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	Lidocaine Hydrochloride Jelly USP, 2%
Synonyms	acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride
Stock Number	3011-SP, 3012-SP, 3013-SP, 3015-SP
NDC Number	76329-3011-5, 76329-3012-5, 76329-3013-5, 76329-3015-5
Unit Size	5 mL (3011-SP, 3012-SP), 10 mL (3013-SP), 20 mL (3015-SP)
Intended Use	Rx Only. Lidocaine Hydrochloride Jelly USP, 2% is indicated for prevention and control of pain in procedures involving the male and female urethra for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).
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	Gel Clear to yellow Odorless Excessive dosage, or short intervals between doses, can result in high plasma levels and serious adverse effects which may require the use of resuscitative equipment, oxygen, and other resuscitative drugs.
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 numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. Drowsiness following the administration of lidocaine is usually an early sign of a high blood

Approved By/Date:
8/5/14

Potential Health Effect (cont.)	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:** cutaneous lesions, urticaria, edema or anaphylactoid reactions.	
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: 2%	RTECS No. AN7600000
	EC Number: 200-803-8	CAS #: 73-78-9
Inactive Ingredients	Sodium Carboxymethylcellulose Sodium Hydroxide Water for injection	
Chemical Formula	$C_{14}H_{22}N_2O \bullet HCl$	

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. Patients should be instructed to strictly adhere to the recommended dosage and administration guidelines as set forth in this package insert. The management of serious adverse reactions may require the use of resuscitative equipment, oxygen and other resuscitative drugs.

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	Fine particles (such as dust and mists) may fuel fires/explosions
Hazardous Combustion Products	Unknown
Flash Point	Unknown
Auto-Ignition Temperature	Unknown

Approved By/Date: Stephen Campbell 8/5/14

Flammable Limits	LEL	Unknown
	UEL	Unknown

SECTION VI. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Use proper PPE and clean up spill according to handling and disposal regulations.
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	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Contents under pressure, do not puncture or incinerate. Environmental release should be avoided. Once the unit is opened and used, any remaining portion must be discarded with the entire unit. Do not assemble until ready to use. Improper engaging may cause 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 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	Local ventilation adequate.

SECTION IX. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance and Odor	Clear to yellowish, viscous, odorless solution
Physical State	Gel
pH	6 – 7
Molecular Weight	Unknown
Melting Point(°C)	Not applicable
Freezing Point(°C)	Unknown
Boiling Point(°C)	Unknown
Evaporation Rate	Unknown
Vapor Pressure	Unknown
Vapor Density	Unknown
Relative Density	Unknown

Approved By/Date:

Stephen Campbell 8/5/14

Solubility(ies)	Soluble in water
Partition coefficient	Unknown
Decomposition Temperature	Unknown
Viscosity	Unknown
Flammability	See **Section V: Fire Fighting Measures** for flammability/explosivity information.

SECTION X. STABILITY AND REACTIVITY

Stability/Reactivity	Stable under normal conditions of use.
Hazardous Reactions	Not determined.
Incompatibilities/ Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/ explosions. Keep away from strong oxidizers.
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 (as the salt)	Species
LD50	Oral	459 (346-773)	mg/kg	Non-fasted female rat
LD50	Oral	214 (159-324)	mg/kg	Fasted female rat

Repeat Dose Toxicity Data

Subchronic/ Chronic Toxicity	In clinical use target organ effects include central nervous system, cardiovascular system.
Reproductive/ Developmental Toxicity	Teratogenic Effects: Pregnancy Category B Reproduction studies for lidocaine have been performed in both rats and rabbits. There was no evidence of harm to the fetus at subcutaneous doses of up to 50 mg/kg lidocaine (300 mg/m2 on a body surface area basis) in the rat model. In the rabbit model, there was no evidence of harm to the fetus at a dose of 5 mg/kg, s.c. (60 mg/m2 on a body surface area basis). Treatment of rabbits with 25 mg/kg (300 mg/m2) produced evidence of maternal toxicity and evidence of delayed fetal development, including a non-significant decrease in fetal weight (7%) and an increase in minor skeletal anomalies (skull and sternebral defect, reduced ossification of the phalanges). The effect of lidocaine on post-natal development was examined in rats by treating pregnant female rats daily subcutaneously at doses of 2, 10, and 50 mg/kg (12, 60, and 300 mg/m2) from day 15 of pregnancy and up to 20 days post partum. No signs of adverse effects were seen either in dams or in the pups up to and including the dose of 10 mg/kg (60 mg/m2); however, the number of surviving pups was reduced at 50 mg/kg (300 mg/m2), both at birth and the duration of lactation period, the effect most likely being secondary to maternal toxicity. No other effects on litter size, litter weight, abnormalities in the pups and physical developments of the pups were seen in this study.

Approved By/Date:
Stephen Campbell
8/5/14

Reproductive/ Developmental Toxicity (cont.)	A second study examined the effects of lidocaine on post-natal development in the rat that included assessment of the pups from weaning to sexual maturity. Rats were treated for 8 months with 10 or 30 mg/kg, s.c. lidocaine (60 mg/m2 and 180 mg/m2 on a body surface area basis, respectively). This time period encompassed 3 mating periods. There was no evidence of altered post-natal development in any offspring; however, both doses of lidocaine significantly reduced the average number of pups per litter surviving until weaning of offspring from the first 2 mating period. 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 be used during pregnancy only if clearly needed.
Mutagenicity/ Genotoxicity	The mutagenic potential of lidocaine has been tested in the Ames Salmonella reverse mutation assay, an in vitro chromosome aberrations assay in human lymphocytes and in an in vivo mouse micronucleus assay. There was no indication of any mutagenic effect in these studies.
Carcinogenicity	Long-term studies in animals have not been performed to evaluate the carcinogenic potential of lidocaine.

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 regulations.

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	
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.

Approved By/Date:
Stephen Campbell
8/5/14

MATERIAL SAFETY DATA SHEET

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
SARA	Superfund Amendments and Reauthorization Act
TSCA	Toxic Substance Control Act
UEL	Upper Exposure Limit
Hazard Symbols 	Irritant
Revision Date	07/25/14
Supersedes Date	03/29/12

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.

Approved By/Date: 8/5/14