


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 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 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
USES	Anesthetic (local)

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. The substance is a powerful local anaesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion.
AUSTRALIA-ONLY HAZARDS	Not Applicable.
PRECAUTIONARY STATEMENT(S)	Prevention Wash thoroughly after handling. 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 must not be allowed out of the workplace. Wear protective gloves. Avoid release to the environment

Response	IF SWALLOWED: Immediately call a poison center or medical professional; 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 advice/attention. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a poison center or medical professional. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing 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	C ₁₄ H ₂₂ N ₂ O HCl H ₂ O								
CAS NUMBER	6108-05-0								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	288.8165								
COMPOSITION	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #00a651; color: white;"> <th style="text-align: left;">CHEMICAL NAME</th> <th style="text-align: left;">CAS NUMBER</th> <th style="text-align: left;">% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>LIDOCAINE HCl (monohydrate)</td> <td>6108-05-0</td> <td>100</td> </tr> </tbody> </table>			CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	LIDOCAINE HCl (monohydrate)	6108-05-0	100
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LIDOCAINE HCl (monohydrate)	6108-05-0	100							
NOTES	<p>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.</p> <p>Chemical family: Aniline derivative; amino amide.</p>								

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
SYMPTOMS AND EFFECTS	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.
EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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.

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 unlabelled 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. 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. Preserve in well-closed containers. Protected from light. Store at controlled room temperature.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

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.

SPECIFIC ENGINEERING CONTROLS

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

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

ODOR THRESHOLD

Not available

pH

4 - 5.5 (0.5%)

MELTING POINT

 (74-79)°C,
(165.2-174.2)°F

BOILING POINT

Not available

FREEZING POINT

 (74-79)°C,
(165.2-174.2)°F

FLASH POINT

Not available

SPECIFIC GRAVITY

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

**UPPER FLAMMABLE/
EXPLOSIVE LIMIT(S)**

Not available

**LOWER FLAMMABLE/
EXPLOSIVE LIMIT(S)**

Not available

VAPOR PRESSURE

 < 0.0000001 kPa
(25°C)

**VAPOR DENSITY
(AIR = 1)**

Not available

**RELATIVE DENSITY
(WATER = 1)**

Not available

**log P
(OCTANOL-WATER)**

1.39

**AUTO-IGNITION
TEMPERATURE**

 (500 - 550)°C,
(932-1022)°F

**DECOMPOSITION
TEMPERATURE**

Not available

VISCOSITY

Not available

NOTES

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

SECTION 10: STABILITY AND REACTIVITY
REACTIVITY

Not established

STABILITY

Stable under recommended storage conditions

MATERIALS TO AVOID

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	<p>Oral: Rat: LD50: (mg/kg): 159 - 324 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available</p>
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met.
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes eye irritation.
RESPIRATORY OR SKIN SENSITIZATION	<p>Respiratory sensitization: Suspected sensitiser 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. Suspected skin sensitiser: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability)</p>
GERM CELL MUTAGENICITY	<p>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</p>
CARCINOGENICITY	<p>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.</p>
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	<p>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.</p>
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Based on available data, the classification criteria are not met.
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Based on available data, the classification criteria are not met.
ASPIRATION HAZARDS	Based on available data, the classification criteria are not met.
SIGNS AND SYMPTOMS OF EXPOSURE	<p>The substance is a powerful local anaesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion.</p> <p>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.</p> <p>Cross Sensitivity: Persons sensitive to other amide-type anesthetics, flecainide or tocainide may be sensitive to this material also.</p>

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.

NOTES
SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	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 *DEMETRA Daphnia Magna toxicity model in VEGA (Q)SAR platform prediction (good reliability) **Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION
UNITED STATES & CANADA

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

AUSTRALIA

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
HAZCHEM	Not applicable

ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
LIDOCAINE HCl, 6108-05-0	N/L	Listed as Schedule 4*	N/L

NOTES

*Lidocaine base

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

LAST REVISION

11/2018

SUPERSEDES

05/2016

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.