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	Sodium Bicarbonate Injection USP, 8.4%
Synonyms	Baking Soda; Bicarbonate of soda; Sodium acid carbonate; Monosodium carbonate; Sodium hydrogen carbonate; Carbonic acid monosodium salt
Stock Number	3352
NDC Number	76329-3352-1
Unit Size	50 mEq (4.2 g) / 50 mL (one single dose vial with a prefilled syringe)
Intended Use	Rx Only. Sodium Bicarbonate Injection, USP is indicated in the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis. Sodium bicarbonate is further indicated in the treatment of certain drug intoxications, including barbiturates (where dissociation of the barbiturate-protein complex is desired), in poisoning by salicylates or methyl alcohol and in hemolytic reactions requiring alkalinization of the urine to diminish nephrotoxicity of hemoglobin and its breakdown products. Sodium bicarbonate also is indicated in severe diarrhea which is often accompanied by a significant loss of bicarbonate.
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	Liquid Clear/colorless Odorless Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention. In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention. The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. Extravascular infiltration should be avoided.

Statement of Hazard	Non-hazardous in accordance with international standards for workplace safety. Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.	
Potential Health Effect	Overly aggressive therapy with Sodium Bicarbonate Injection, USP can result in metabolic alkalosis (associated with muscular twitching, irritability, and tetany) and hypernatremia. Inadvertent extravasation of intravenously administered hypertonic solutions of sodium bicarbonate have been reported to cause chemical cellulitis because of their alkalinity, with tissue necrosis, ulceration or sloughing at the site of infiltration. Prompt elevation of the part, warmth and local injection of lidocaine or hyaluronidase are recommended to reduce the likelihood of tissue sloughing from extravasated I.V. solutions.	
Hazard Class	Not applicable	
Hazard Category	GHS Classification	Not available
	Classification according to EC Directive 1272/2008	Not applicable
	Classification according to EC Directives 64/548/EEC (substances) or 1999/45/EC (mixtures)	Not applicable

SECTION III. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient	Sodium Bicarbonate USP	
	Approximate % by weight: 8.4%	RTECS No. VZ0950000
	EC Number: 205-633-8	CAS #: 144-55-8
Inactive Ingredients	Carbon dioxide USP Water for injection USP	
Chemical Formula	$NaHCO_3$	

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. Seek medical attention if needed or if signs of toxicity occur
Ingestion	Remove from source of exposure. Seek medical attention if needed or if signs of toxicity occur
Effect and Treatment of Overdosage	Sodium bicarbonate should be discontinued and the symptoms of alkalosis controlled by rebreathing expired air from a paper bag or rebreathing mask or, if more severe, by parenteral injections of calcium gluconate. Severe alkalosis may be corrected by I.V. infusion of 2.14% ammonium chloride solution, except in patients with hepatic disease, in whom ammonia use is contraindicated. Sodium chloride (0.9%) I.V. or potassium chloride may be indicated if there is hypokalemia. Calcium gluconate is administered to control tetany.

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	Not applicable

Hazardous Combustion Products		Unknown
Flash Point		Unknown
Auto-Ignition Temperature		Not applicable
Flammable Limits	LEL	Unknown
	UEL	Unknown

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	Store as directed by product packaging.

SECTION VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION	
Exposure Limits	Not applicable
Personal Protective Equipment (PPE)	
Eye Protection	Adequate eye protection recommended including safety glasses.
Skin Protection	Adequate skin protection recommended including gloves. Lab coats or additional precaution 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.
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	8.0 (7.5 to 8.5)
Molecular Weight	Unknown
Melting Point(°C)	Not applicable

Freezing Point(°C)	Unknown
Boiling Point(°C)	Unknown
Evaporation Rate	Water solvent will slowly evaporate
Vapor Pressure	Unknown
Vapor Density	Unknown
Relative Density	Unknown
Solubility(ies)	Miscible with water
Partition coefficient	Unknown
Decomposition Temperature	Unknown
Viscosity	Not applicable
Flammability	See **Section V: Fire Fighting Measures** for flammability/explosivity information.

SECTION X. STABILITY AND REACTIVITY

Stability/Reactivity	Stable under ordinary conditions of use and storage.
Hazardous Reactions	Not determined.
Incompatibilities/ Conditions to Avoid	Sodium bicarbonate is physically and/or chemically incompatible with many drugs including acids, acidic salts, and many alkaloidal salts, but the compatibility depends on several factors (e.g., concentrations of the drugs, specific diluent used, resulting pH, temperature). The addition of sodium bicarbonate to parenteral solutions containing calcium should be avoided, except where compatibility has been previously established. Precipitation or haze may result from sodium bicarbonate-calcium admixtures. Should this occur, such a solution should be immediately discarded. Specialized references should be consulted for specific compatibility information. Freezing conditions or temperatures outside of 15°C to 30°C should also be avoided.
Hazardous Decomposition Products	Not determined.
Hazardous Polymerization	Not anticipated to occur with this product.

SECTION XI. TOXICOLOGICAL INFORMATION

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

Acute Toxicity

Test Type	Route of Administration	Value	Units	Species
LD50	Oral	4220	Mg/kg	Rat
LD50	Oral	3360	Mg/kg	Mouse
LC50	Inhalation	>900	Mg/m^3	Rat

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Repeat Dose Toxicity Data

Subchronic/Chronic Toxicity	Not available

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Reproductive/ Developmental Toxicity	Pregnancy Category C – Animal reproduction studies have not been conducted with sodium bicarbonate. It is also not known whether sodium bicarbonate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium bicarbonate should be given to a pregnant woman only if clearly needed.
Mutagenicity/Genotoxicity	Long term studies of Sodium Bicarbonate in animals to evaluate the mutagenic potential have not been conducted
Carcinogenicity	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
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	Not listed
U.S. OSHA Classification	Non-hazardous in accordance with international standards for workplace safety.
TSCA Listing	Listed
GHS Classification	Not applicable
Symbol	Unknown
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.

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7/23/14

Abbreviations	
ADR	Agreement on Dangerous Goods by Road
CAS	Chemical Abstracts Service Number
DOT	US Department of Transportation Regulations
IATA	International Air Transport Association
IMDG/IMO	International Maritime Dangerous Goods Code/International Maritime Organization
LC50	Concentration producing 50% mortality
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
Revision Date	07/11/14
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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7/23/14