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 Topical Solution USP, 4% (Laryng-O-Jet®)
Synonyms	2-(diethylamino)-N-(2, 6 dimethyl-phenyl)-monohydrochloride
Stock Number	6300
NDC Number	76329-6300-5
Unit Size	160mg/4 mL Laryng-O-Jet®
Intended Use	Rx Only. Lidocaine HCI Topical Solution, 4% is indicated for the production of topical anesthesia of the mucous membranes of the respiratory tract.
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 In clinical use, this material is used to numb body tissues. Lidocaine is toxic by ingestion and besides its numbing effects, can affect the central nervous system, respiratory system, and cardiovascular system.
Statement of Hazard	Non-hazardous in accordance with international standards for workplace safety.
Potential Health Effect	Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, 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**: lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or

Potential Health Effect (cont.)	numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest; drowsiness merging into unconsciousness and respiratory arrest. Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption. **Cardiovascular System**: bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest. **Allergic reactions**: cutaneous lesions, urticaria, edema or anaphylactoid reactions. **Neurologic effects**	
Hazard Class	Not applicable	
Hazard Category	GHS Classification	Not applicable
	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	
	Approximate % by weight: 4%	RTECS No.: AN7600000
	EC Number: 200-803-8	CAS #: 73-78-9
Inactive Ingredients	Sodium Hydroxide Hydrochloric Acid 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	Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics. Lidocaine HCl Topical Solution should be employed only by clinicians who are well versed in diagnosis and management of dose-related toxicity and other acute emergencies that might arise and then only after ensuring the immediate availability of oxygen, other resuscitative drugs, cardiopulmonary equipment and the personnel needed for proper management of toxic reactions and related emergencies. Delay in proper management of dose-related toxicity, underventilation from any cause and/or altered sensitivity may lead to the development of acidosis cardiac arrest and, possibly death.

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
Hazardous Combustion Products		Unknown
Flash Point		Unknown
Auto-Ignition Temperature		Unknown
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. Avoid breathing mist or vapors. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Use only with adequate ventilation. Wash thoroughly after handling.
Storage	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

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 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. Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.
Engineering Controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

SECTION IX. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance and Odor	Clear, colorless, 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	Not applicable
Decomposition Temperature	Not applicable
Viscosity	Unknown
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	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	Species
LD_{50}	Oral	220	mg/kg	Mouse
LD_{50}	Subcutaneous	264 (203-304)	mg/kg	Female mice
LD_{50}	Intravenous	26 (21-31)	mg/kg	Female mice

Repeat Dose Toxicity Data

Subchronic/ Chronic Toxicity	Based on clinical use, possible target organs include the central nervous system and 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. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering lidocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place. Lidocaine is not contraindicated in labor and delivery. Should lidocaine HCl topical solution be used concomitantly with other products containing lidocaine, the total dose contributed by all formulation must be kept in mind
Mutagenicity/ Genotoxicity	Long term studies of lidocaine in animals to evaluate the mutagenic potential have not been conducted
Carcinogenicity	Long term studies of lidocaine in animals to evaluate the carcinogenic potential 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 Regulated
U.S. OSHA Classification	Target Organ Toxin, Possible Irritant
TSCA Listing	Not Regulated
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
IMDG/IMO	International Maritime Dangerous Goods Code/International Maritime Organization
LD50	Dosage producing 50% mortality
LEL	Lower Exposure Limit
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	09/01/2022
Supersedes Date	05/17/18

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.