INTERNATIONAL MEDICATION SYSTEMS, LIMITED
1886 SANTA ANITA AVENUE, SOUTH EL MONTE, CALIFORNIA 91733
AREA CODE (800) 423-4136, (909) 980-9484 (INTERNATIONAL)
FAX (626) 459-5255

MATERIAL SAFETY DATA SHEET

SECTION I. IDENTIFICATION	
Identity/Material Name	Epinephrine Injection USP, 1:10,000 (0.1 mg/mL)
Synonyms	(-)-3,4-Dihydroxy-α-[(methyl-amino) methyl] benzyl alcohol
Stock Number	3316
NDC Number	76329-3316-1
Unit Size	1 mg/ 10 mL (in a single use prefilled syringe)
Intended Use	Rx Only. Epinephrine's cardiac effects may be of use in the treatment and prophylaxis of cardiac arrest due to various causes in the absence of ventricular fibrillation and attacks of transitory atrioventricular (AV) heart block with syncopal seizures (Stokes-Adams syndrome), but it is not used in cardiac failure or in hemorrhagic, traumatic or in cardiogenic shock. Epinephrine may be used to stimulate the heart in syncope due to complete heart block or carotid sinus hypersensitivity. Epinephrine is also used for resuscitation in cardiac arrest following anesthetic accidents. In cardiopulmonary resuscitation, intracardiac puncture and intramyocardial injection of epinephrine may be effective when external cardiac compression and attempts to restore the circulation by electrical defibillation or use of a pacemaker fail. Epinephrine is seldom used as a vasopressor except in the treatment of anaphylactic shock and under certain conditions in insulin shock.
Company Information	
Manufacture	International Medication Systems, Limited (IMS) 1886 Santa Anita Avenue, South El Monte, California 91733 Tel (800) 423-4136 Fax (626) 459-5255
Emergency Number	(800) 423-4136 (US Domestic), (909) 980-9484 (International)

SECTION II. HAZARD(S) IDENTIFICATION	
Emergency Overview	Clear, colorless Liquid Odorless Contains sodium bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.
Statement of Hazard	Though not well absorbed, inhalation or topical application can produce systemic effects. Avoid liquid aerosol generation and skin contact.

Potential Health Effect	Anxiety, headache, fear, and palpitations often occur with therapeutic doses, especially in hyperthyroid and hypertensive individuals. Cardiac arrhythmias and excessive rise in blood pressure may occur with therapeutic doses or inadvertent overdosage.	
Hazard Class	Not applicable	
Hazard Category	GHS Classification	Not applicable
	Classification according to EC Directive 1272/2008	Not available
	Classification according to EC Directives 64/548/EEC (substances) or 1999/45/EC (mixtures)	Not available

SECTION III. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient	Epinephrine USP (formulated as hydrochloride salt)	
	Approximate % by weight: ≤ 0.1	RTECS No. DO3150000
	EC Number: Not applicable	CAS #: 55-31-2
Inactive Ingredients	Sodium Chloride USP Citric Acid monohydrate USP Sodium Citrate Dihydrate USP Sodium Bisulfite NF Hydrochloric Acid NF Water for Injection USP	
Chemical Formula	$C_9H_{13}NO_3$	

SECTION IV. FIRST-AID MEASURES

Eye Contact	Flush eyes immediately with copious amounts of water. Seek medical attention if deemed necessary.
Skin Contact	Avoid direct skin contact. Wash affected skin surfaces immediately with mild soap and copious amounts of water.
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.
Effect and Treatment of Overdosage	Most toxic effects can be counteracted by injection of an alpha-adrenergic blocker and a beta-adrenergic blocker. In the event of a sharp rise in blood pressure, rapid acting vasodilators such as the nitrites, or alpha-adrenergic blocking agents can counteract the marked pressor effects. If prolonged hypotension follows, it may be necessary to administer another pressor drug, such as norepinephrine. If an epinephrine overdose induces pulmonary edema that interferes with respiration, treatment consists of a rapidly acting alpha-adrenergic blocking drug such as phentolamine and/or intermittent positive pressure respiration. Treatment of cardiac arrhythmias consists of a beta-adrenergic blocking drug such as propranolol. Epinephrine overdosage can also cause transient bradycardia followed by tachycardia; these may be accompanied by potentially fatal cardiac arrhythmias. Ventricular

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Effect and Treatment of Overdosage (cont.)	premature contractions may appear within one minute after injection and may be followed by multifocal ventricular tachycardia (prefibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia, and occasionally, by atrioventricular block. Overdosage sometimes results in extreme pallor and coldness of the skin, metabolic acidosis and kidney failure. Take suitable corrective measures.

SECTION V. FIRE-FIGHTING MEASURES		
Extinguishing Media		Water, carbon dioxide, dry chemical or foam.
Special Fire-Fighting Precautions		No special precautions determined for this product.
Flammability		
Fire/Explosion Hazards		None anticipated from this product.
Hazardous Combustion 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).
Flash Point		Unknown
Auto-Ignition Temperature		Unknown
Flammable Limits	LEL	Not available
	UEL	Not available

SECTION VI. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Steps to be Taken if Released or Spilled	Absorb onto paper. Wash spill site with copious amounts of water.

SECTION VII. HANDLING AND STORAGE	
Handling	No special handling required under conditions of normal product use
Storage	Avoid freezing and light exposure. Store at controlled room temperature 15° to 30°C (59° to 86°F).

SECTION VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION	
Exposure Limits	Not available
Personal Protective Equipment (PPE)	
Eye Protection	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance
Skin Protection	Adequate skin protection recommended including gloves. Lab coats or additional protection may be required based on procedure or level of exposure. Consult your site safety staff for guidance.
Respiratory Protection	Respiratory protection is not needed during normal product use.

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Engineering Controls	The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

SECTION IX. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance and Odor	Clear, colorless, odorless solution
Physical State	Liquid
pH	2.2-5.0
Molecular Weight	Unknown
Melting Point(°C)	Not available
Freezing Point(°C)	Not available
Boiling Point(°C)	Not available
Evaporation Rate	Water solvent will slowly evaporate
Vapor Pressure	Not available
Vapor Density	Not available
Relative Density	Not available
Solubility(ies)	With acids, forms salts that are freely soluble in water
Partition coefficient	Not available
Decomposition Temperature	Not available
Viscosity	Not available
Flammability	See **Section V: Fire Fighting Measures** for flammability/explosivity information.

SECTION X. STABILITY AND REACTIVITY	
Stability/Reactivity	Not determined.
Hazardous Reactions	Not determined.
Incompatibilities/ Conditions to Avoid	Epinephrine is readily destroyed by alkalies and oxidizing agents. In the latter category are oxygen, chlorine, bromine, iodine, permanganates, chromates, nitrites, and salts of easily reducible metals, especially iron. Avoid freezing and light exposure. Do not store at temperatures outside the range of 15-30°C. The solution should not be used if it is pinkish or darker than slightly yellow or if it contains a precipitate.
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.

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SECTION XI. TOXICOLOGICAL INFORMATION

The data presented below is for this product or for a structurally similar product.

Acute Toxicity

Information for 100% Epinephrine Hydrochloride is presented below

Test Type	Route of Administration	Value	Units	Species
LD50	Oral	24	mg/kg	Rat
LD50	Intravenous	140	mcg/kg	Mouse
LD50	Intraperitoneal	4.7	mg/kg	Mouse

Repeat Dose Toxicity Data

Subchronic/ Chronic Toxicity	Repeated local injections can result in necrosis at sites of injection from vascular construction. Cerebral hemorrhage; hemiplegia; subarachnoid hemorrhage; anginal pain in patients with angina pectoris; anxiety; restlessness; throbbing headache; tremor; weakness; dizziness; pallor; respiratory difficulty; palpitation; apprehensiveness; sweating; nausea; vomiting. "Epinephrine-fastness" can occur with prolonged use.
Reproductive/ Developmental Toxicity	Pregnancy Category C. Epinephrine is teratogenic in small animals when given in doses about 25 times the human dose. There are no adequate and well control studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. Parenteral administration of epinephrine, if used to support blood pressure during low or other spinal anesthesia for delivery, can cause acceleration of fetal heart rate and should not be used in obstetrics when maternal blood pressure exceeds 130/80.
Mutagenicity/ Genotoxicity	Unknown
Carcinogenicity	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 supurative inflammation, dilation of the nasal glands in rats and mice, and hyperplasia of the respiratory epithelium in rats only were noted in this study.

SECTION XII. ECOLOGICAL INFORMATION

Ecotoxicity Data	Not determined for this product
Environmental Data	Not determined for this product

SECTION XIII. DISPOSAL CONSIDERATIONS

Method of Disposal	Approved chemical waste incineration or approved aqueous discharge to municipal or on-site wastewater treatment systems.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

SECTION XIV. TRANSPORT INFORMATION

This material is not subject to the transportation regulation of USDOT, EUADR, IATA or IMDG/IMO

SECTION XV. REGULATORY INFORMATION

US State Regulations	Check state requirements for ingredient listing.
RCRA Status	Epinephrine – Listed. The US Federal EPA waste listing for epinephrine does not include epinephrine salts.
U.S. OSHA	Possible Irritant

Approved By/Date:

Stephen Campbell
8/15/14

Classification	Target Organ Toxin
TSCA Listing	Listed
GHS Classification	Not applicable
Symbol	
Response	See First Aid measures **(Section IV)**

SECTION XVI. OTHER INFORMATION

Pharmaceutical Use	This product is Rx Only. Please follow instructions in the package insert.
Abbreviations	
ADR	Agreement on Dangerous Goods by Road
CAS	Chemical Abstracts Service Number
DOT	US Department of Transportation Regulations
IATA	International Air Transport Association
IMO	International Maritime Organization
LD50	Dosage producing 50% mortality
LEL	Lower Exposure Limit
N/A	Not applicable
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
TSCA	Toxic Substance Control Act
UEL	Upper Exposure Limit
Hazard Symbols	
	Irritant
Revision Date	07/10/14
Supersedes Date	09/04/08

Rx Only. Refer to package insert for additional information.

The information contained herein is believed to be complete and accurate. However, it is the user's responsibility to determine the suitability of the information for their particular purpose. The company assumes no additional liability or responsibility resulting from the usage of, or reliance on this information.

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8/5/14