


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	LIDOCAINE HYDROCHLORIDE, USP
PRODUCT CODE	0082
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Manufacturing and Compounding
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 3) Sensitization - Skin (Category 1) Sensitization - Respiratory (Category 1) Eye Irritation (Category 2B) Acute Aquatic Toxicity (Category 2)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Toxic if swallowed. Toxic to aquatic life. Causes eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. The substance is a powerful local anaesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.

PRECAUTIONARY STATEMENT(S)
Prevention

Wash hands thoroughly after handling. Do not touch eyes.
 Do not eat, drink or smoke when using this product.
 Avoid breathing dust, fume, gas, mist, vapors, spray.
 In case of inadequate ventilation wear respiratory protection.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves.
 Avoid release to the environment

Response

IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth.
 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 help.
 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms, get medical help immediately call a poison center or medical professional.
 IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help advice/attention. Take off contaminated clothing and wash it before reuse.
 COLLECT SPILLAGE

Storage

Store locked up.

Disposal

Dispose of contents and container in accordance with local regulations.

HMIS CLASSIFICATION
Health Hazard

2

Flammability

0

Reactivity

0

Personal Protection

G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
CHEMICAL NAME

2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide monohydrochloride monohydrate

BOTANICAL NAME

Not applicable

SYNONYM

Lignocaine Hydrochloride (monohydrate)

CHEMICAL FORMULA

C₁₄H₂₂N₂O HCl H₂O

CHEMICAL FAMILY

Aniline derivative; amino amide

CAS NUMBER

6108-05-0

ALTERNATE CAS NUMBER

Not applicable

MOLECULAR WEIGHT

288.8165

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
LIDOCAINE HCl (monohydrate)	6108-05-0	612-079-4	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES
IN CASE OF EYE CONTACT

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

MEDICAL ATTENTION AND SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

May cause irritation and numbness.

SECTION 5: FIREFIGHTING MEASURES**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL**

Not applicable

FLAMMABLE PROPERTIES

This material is assumed to be combustible

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. As with all fires, evacuate personnel to a safe area.

NOTES

As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Dust explosion properties: Minimum ignition energy (MIE) – dust cloud: 10 - 30 mJ

SECTION 6: ACCIDENTAL RELEASE MEASURES**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store at controlled room temperature. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: LIDOCAINE HCl (monohydrate) **CAS #:** 6108-05-0

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

The substance is a powerful local anaesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White, odorless, crystalline powder.

SOLUBILITY

Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.

ODOR

Odorless or characteristic odor

FLAMMABILITY

This material is assumed to be combustible

AUTO-IGNITION TEMPERATURE	(500 - 550)°C, (932-1022)°F	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	1.39	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(74-79)°C, (165.2-174.2)°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	4 - 5.5 (0.5%)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidizing agents and strong mineral acids.
HAZARDOUS DECOMPOSITION PRODUCTS	When heated to decomposition, material emits toxic fumes of NO _x . Emits toxic fumes under fire conditions.
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, Sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 159 - 324 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data, the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes eye irritation.
RESPIRATORY SENSITIZATION	Suspected sensitiser

SKIN SENSITIZATION

Skin sensitization: Local anaesthetics may provoke types I and IV hypersensitivity reactions. Type I reactions (e.g. anaphylaxis) to local anaesthetics are generally rare. Nevertheless, severe or fatal reactions have been associated. Based on available data, the classification criteria are not met.
 Suspected skin sensitiser: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability)

GERM CELL MUTAGENICITY

Based on available data, the classification criteria are not met.
 Suspected mutagen: The Toolbox profiler 'Protein binding alerts for Chromosomal aberration by OASIS v1.1' gives an alert for mutagenicity.
 Ames test; Result: Negative.
 Chromosome aberration; Result: Negative.
 Mouse: Micronucleus test; Result: Negative.

CARCINOGENICITY

OSHA LIDOCAINE HYDROCHLORIDE is not listed.
NTP LIDOCAINE HYDROCHLORIDE is not listed.
IARC LIDOCAINE HYDROCHLORIDE is not evaluated.
California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.
 Metabolites of lidocaine have been shown to be carcinogenic in laboratory animals.

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met.
 Suspected toxic for reproduction: The Toolbox profiler 'DART scheme v.1.0' gives an alert for toxicity to reproduction
 Serious adverse effects of epidural anaesthesia are rare but lidocaine may have transient effects on the neonatal auditory system.
 No adverse effects have been seen in breastfed infants whose mothers were receiving lidocaine, and the American Academy of Pediatrics considers that it is therefore usually compatible with breast feeding.
 Rat: 30 mg/kg Reproductivity / developmental, No effect on fertility or reproductive performance.
 Rabbit: 5 mg/kg Reproductivity / developmental, No harm to fetus; Species: Rabbit
 Rat: 72 mg/kg/day Reproductivity / developmental, No adverse developmental effects.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data, the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data, the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE

ROUTES OF EXPOSURE:
 Oral, Dermal, Inhalation, Eye contact
EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:
 Not available
DELAYED HEALTH EFFECT FROM EXPOSURE:
 Not available

The substance is a powerful local anaesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion.

Symptoms related to the physical, chemical, and toxicological characteristics:
 Local anesthetics: Headache. Numbness. Neck or back pain. Chest pain. Change in vision. Slurred speech. Dizziness. Drowsiness. Weakness. Feeling hot or cold. Ringing in ears. Anxiety. Nervousness. Excitement. Confusion. Difficulty in breathing. Gastrointestinal disturbances.

Cross Sensitivity:
 Persons sensitive to other amide-type anesthetics, flecainide or tocainide may be sensitive to this material also.

POTENTIAL HEALTH EFFECTS

Inhalation Harmful if inhaled. May cause respiratory tract irritation. Readily absorbed from mucous membranes. May cause allergic reaction.
Ingestion Toxic if swallowed. Readily absorbed from the gastrointestinal tract. May cause allergic reaction.

Skin	Harmful if absorbed through skin. Causes skin irritation. May cause allergic reaction. May cause erythema or pigmentation. Readily absorbed through damaged skin
Eyes	Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 5.4* LC50: 96 Hr: Fish: (mg/L): 75.44** EC50: 96 Hr: Green Algae: (mg/L): 3.59**
PERSISTENCE AND DEGRADABILITY	Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable
BIOACCUMULATIVE POTENTIAL	Low potential for bioaccumulation: LogPow:1.39
MOBILITY IN SOIL	Very soluble in water
OTHER ADVERSE EFFECTS	Not available
NOTES	This product is not intended to be released into the environment *DEMETERA Daphnia Magna toxicity model in VEGA (Q)SAR platform prediction (good reliability) **Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
AUSTRALIA	
HAZCHEM	Not applicable
EU	
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not listed
ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
LIDOCAINE HCl, 6108-05-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
LIDOCAINE HCl, 6108-05-0	N/L	Listed as Schedule 4*	N/L	Listed*	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
LIDOCAINE HCl, 6108-05-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

NOTES

*Listed as Lidocaine base

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** - American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** - Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** - Chemical Abstract Service; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** - Effective Concentration, 50%; **EPA** - Environmental Protection Agency; **GHS** - Global Harmonized System; **HMIS** - Hazardous Materials Information System; **HSE** - Health and Safety Executive; **HSIS** - Hazardous Substances Information System; **IARC** - International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** - Ready Biodegradability Model; **ISS** - Istituto Superiore Sanità; **LC50** - Lethal Concentration, 50%; **LD50** - Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** - National Institute for Occupational Safety and Health; **NTP** - National Toxicology Program; **OSHA PEL** - Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** - Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** - Superfund Amendments and Reauthorization Act; **STEL** - Short Term Exposure Limit; **TLV** - Threshold Limit Value; **TWA** - Time Weighted Average; **WHMIS** - Workplace Hazardous Materials Information System

LAST REVISION

03/2023

SUPERSEDES

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA[®] shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.