sodium chloride and sodium metabisulfite. Hydrochloric acid is added to adjust the pH.

### 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 such as carbon dioxide, dry chemical extinguishing powder or foam.

**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 control 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**

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Isoproterenol Hydrochloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 AIHA WEEL: Workplace Environmental Exposure Level  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.

**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**

<b>Appearance/Physical State</b>	Clear, colorless aqueous liquid
<b>Odor</b>	Odorless
<b>Odor Threshold</b>	NA
<b>pH</b>	2.5 - 4.5
<b>Melting point/Freezing Point</b>	NA
<b>Initial Boiling Point/Boiling Point Range</b>	NA
<b>Flash Point</b>	NA
<b>Evaporation Rate</b>	NA
<b>Flammability (solid, gas)</b>	NA
<b>Upper/Lower Flammability or Explosive Limits</b>	NA
<b>Vapor Pressure</b>	NA
<b>Vapor Density (Air =1)</b>	NA
<b>Relative Density</b>	NA
<b>Solubility</b>	1 gram dissolves in 3 ml of water and in 50 ml of alcohol; less soluble in absolute ethanol and practically insoluble in chloroform, ether, benzene
<b>Partition Coefficient: n-octanol/water</b>	-2.69
<b>Auto-ignition Temperature</b>	NA
<b>Decomposition Temperature</b>	NA
<b>Viscosity</b>	NA

**10. STABILITY AND REACTIVITY**

<b>Reactivity</b>	Not determined
<b>Chemical Stability</b>	Stable under standard use and storage conditions. Solutions become pink to brownish-pink on standing exposed to air and almost immediately when made alkaline.
<b>Hazardous Reactions</b>	Not determined
<b>Conditions to Avoid</b>	To minimize decomposition, protect from light.
<b>Incompatibilities</b>	Not determined
<b>Hazardous Decomposition Products</b>	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.
<b>Hazardous Polymerization</b>	Not anticipated to occur with this material.

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity** – Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Isoproterenol Hydrochloride	100	LD50	Oral	2221	mg/kg	Rat
				1260	mg/kg	Mouse
				3070	mg/kg	Rabbit
				600	mg/kg	Dog
Isoproterenol Hydrochloride	100	LD50	Intravenous	26.9	mg/kg	Rat
				77	mg/kg	Mouse
				27	mg/kg	Rabbit
				50	mg/kg	Dog

LD 50: Dosage that produces 50% mortality.

<b>Occupational Exposure Potential</b>	Clinically, the material 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 aerosol generation and avoid skin contact.
<b>Signs and Symptoms</b>	None anticipated from normal handling of this product. Isoproterenol stimulates the central nervous system; it also stimulates 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 broncho-dilating properties. 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 overdosage 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. This product contains sodium metabisulfite which may cause allergic-type reactions, including anaphylactic symptoms and/or life-threatening asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown, but occurs more frequently in asthmatics than in non-asthmatics.
<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact with skin may produce mild irritation. This material has some potential to be absorbed through skin and mucus membranes.

**11. TOXICOLOGICAL INFORMATION: continued**

<b>Ocular Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. However, this product contains sodium metabisulfite which may cause allergic-type reactions in people sensitive to sulfites.
<b>Reproductive Effects</b>	None anticipated from normal handling of this product. Reproduction studies have been performed in rats and rabbits 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 doses produced some evidence of fetal and maternal toxicity, there was no evidence for teratogenicity in this study.
<b>Mutagenicity</b>	Isoproterenol was negative in the Ames test for mutagenicity in the presence and absence of metabolic activation. In an <i>in vitro</i> chromosomal aberration assay, isoproterenol hydrochloride was negative in the absence of metabolic activation but positive in the presence of metabolic activation.
<b>Carcinogenicity</b>	Long-term studies in animals to evaluate the carcinogenic potential of isoproterenol hydrochloride have not been conducted.
<b>Carcinogen Lists</b>	<b>IARC:</b> Not listed <b>NTP:</b> Not listed <b>OSHA:</b> Not listed
<b>Specific Target Organ Toxicity – Single Exposure</b>	NA
<b>Specific Target Organ Toxicity – Repeat Exposure</b>	Based on clinical use, possible target organs include the central nervous system, respiratory system, cardiovascular system, and smooth muscle.

**12. ECOLOGICAL INFORMATION**

<b>Aquatic Toxicity</b>	Not determined for product.
<b>Persistence/Biodegradability</b>	Not determined for product.
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

Notes:

**13. DISPOSAL CONSIDERATIONS**

<b>Waste Disposal</b>	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

### 14. TRANSPORTATION INFORMATION

<b>ADR/ADG/ DOT STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>ICAO/IATA STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>IMDG STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA

Notes: DOT - US Department of Transportation Regulations

### 15. REGULATORY INFORMATION

<b>US TSCA Status</b>	Exempt
<b>US CERCLA Status</b>	Not listed
<b>US SARA 302 Status</b>	Not listed
<b>US SARA 313 Status</b>	Not listed
<b>US RCRA Status</b>	Not listed
<b>US PROP 65 (Calif.)</b>	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

**GHS/CLP 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.

<b>Hazard Class</b>	<b>Hazard Category</b>	<b>Pictogram</b>	<b>Signal Word</b>	<b>Hazard Statement</b>
NA	NA	NA	NA	NA

**Prevention**  
Do not breathe vapor or spray.  
Wash hands thoroughly after handling.

**Response**  
Get medical attention if you feel unwell.  
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.

**EU Classification\***

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

<b>Classification(s)</b>	NA
<b>Symbol</b>	NA
<b>Indication of Danger</b>	NA
<b>Risk Phrases</b>	NA
<b>Safety Phrases</b>	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
LD <sub>50</sub>	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS  
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