

MATERIAL SAFETY DATA SHEET

Product Name: Epinephrine Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira Inc.
 275 North Field Drive
 Lake Forest, Illinois USA
 60045

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Hospira, Inc., Non-Emergency 224-212-2000

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Synonyms 4-[1-hydroxy-2-(methylamino) ethyl]-1,2 benzenediol.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name L-Epinephrine

Chemical Formula C₉H₁₃NO₃

Preparation Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride, citric acid, sodium citrate, sodium metabisulfite and hydrochloric acid.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
L-Epinephrine	≤0.1	51-43-4	DO2625000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
L-Epinephrine	Not Listed	Not Listed	Not Listed

Emergency Overview Epinephrine Injection is a solution containing epinephrine, a vasoconstrictor agent. In clinical use, epinephrine is used to relieve respiratory distress due to bronchospasm, to provide rapid relief of hypersensitivity reactions to drugs and other allergens, and to prolong the action of anesthetics. Its cardiac effects may be of use in restoring cardiac rhythm in cardiac arrest due to various causes. In the workplace, this material should be considered a potent drug and possibly irritating to the skin and eyes. Based on clinical use, possible target organs include the nervous system, cardiovascular system, eyes, and respiratory system.

Occupational Exposure Potential Though not well absorbed, inhalation or topical application can produce systemic effects. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms None known from occupational exposure. In clinical use, serious adverse effects may include rapid and large increases in blood pressure, cerebral hemorrhage, pulmonary arterial hypertension resulting in edema, hyperglycemia, and cardiac arrhythmia with ventricular fibrillation. Other adverse effects may include fearfulness, anxiety, sweating, nervousness,

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palpitations, tenseness, restlessness, headache, tremor, dizziness and lightheadedness, fever, chills, nausea, vomiting, respiratory difficulty, tachycardia, dilated pupils, blurred vision, cyanosis, ECG changes, disruption of cardiac rhythm, hypertension, metabolic acidosis, and injury to the heart. Locally, tissue necrosis can result at the injection site due to vasoconstriction. Ocular use has produced conjunctival irritation (burning, stinging, tearing and rebound redness).

Medical Conditions Aggravated by Exposure Pre-existing nervous system, cardiovascular system, ocular, or respiratory system ailments. Pre-existing hypersensitivity to this material.

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 from this aqueous product.

Fire & Explosion Hazard None anticipated from 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 any 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 are required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Type	Exposure limits			Note
		mg/m3	ppm	µg/m3	
L-Epinephrine	Hospira EEL	N/A	N/A	1	8 Hr TWA
L-Epinephrine	Hospira STEL	N/A	N/A	20	

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

Appearance/Physical State	Liquid
Color	Clear, colorless liquid
Odor	Not Determined
Odor Threshold:	NA
pH:	3.3 (2.5 to 5.0)
Melting point/Freezing point:	NA
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:	With acids, forms salts that are freely soluble in water
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

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) and nitrogen oxides (NOx).
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:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Epinephrine	100	LD50	Intravenous	150	mcg/kg	Rat
				217	mcg/kg	Mouse
				50	mcg/kg	Rabbit
				100	mcg/kg	Dog
Epinephrine	100	LD50	Dermal	62	mg/kg	Rat
Epinephrine Hydrochloride	100	LD50	Oral	24	mg/kg	Rat
Epinephrine Hydrochloride	100	LD50	Intravenous	140	mcg/kg	Mouse
Epinephrine Hydrochloride	100	LD50	Intraperitoneal	4.7	mg/kg	Mouse

Aspiration Hazard	None anticipated from normal handling of this product. Inadvertent inhalation of small amounts of this product may produce irritation and possibly bronchial dilation.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation, dilated pupils, and blurred vision.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product.
Reproductive Effects	No teratogenic effect was noted in offspring of pregnant rats given continuous infusions of epinephrine at a dose about 8 times the normal human dose. An increase in the frequency of cleft palate was noted in the offspring of one strain

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of mice treated during pregnancy with epinephrine at doses that were 40-80 times the normal human dose. An increase in the frequency of fetal loss was noted in pregnant mice and rabbits given epinephrine at doses that were 200 and 85 times, respectively, the human therapeutic dose. The frequency of malformations was not increased in offspring of hamsters treated during pregnancy with 25 times the human subcutaneous dose.

Mutagenicity Salmonella gene mutation tests with L-epinephrine were negative in the TA100 strain in the presence of S9 metabolic activation, but equivocal in the absence of S9. No mutagenic activity was observed in strains TA98, TA1535, or TA1537 with or without S9. Results noted in a CHO cell assay for induction of sister chromatid exchanges were considered negative and equivocal in the presence and absence of S9 activation, respectively.

Carcinogenicity No data found for epinephrine. By analogy, in a chronic aerosol inhalation studies in rats and mice, epinephrine hydrochloride did not significantly increase the incidence of tumors over controls in these animals. Increased incidences of suppurative inflammation, dilatation of the nasal glands in rats and mice, and hyperplasia of the respiratory epithelium in rats only were noted in this study.

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

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 wastes must be properly characterized by the waste generator. 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

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
L-Epinephrine	Listed	Listed	Not Listed	Not Listed	Not Listed

RCRA Status Epinephrine – Listed. The US Federal EPA waste listing for epinephrine does not include epinephrine salts.

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 L-Epinephrine

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: R00 - Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24 - Avoid contact with skin.
S25 - Avoid contact with eyes.
S37 - Wear suitable gloves.
S39 - Wear 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: Hospira GEHS

Date Prepared: 10/18/2012

Obsolete Date: 09/19/2011

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