

0641142035



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 60045
USA

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

Product Name Epinephrine Injection, USP

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name L-Epinephrine
Chemical Formula $C_9H_{13}NO_3$

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

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.

3. HAZARD INFORMATION

Emergency Overview Epinephrine Injection, USP, contains epinephrine, a vasoconstrictor agent. 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, 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.

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 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 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 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.
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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 USP controlled room temperature 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 controls.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
L-Epinephrine	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 1 mcg/m ³ STEL: 20 mcg/m ³

Notes: OSHA PEL: US Occupational Safety and Health Administration -- Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists -- Threshold Limit Value.
 EEL: Employee Exposure Limit.
 TWA: 8 hour Time Weighted Average.
 STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, or respiratory protection is desired, 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. 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	Epinephrine is a white, crystalline powder. Epinephrine Injection is a 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 (Air = 1)	NA
Evaporation Rate	NA
Specific Gravity	NA
Solubility	Very soluble in water and alcohol.
Log 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

LD 50: Dosage that produces 50% mortality.

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.

11. TOXICOLOGICAL INFORMATION - continued

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 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.

Product Name: Epinephrine Injection, USP



14. TRANSPORTATION INFORMATION

DOT STATUS: Not Regulated
Proper Shipping Name: NA
Hazard class: NA
Un number: NA
Packing group: NA
Reportable quantity: NA

ICAO/IATA STATUS: Not regulated
Proper shipping name: NA
Hazard class: NA
Un number: NA
Packing group: NA
Reportable quantity: NA

IMDG STATUS: Not regulated

Proper shipping name: NA
Hazard class: NA
Un number: NA
Packing group: NA
Reportable quantity: NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status: Product is exempt.
CERCLA Status: Epinephrine - Listed. The US Federal EPA waste listing for epinephrine does not include epinephrine salts. Disposal should be performed in accordance with all federal, state, and local regulatory requirements.
SARA 302 Status: Not listed
SARA 313 Status: Not listed
RCRA Status: Epinephrine - Listed. The US Federal EPA waste listing for epinephrine does not include epinephrine salts. Disposal should be performed in accordance with all federal, state, and local regulatory requirements.
PROP 65 (Calif.): 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

U.S. OSHA Classification: Possible Irritant
Target Organ Toxin

REGULATORY INFORMATION - continued

GHS Classification* *In circumstances where medicinal products are not exempt, the recommended GHS classification is as follows:

Hazard Class	Acute Oral Toxicity	Eye Irritation	Target Organ Toxicity
Hazard Category	Unclassified	2B	2
Symbol			
Signal Word		Warning	Warning
Hazard Statement		Causes eye irritation	May cause damage to the nervous system, cardiovascular system eyes, and respiratory system through prolonged or repeated exposure.

Prevention: Do not breathe vapor or 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 Classifications*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance epinephrine.

Classification(s):	Toxic	Irritant
Symbol:		
Indication of Danger	T	Xi
Risk Phrases:	R24 - Toxic if swallowed R25 - Toxic in contact with skin R36/37/8 - Irritating to eyes, respiratory system and skin	
Safety Phrases:	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 ₅₀	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: September 15, 2005
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