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

SAFETY DATA SHEET

SECTION I. IDENTIFICATION	
Identity/Material Name	Lidocaine Hydrochloride Injection USP, 2%
Synonyms	2-(Diethylamino)-2', 6'-acetoxylidide monohydrochloride
Stock Number	3390
NDC Number	76329-3390-1
Unit Size	100 mg/5 mL (one single dose vial and a Leur-Jet™ vial injector)
Intended Use	Rx Only. Lidocaine hydrochloride administered intravenously, is specifically indicated in the acute management of ventricular arrhythmias such as those occurring in relation to acute myocardial infarction, or during cardiac manipulation, such as cardiac surgery.
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 to yellow Odorless Lidocaine Hydrochloride Injection is a solution containing lidocaine hydrochloride, an amide-type local anesthetic used as a local anesthetic for pain management. In the workplace, this product should be considered possibly irritating to the skin, eyes and respiratory tract. Possible target organs include the nervous system and cardiovascular system.
Statement of Hazard	Non-hazardous in accordance with international standards for workplace safety. In order to manage possible adverse reactions, resuscitative equipment, oxygen and other resuscitative drugs should be immediately available when lidocaine hydrochloride injection is used.
Potential Health Effect	Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. Adverse experiences may result from high plasma levels caused by excessive dosage or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported: **Central Nervous System:** light-headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest.

Potential Health Effect (cont.)	**Cardiovascular System:** bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest. **Allergic reactions** **Neurologic effects**	
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)	R22

SECTION III. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient	Lidocaine Hydrochloride USP	
	Approximate % by weight: 2%	RTECS No. AN7600000
	EC Number: 200-803-8	CAS #: 73-78-9
Inactive Ingredients	Sodium hydroxide NF Sodium chloride USP Water for injection USP	
Chemical Formula	$C_{14}H_{22}N_2O \cdot HCl$	

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. If signs of toxicity occur, seek medical attention. Provide symptomatic or supportive care as necessary.
Effect and Treatment of Overdosage	Overdosage of lidocaine hydrochloride usually results in signs of central nervous system or cardiovascular toxicity. In order to manage possible adverse reactions, resuscitative equipment, oxygen and other resuscitative drugs should be immediately available when lidocaine hydrochloride injection is used.

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 aqueous product.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire.
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. Improper engaging may cause glass breakage and subsequent injury.
Storage	Avoid freezing. Do not store at temperatures outside the range of 15-30 °C.

SECTION VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION	
Exposure Limits	Unknown
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 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. Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.
Engineering Controls	Local ventilation adequate.

SECTION IX. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance and Odor	Clear, slightly yellow, odorless solution.
Physical State	Liquid
pH	5.0-7.0
Molecular Weight	Unknown
Melting Point(°C)	Not applicable
Freezing Point(°C)	Not applicable
Boiling Point(°C)	Not applicable
Evaporation Rate	Water solvent will slowly evaporate
Vapor Pressure	Not applicable
Vapor Density	Not applicable
Relative Density	Not applicable
Solubility(ies)	Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.

Partition coefficient	Unknown
Decomposition Temperature	Unknown
Viscosity	Viscous
Flammability	See **Section V: Fire Fighting Measures** for flammability/explosivity information.

SECTION X. STABILITY AND REACTIVITY

Stability/Reactivity	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined.
Incompatibilities/ Conditions to Avoid	Incompatible with strongly alkaline conditions, methyl vinyl ether; zinc. Lidocaine hydrochloride should be used with caution in patients with digitalis toxicity accompanied by atrioventricular block. Concomitant use of beta-blocking agents may reduce hepatic blood flow and thereby reduce lidocaine clearance. Lidocaine and tocainide are pharmacologically similar. The concomitant use of these two agents may cause an increased incidence of adverse reactions, including central nervous system adverse reactions, such as seizure.
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides and nitrogen oxides (NOx), and hydrogen chloride.
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 (as the salt)	Species
LD50	Oral	459 (346-773)	mg/kg	Rat (non-fasted)
LD50	Oral	214 (159-324)	mg/kg	Rat (fasted)

Repeat Dose Toxicity Data

Subchronic/ Chronic Toxicity	In clinical use target organ effects include central nervous system, cardiovascular system.
Reproductive/ Developmental Toxicity	Pregnancy Category B. Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no significant findings. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should not be used during pregnancy unless clearly needed.
Mutagenicity/ Genotoxicity	Long term studies of lidocaine in animals to evaluate the mutagenic potential or the effect on fertility have not been conducted.
Carcinogenicity	Long term studies of lidocaine in animals to evaluate the carcinogenic effects have not been conducted.

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	Target Organ Toxin Possible Irritant
TSCA Listing	Listed
GHS Classification	Not available
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
IMDG/IMO	International Maritime Dangerous Goods Code/International Maritime Organization
LD50	Dosage producing 50% mortality
LEL	Lower Exposure Limit
NA/UN	North America/United Nation
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	05/17/18
Supersedes Date	07/10/14

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.