

# MATERIAL SAFETY DATA SHEET

Version No: MSDS/Lido-AUS/DP-001

Effective Date: 09<sup>th</sup> December 2019

## Lidocaine Hydrochloride Solution for injection 10 mg/mL and 20 mg/mL

### SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Lidocaine Hydrochloride Solution for injection 10 mg/mL and 20 mg/mL

Sponsor	Manufacturer
Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia	Intas Pharmaceuticals Ltd. Plot No. 457, 458 Sarkhej-Bavla Highway, Matoda, Tal. Sanand, Dist. Ahmedabad- 382210, Gujarat, India

### SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

**Active:** Lidocaine (lignocaine) hydrochloride.

**Inactive:** Sodium Chloride, Hydrochloric Acid, Sodium Hydroxide and Water for Injections.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Lidocaine Hydrochloride	≤ 5.0%	73-78-9	AN7600000

Non-hazardous ingredients include Water for Injection

Hazardous ingredients present at less than 1% may include sodium chloride; sodium hydroxide and/or hydrochloric acid are used to adjust the pH.

### SECTION 3 - HAZARDS IDENTIFICATION

**Emergency Overview:** 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 potentially irritating to the skin, eyes and respiratory tract. Possible target organs include the nervous system and cardiovascular system.

#### U.S. OSHA GHS Classification:

	Hazard Class	Hazard Category
Physical Hazards	Not Classified	Not Classified
Health Hazards	STOT – RE	2

**Label Element(s):**

**Pictogram:**

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**Signal Word:** Warning

**Hazard Statement(s):** May cause damage to organs through prolonged or repeated exposures

**Precautionary Statement(s):**

**Prevention:**

Do not breathe vapor or spray  
Wash hands thoroughly after handling

**Response:**

Get medical attention if you feel unwell.

**IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

## SECTION 4 - EMERGENCY & FIRST AID MEASURES

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

## SECTION 5 - FIRE FIGHTING MEASURES

**Flammability:** None anticipated from this aqueous product.

**Fire & Explosion Hazard:** None anticipated from this aqueous product.

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**Extinguishing Media:** As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

**Special Fire Fighting Procedures:** No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Spill Cleanup and Disposal:** Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb any liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

## SECTION 7 - HANDLING AND STORAGE

**Handling:** No special handling required under conditions of normal product use.

**Storage:** No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions:** No special precautions required for hazard control.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines:

Component	Exposure Limits		
	OSHA-PEL	ACGIH-TLV	AIHA WEEL
Lidocaine	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established
Hydrochloride	Established	Established	Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
AIHA WEEL: Workplace Environmental Exposure Level  
EEL: Employee Exposure Limit.  
TWA: 8 hour Time Weighted Average.

**Respiratory Protection:** Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer

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a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin Protection:** If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye Protection:** Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls:** Engineering controls are normally not needed during the normal use of this product.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance/Physical State</b>	: Clear, colorless liquid
<b>Odor</b>	: NA
<b>Odor Threshold</b>	: NA
<b>pH</b>	: Between 5.0 and 7.0
<b>Melting point/Freezing Point</b>	: NA
<b>Initial Boiling Point/Boiling Point Range</b>	: NA
<b>Flash Point</b>	: NA
<b>Evaporation Rate</b>	: NA
<b>Flammability (solid, gas)</b>	: NA
<b>Upper/Lower Flammability or Explosive Limits</b>	: NA
<b>Vapor Pressure</b>	: NA
<b>Vapor Density (Air =1)</b>	: NA
<b>Relative Density</b>	: NA
<b>Solubility</b>	: Very soluble in water and in alcohol; soluble in chloroform, insoluble in ether.
<b>Partition Coefficient: n-octanol/water</b>	: NA
<b>Auto-ignition Temperature</b>	: NA
<b>Decomposition Temperature</b>	: NA
<b>Viscosity</b>	: NA

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## SECTION 10 - STABILITY AND REACTIVITY

**Reactivity:** Not determined.

**Chemical Stability:** Stable under standard use and storage conditions.

**Hazardous Reactions:** Not determined

**Conditions to Avoid:** Not determined

**Incompatibilities:** Strongly alkaline conditions. Methyl vinyl ether; zinc.

**Hazardous Decomposition Products:** Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), and hydrogen chloride.

**Hazardous Polymerization:** Not anticipated to occur with this product.

## SECTION 11 - TOXICOLOGY INFORMATION

**Acute Toxicity:** - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Lidocaine Hydrochloride	100	LD50	Oral	220	mg/kg	Mouse
				292	mg/kg	Mouse
Lidocaine Hydrochloride	100	LD50	Intraperitoneal	122	mg/kg	Rat
				63	mg/kg	Mouse
Lidocaine Hydrochloride	100	LD50	Intravenous	21	mg/kg	Rat
				15	mg/kg	Mouse
				25.6	mg/kg	Rabbit
				24.5	mg/kg	Guinea Pig
Lidocaine Hydrochloride	100	LD50	Intratracheal	28	mg/kg	Rabbit

LD 50: Dosage that produces 50% mortality.

**Occupational Exposure Potential:** Information on the absorption of this product via inhalation or skin contact is not available. Published reports suggest that some local anesthetics have some potential to be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.

**Signs and Symptoms:** None anticipated from normal handling of this product. Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product

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produces numbness when injected. In normal clinical use, adverse effects may include fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.

**Aspiration Hazard:** None anticipated from normal handling of this product.

**Dermal Irritation/ Corrosion:** None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.

**Ocular Irritation/ Corrosion:** None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation, numbness, and blurred vision.

**Dermal or Respiratory Sensitization:** None anticipated from normal handling of this product. Rarely, allergic-type reactions have been reported during the clinical use of lidocaine.

**Reproductive Effects:** None anticipated from normal handling of this product. In a fertility study in rats, lidocaine given subcutaneously at a dosage of 30 mg/kg (180 mg/m<sup>2</sup>) to mating pairs did not produce alterations in fertility or general reproductive performance of rats. Subcutaneous administration of lidocaine to pregnant rats at a dosage of to 50 mg/kg did not produce evidence of harm to the fetus. In rabbits, there was no evidence of harm to the fetus at a subcutaneous dosage of 5 mg/kg. Treatment of rabbits with a subcutaneous dosage of 25 mg/kg produced evidence of maternal toxicity and evidence of delayed fetal development, including a non-significant decrease in fetal weight and an increase in minor skeletal anomalies. The effect of lidocaine on postnatal development was evaluated in rats by treating pregnant female rats daily subcutaneously at dosages of 2, 10, and 50 mg/kg 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; however, the number of surviving pups was reduced at 50 mg/kg, both at birth and the duration of lactation period; this effect is most likely secondary to maternal toxicity. A second study evaluated 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 subcutaneously for 8 months with 10 or 30 mg/kg lidocaine, a treatment duration that included 3 mating periods. There was no evidence

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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 periods.

**Mutagenicity:** The mutagenic potential of lidocaine was evaluated 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 to evaluate the carcinogenic potential of most local anesthetics, including lidocaine, have not been conducted.

**Carcinogen Lists:**

**IARC:** Not listed

**NTP:** Not listed

**OSHA:** Not listed

**Specific Target Organ Toxicity – Single Exposure:** NA

**Specific Target Organ Toxicity – Repeat Exposure:** Based on clinical use, possible target organs include the nervous system and the cardiovascular system.

## SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

**Aquatic Toxicity:** Not determined for product.

**Persistence/Biodegradability:** Not determined for product.

**Bioaccumulation:** Not determined for product.

**Mobility in Soil:** Not determined for product.

## SECTION 13 - DISPOSAL INFORMATION

**Waste Disposal:** All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

**Container Handling and Disposal:** Dispose of container and unused contents in accordance with federal, state and local regulations.

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## SECTION 14 - TRANSPORTATION INFORMATION

**ADR/ADG/ DOT STATUS** : Not regulated  
**Proper Shipping Name** : NA  
**Hazard Class** : NA  
**UN Number** : NA  
**Packing Group** : NA  
**Reportable Quantity** : NA  
**ICAO/IATA STATUS** : Not regulated  
**Proper Shipping Name** : NA  
**Hazard Class** : NA  
**UN Number** : NA  
**Packing Group** : NA  
**Reportable Quantity** : NA  
**IMDG STATUS** : Not regulated  
**Proper Shipping Name** : NA  
**Hazard Class** : NA  
**UN Number** : NA  
**Packing Group** : NA  
**Reportable Quantity** : NA

Notes: DOT - US Department of Transportation Regulations

## SECTION 15 - REGULATORY INFORMATION

**US TSCA Status** : Exempt. However, lidocaine hydrochloride is listed on the TSCA inventory  
**US CERCLA Status** : Not listed  
**US SARA 302 Status** : Not listed  
**US SARA 313 Status** : Not listed  
**US RCRA Status** : Not listed  
**US PROP 65 (Calif.)** : Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

### GHS/CLP Classification\*

\*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

**Hazard Class** : NA  
**Hazard Category** : NA  
**Pictogram** : NA  
**Signal Word** : NA  
**Hazard Statement** : NA



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## Prevention:

Do not breathe vapor or spray  
Wash hands thoroughly after handling

## Response:

Get medical attention if you feel unwell.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

## EU Classification\*

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

**Classification(s)** : NA  
**Symbol** : NA  
**Indication of Danger** : NA  
**Risk Phrases** : NA

## Safety Phrases:

S23 : Do not breathe vapor/spray  
S24 : Avoid contact with the skin  
S25 : Avoid contact with eyes  
S37/39 : Wear suitable gloves and eye/face protection.

## SECTION 16 - OTHER DATA

### Notes:

ACGIH TLV : American Conference of Governmental Industrial Hygienists – Threshold Limit Value  
CAS : Chemical Abstracts Service Number  
CERCLA US EPA law : Comprehensive Environmental Response, Compensation, and Liability Act  
DOT US : Department of Transportation Regulations  
EEL : Employee Exposure Limit  
IATA : International Air Transport Association  
LD50 : Dosage producing 50% mortality  
NA : Not applicable/Not available  
NE : Not established  
NIOSH : National Institute for Occupational Safety and Health  
OSHA PEL : US Occupational Safety and Health Administration – Permissible Exposure Limit  
Prop 65 : California Proposition 65  
RCRA US EPA : Resource Conservation and Recovery Act  
RTECS : Registry of Toxic Effects of Chemical Substances

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SARA : Superfund Amendments and Reauthorization Act  
STEL : 15-minute Short Term Exposure Limit  
STOT - SE : Specific Target Organ Toxicity – Single Exposure  
STOT - RE : Specific Target Organ Toxicity – Repeated Exposure  
TSCA : Toxic Substance Control Act  
TWA 8-hour : Time Weighted Average

**Data Sources:** Information from published literature.

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