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

MATERIAL SAFETY DATA SHEET

SECTION I - MATERIAL IDENTIFICATION

Identity/Material Name:	Epinephrine Injection USP, 1:1000 (1 mg/mL)
Stock Number:	9061
NDC Number:	0548-9061-00
Unit Size:	30 mg / 30 mL (multiple dose vial)
Manufacture's Name:	International Medication Systems, Limited (IMS) Telephone (800)423-4136
Address:	1886 Santa Anita Avenue, South El Monte, California 91733 Fax: (626)459-5255

SECTION II - HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

Ingredient Name:	Amount per mL:	Permissible Exposure Level:
Epinephrine USP	1 mg	Unknown
Sodium Chloride USP	Adjustment of Tonicity	Unknown
Chlorobutanol Hemihydrate USP/NF	0.5%	Unknown
Sodium Metabisulfite NF	NMT 0.15%	Unknown
Sodium Hydroxide NF	pH Adjustment	Unknown
Hydrochloric Acid NF	pH Adjustment	Unknown
Water for Injection USP	QS Ad	N/A

SECTION III - PHYSICAL CHEMICAL DATA

Boiling Point (°C):	Unknown	Melting Point (°C):	N/A
Viscosity:	N/A	Vapor Pressure:	Unknown
Specific Gravity:	N/A	Percentage Volatile:	N/A
Vapor Density:	Unknown	Evaporation:	Water solvent will slowly evaporate
Solubility in Water:	Miscible with water		
Appearance and Odor:	Clear, colorless, odorless solution.		

SECTION IV - FIRE AND EXPLOSION DATA

Flash Point:	Unknown	Flammable Limits:	LEL	N/A	UEL N/A
Extinguishing Media:	Water, carbon dioxide, dry chemical or foam.				
Special Fire Procedures:	Unknown				
Approved By:	RA Diane Jones	Date Prepared:	6-25-02		

SECTION V REACTIVITY DATA	
Stability:	Stable under ordinary conditions of use and storage. Protection from light and freezing.
Conditions to Avoid:	Temperature outside of 15°C to 30°C, freezing, and light exposure. The solution should not be used if it is pinkish or darker than slightly yellow or if it contains a precipitate.
Incompatibility (Materials 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.
Hazardous Decomposition Products:	Unknown
SECTION VI HEALTH HAZARDS DATA	
LD_{50}	Unknown
Pregnancy, Fertility and Lactation:	Teratogenic Effect – Pregnancy Category C: Epinephrine has been shown to be teratogenic in rats when given in doses about 25 times the human dose. There are not adequate and well-controlled studies in pregnant women. Epinephrine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Effect and Treatment of Overdosage:	Symptoms: Erroneous administration of large doses of epinephrine may lead to precordial distress, vomiting, headache, dyspnea, as well as unusually elevated blood pressure. Treatment: 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 hypotention 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 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 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.
Eye Contact:	Flush eyes immediately with copious amounts of water. Seek medical attention if deemed necessary.
Inhalation:	Unknown
Skin Irritation:	Avoid direct skin contact. Wash affected skin surfaces immediately with mild soap and copious amounts of water.
Approved By: RA Diane Smith	Date Prepared: 6-25-02

Accidental Ingestion: Seek physician's care.

Systemic: Epinephrine Injection USP is a sterile, nonpyrogenic solution intended for subcutaneous or intramuscular injection. In general, the most common uses of epinephrine are 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 infiltration anesthetics. Its cardiac effects may be of use in restoring cardiac rhythm in cardiac arrest due to various causes, but is not used in cardiac failure or in hemorrhagic, traumatic, or cardiogenic shock.

Epinephrine is a sympathomimetic drug. It activates and adrenergic receptive mechanism on effector cells and imitates all actions of the sympathetic nervous system except those on the arteries of the face and sweat glands. Epinephrine acts on both alpha and beta receptors and is the most potent alpha receptor activator. Epinephrine relaxes the smooth muscle of the bronchi and iris and is a physiologic antagonist of histamine. The drug also produces an increase in blood sugar and glycogenolysis in the liver.

Epinephrine is contraindicated in narrow angle (congestive) glaucoma, shock, during general anesthesia with halogenated hydrocarbons or cyclopropane and in individuals with organic brain damage. Epinephrine is also contraindicated with local anesthesia of certain areas, e.g., fingers, toes, because of the danger of vasoconstriction producing sloughing of tissue; in labor because it may delay the second stage; in cardiac dilatation and coronary insufficiency. Epinephrine should not be used in those cases where vasopressor drugs may be contraindicated, e.g., in thyrotoxicosis, diabetes, in obstetrics when maternal blood pressure is excess of 130/80, and in hypertension and other cardiovascular disorders.

Administer with caution to elderly people, to those with cardiovascular disease, hypertension, diabetes, or hyperthyroidism; in psychoneurotic individuals; and in pregnancy. Patients with long-standing bronchial asthma and emphysema who have developed degenerative heart disease should be administered the dug with extreme caution. Overdosage or inadvertent intravenous injection of epinephrine may cause cerebrovascular hemorrhage resulting from the sharp rise in blood pressure. Fatalities may also result from pulmonary edema because of the peripheral constriction and cardiac stimulation produced. Rapidly acting vasodilators, such as nitrites, or alpha blocking agents may counteract the marked pressor effects of epinephrine. Epinephrine 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. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic rather than in non-asthmatic people. Epinephrine is the preferred treatment of serious allergic or other emergency situations even though this product contains sodium metabisulfite, a sulfite that may in other products cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternative to using epinephrine in a life-threatening situation may not be satisfactory. The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations.

Cardiovascular effects: Inadvertently induced high arterial blood pressure may result in angina pectoris (especially when coronary insufficiency is present), or aortic rupture. Epinephrine may induce potentially serious cardiac arrhythmias in patients not suffering from

SECTION VI - HEALTH HAZARDS DATA (CONTINUED)

Systemic: (Continued)	heart disease and patients with organic heart disease or who are receiving drugs that sensitize the myocardium. With Epinephrine 1:10,000, a paradoxical but transient lowering of blood pressure, bradycardia and apnea may occur immediately after injection. *Cerebrovascular hemorrhage:* Overdosage or inadvertent I.V. injection of epinephrine may cause cerebrovascular hemorrhage resulting form the sharp rise in blood pressure. *Pulmonary edema:* Fatalities may also result from pulmonary edema because of the peripheral constriction and cardiac stimulation produced. Drug interaction: Use of epinephrine with excessive doses of digitalis, mercurial diuretics, or other drugs that sensitize the heart to arrhythmias is not recommended. Anginal pain may be induced when coronary insufficiency is present. The effects of epinephrine may be potentiated by tricyclic antidepressants certain antihistamines, e.g., diphenhydramine, tripelennamine, d-chlorpheniramine; and sodium l-thyroxine. In obstetrics, if vasopressor drugs are used either to correct hypotension or added to the local anesthetic solution, some oxytocic drugs may cause severe persistent hypertension; even rupture of a cerebral blood vessel may occur during the postpartum period. All vasopressors should be used cautiously in patients taking monoamine oxidase (MAO) inhibitors. Cyclopropane or halogenated hydrocarbon anesthetics such as halothane which sensitize the myocardium administration of a beta-adrenergic blocking drug. Diuretic agents may decrease vascular response to pressor drugs such as epinephrine. Epinephrine may antagonize the neuron blockade produced by guanethidine resulting in decreased antihypertensive effect and requiring increased dosage of the latter. Use of epinephrine with excessive doses of digitalis, mercurial diuretics or other drugs that sensitize the heart to arrhythmias is not recommended. Rapidly acting vasodilators such as nitrites or alpha-blocking agents may counteract the marked pressor effects of epinephrine. Propranolol administered concomitantly with epinephrine may block the beta-adrenergic effects of epinephrine, causing hypertension. Epinephrine should be administered with caution to infants and children. Syncope has occurred following the administration of epinephrine to asthmatic children. Transient and minor side effects of anxiety, headache, fear, and palpitations often occur with therapeutic doses, especially in hyperthyroid individuals. Repeated local injections can result in necrosis at sites of injection from vascular constriction. ``Epinephrine-fastness" can occur with prolonged use. Local: Repeated local injections can result in necrosis at sites of injection form vascular constriction. Systemic: 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.

Approved By: RA | Date Prepared: 6-25-02

SECTION VI - PRECAUTIONS FOR SAFE HANDLING AND USE	
Precautions:	Epinephrine injection should be protected from exposure to light. Do not remove vial from carton until ready to use. The solution should not be used if it is pinkish or darker than slightly yellow or if it contains a precipitate.
Steps to be Taken if Released or Spilled:	Absorb onto paper. Wash spill site with copious amounts of water.
Waste Disposal:	Approved chemical waste incineration or approved aqueous discharge to municipal or on-site wastewater treatment systems.
SECTION VII - CONTROL MEASURES	
Respiratory Protection:	N/A
Ventilation:	Local ventilation adequate.
Skin Protection:	Adequate skin protection recommended including gloves.
Eye Protection:	Adequate eye protection recommended including safety glasses.
Approved By: RA/	Date Prepared: 6-25-02

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. International Medication Systems, Limited assumes no additional liability or responsibility resulting from the usage of, or reliance on this information.