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:	Dextrose Injection USP, 50%
Stock Number:	1001
NDC Number:	0548-1001-00
Unit Size:	25 g / 50 mL (in unit-use packages containing a MIN-I-JET prefilled syringe)
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:
Dextrose Monohydrate USP Water for Injection USP	500 mg QS Ad	Unknown 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		

SECTION V REACTIVITY DATA

Stability:	Stable under ordinary conditions of use and storage.
Approved By: QA	Date Prepared: 6-21-02

SECTION V – REACTIVITY DATA (CONTINUED)	
Stability:	Stable under ordinary conditions of use and storage.
Conditions to Avoid:	Temperature outside of 15°C to 30°C; freezing; or if a precipitate is present.
Incompatibility (Materials to Avoid):	Unknown
Hazardous Decomposition Products:	Unknown
SECTION VI – HEALTH HAZARDS DATA	
LD_{50}	Unknown
Pregnancy, Fertility and Lactation:	Teratogenic Effect – Pregnancy Category C: Safety for use during pregnancy has not been established. Dextrose should be used only when clearly needed and when the potential benefits outweigh the unknown potential hazards to the fetus.
Effect and Treatment of Overdosage:	In the event of a fluid or solute overload during parenteral therapy, the patient's condition should be reevaluated and appropriate corrective treatment instituted. A number of serious reactions have been reported following the intravenous injection of dextrose, which can be attributed to the solution or error in technique. These include: febrile response; infection at the injection site; tissue necrosis; venous thrombosis or phlebitis extending from the site of injection; extravasation; hypovolemia; hypervolemia; dehydration; mental confusion or unconsciousness. It has been claimed that dextrose may produce allergic reactions in corn-sensitive persons, but this allegation has been refuted. The largest available peripheral vein and a well-placed small bore needle should be used. Thrombophlebitis may result from the use of hypertonic solutions via the intravenous route of administration. Rapid infusion (e.g., 50 to 100 g over three minutes, as in an intravenous glucose tolerance test) may occasionally cause a generalized flush. This subsides within ten minutes. Significant hyperglycemia, hyperosmolar syndrome and glycosuria may occur with too rapid administration of hypertonic solutions. They are more likely to cause irritation and should therefore be administered into larger central veins. The administration of dextrose without an adequate provision of certain B vitamins, which form the coenzyme systems in its metabolism, will exhaust tissue stores of these factors, leading to deficiency states. Similarly, the utilization of glucose will cause the intracellular movement of potassium, so that provisions for replacement of this element during periods of dextrose administration may require consideration under certain conditions. The level of blood sugar appears to be one factor in governing the rate of production of certain hormones; hyperglycemia invokes an outpouring of insulin; hypoglycemia causes release of epinephrine and through this latter mechanism, the pituitary–adrenal cortex is stimulated. From the anterior pituitary and adrenal cortex, the anti-insulin factors, which tend to restore the blood sugar to normal are liberated.
Eye Contact:	Flush eyes immediately with copious amounts of water. Seek medical attention if deemed necessary.

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SECTION VI - HEALTH HAZARDS DATA (CONTINUED)

Inhalation:	Unknown
Accidental Ingestion:	Seek physician's care.
Skin Irritation:	Avoid direct skin contact. Wash affected skin surfaces immediately with mild soap and copious amounts of water.
Systemic:	Dextrose, the natural sugar occurring in blood, is the principal source of energy for the body Dextrose Injection, 25%, is used in parenteral hyperalimentation. It is hypertonic solutions and, when administered intravenously, cause cellular dehydration. It has been employed to promote diuresis by increasing the osmotic pressure of the glomerular filtrate. Its hypertonic property makes it valuable in the following special clinical uses, which may be summarized as follows. a) For its concentrated good value in patients in whom more dilute solutions are contraindicated by actual or impending edema, such as exist in surgical as well as nonsurgical patients. b) 25%: Acute symptomatic episodes of hypoglycemia in the neonate or older infant to restore depressed blood glucose levels and control symptoms. c) 50%: Used in the treatment of insulin hypoglycemia (hyperinsulinemia or insulin shock) to restore blood glucose levels. For reduction of increased cerebrospinal pressure and/or cerebral edema due to delirium tremens or acute alcoholic intoxication. Increased cerebrospinal fluid pressure may be depressed for two to four hours after intravenous injection of 50 mL of 50% dextrose solution. Hypertonic solutions of dextrose should not be administered subcutaneously, intramuscularly, or intraperitoneally. Subcutaneous administration of hypertonic solutions may be irritating to the tissues and should be avoided. The intravenous use of strongly hypertonic solutions of dextrose to reduce cerebral edema and/or cerebrospinal pressure is contraindicated in the presence of intracranial or intraspinal hemorrhage and in delirium tremens if the patient is already dehydrated. It is also contraindicated in diabetic coma while blood sugar is excessively high and in patients with glucose-galactose malabsorption syndrome. Dextrose solution I.V. can cause fluid or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. Hypertonic dextrose solutions, even when given intravenously, have a tendency to cause venous thrombosis. Proper technique for intravenous injection should therefore be employed to avoid vein damage. For example: It is suggested that a needle of the smallest practicable bore be used; that the injection be made as slowly as conditions permit; that the bevel of the inserted needle be kept as far away as possible from the wall of the vein (usually the superior vena cava or other equally large vein); blood flow in the punctured vein be increased by the application of heat to that extremity; that the solution itself be warmed to body temperature, or at least to room temperature, before use; and that the tourniquet be removed as soon as the needle is in the vein and before any solution is injected. Dextrose-containing solutions should be used with caution in patients with subclinical or overt diabetes mellitus or carbohydrate intolerance. Rapid administration of hypertonic solutions may produce significant hyperglycemia or hyperosmolar syndrome, especially in patients with chronic uremia or

SECTION VI HEALTH HAZARDS DATA (CONTINUED)	
Systemic: (Continued)	carbohydrate intolerance. When using concentrated solutions of dextrose, it is important that these should be injected very slowly so as not to cause a local rise in the osmotic tension of the blood at the point of injection and administered so that extravasation does not occur. If thrombosis occurs during administration, the injection should be stopped and corrective measures instituted. The use of hypertonic solutions requires particular care. Frequent observation of the tongue and determination of the ratio of red blood cells to plasma (hematocrit) are useful guides. Clinical evaluations and laboratory determinations should be performed to monitor fluid balance, electrolyte concentrations and acid-base balance. The intravenous use of strongly hypertonic solutions of dextrose to reduce cerebral edema and/or cerebrospinal pressure requires very special care. It is significant to note that, following the initial fall in intracranial pressure, there is often a secondary rise, which may necessitate repeated spinal punctures or additional injections of the dextrose injection. Hyperglycemia and glycosuria may be functions of the rate of administration of metabolic insufficiency. To minimize these conditions, the infusion rate should be showed down and the blood and urine glucose monitored. If necessary, insulin may be administered. When concentration dextrose infusion is abruptly withdrawn, administer 5% or 10% dextrose to avoid reactive hypoglycemia. Potassium: Excessive administration of potassium free solutions may result in significant hypokalemia. Potassium should be added to dextrose solutions and administered to fasting patients with good renal function, especially those on digitalis therapy. Parenteral dextrose solutions should be cautiously administered, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin. Dextrose administration may cause vitamin B complex deficiency. Additives may be incompatible. When introducing additives, use aseptic technique, mix thoroughly and do not store. Dextrose should not be administered simultaneously with blood through the same infusion set because pseudoagglutination of red blood cells may occur. Dextrose should be used with caution in infants of diabetic mothers, except as may be indicated in hypoglycemic neonates.

SECTION VII PRECAUTIONS FOR SAFE HANDLING AND USE	
Precautions:	Improper engaging may cause glass breakage and subsequent injury.
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 VIII CONTROL MEASURES	
Respiratory Protection:	N/A
Approved By: QA	Date Prepared: 6-21-02

SECTION VIII: CONTROL MEASURES (CONTINUED)	
Ventilation:	Local ventilation adequate.
Skin Protection:	Adequate skin protection recommended including gloves.
Eye Protection:	Adequate eye protection recommended including safety glasses.
Approved By: QA Director	Date Prepared: 6-21-02

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.