## SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>LIDOCAINE HYDROCHLORIDE, USP</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT CODE</td>
<td>0082</td>
</tr>
<tr>
<td>SUPPLIER</td>
<td>MEDISCA Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.932.1039</td>
</tr>
<tr>
<td></td>
<td>661 Route 3, Unit C, Plattsburgh, NY, 12901</td>
</tr>
<tr>
<td></td>
<td>3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118</td>
</tr>
<tr>
<td></td>
<td>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Pharmaceutique Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.665.6334</td>
</tr>
<tr>
<td></td>
<td>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8</td>
</tr>
<tr>
<td></td>
<td>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Australia Pty Ltd</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.300.786.392</td>
</tr>
<tr>
<td></td>
<td>Unit 7, Heritage Business Park</td>
</tr>
<tr>
<td></td>
<td>5-9 Ricketty Street, Mascot, NSW 2020</td>
</tr>
<tr>
<td>EMERGENCY PHONE</td>
<td>CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300</td>
</tr>
<tr>
<td></td>
<td>NSW Poisons Information Centre: 131 126</td>
</tr>
<tr>
<td>USES</td>
<td>Anesthetic (local)</td>
</tr>
</tbody>
</table>

## 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

![Danger Symbol]

### 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
SAFETY DATA SHEET

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
C₁₄H₂₂N₂O HCl H₂O

CAS NUMBER
6108-05-0

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
288.8165

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
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<tr>
<td>LIDOCAINE HCl (monohydrate)</td>
<td>6108-05-0</td>
<td>100</td>
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</table>

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.

NOTES
Chemical family: Aniline derivative; amino amide.

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, 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.

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

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Calling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<tr>
<td>OSHA PEL</td>
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<td>N/L</td>
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<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>ACGIH TLV</td>
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<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
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<tr>
<td>NIOSH</td>
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<td>N/L</td>
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<td>AIHA WEEL</td>
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<td>Safe Work Australia HSIS</td>
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<td>-</td>
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</table>
SAFETY DATA SHEET

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

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

VISCOITY
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 NOx. Emits toxic fumes under fire conditions.

Last Revision: 11/2018

LIDOCAINE HYDROCHLORIDE, USP
**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
Based on available data, the classification criteria are not met.

#### SERIOUS EYE DAMAGE/EYE IRRITATION
Causes eye irritation.

#### RESPIRATORY OR 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. Suspected skin sensitizer: 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

#### CARCINOGENICITY
<table>
<thead>
<tr>
<th>Agency</th>
<th>Classification</th>
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<tbody>
<tr>
<td>OSHA</td>
<td>LIDOCAINE HYDROCHLORIDE is not listed.</td>
</tr>
<tr>
<td>NTP</td>
<td>LIDOCAINE HYDROCHLORIDE is not listed.</td>
</tr>
<tr>
<td>IARC</td>
<td>LIDOCAINE HYDROCHLORIDE is not evaluated.</td>
</tr>
<tr>
<td>California Prop 65</td>
<td>This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</td>
</tr>
</tbody>
</table>

#### 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.

#### 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
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:

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

<table>
<thead>
<tr>
<th>Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Harmful if inhaled. May cause respiratory tract irritation. Readily absorbed from mucous membranes. May cause allergic reaction.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Toxic if swallowed. Readily absorbed from the gastrointestinal tract. May cause allergic reaction.</td>
</tr>
<tr>
<td>Skin</td>
<td>Harmful if absorbed through skin. Causes skin irritation. May cause allergic reaction. May cause erythema or pigmentation. Readily absorbed through damaged skin</td>
</tr>
<tr>
<td>Eyes</td>
<td>Causes eye irritation.</td>
</tr>
</tbody>
</table>

### NOTES

#### SECTION 12: ECOLOGICAL INFORMATION

#### TOXICITY

<table>
<thead>
<tr>
<th>Test</th>
<th>EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 5.4*</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50: 96 Hr: Fish: (mg/L): 75.44**</td>
<td></td>
</tr>
<tr>
<td>EC50: 96 Hr: Green Algae: (mg/L): 3.59**</td>
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</tr>
</tbody>
</table>

#### 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 biocumulation: LogPow:1.39

#### MOBILITY IN SOIL

Very soluble in water

#### OTHER ADVERSE EFFECTS

This product is not intended to be released into the environment

#### NOTES

*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.

#### SECTION 14: TRANSPORT INFORMATION

**UNITED STATES & CANADA**

<table>
<thead>
<tr>
<th>UN PROPER SHIPPING NAME</th>
<th>Not dangerous good</th>
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<tbody>
<tr>
<td>UN NUMBER</td>
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<td>CLASS</td>
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<td>PACKING GROUP</td>
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**AUSTRALIA**

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<th>UN PROPER SHIPPING NAME</th>
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<tbody>
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<td>UN NUMBER</td>
<td>Not applicable</td>
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<tr>
<td>CLASS</td>
<td>Not applicable</td>
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<tr>
<td>PACKING GROUP</td>
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<tr>
<td>HAZCHEM</td>
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</table>

| ENVIRONMENTAL HAZARDS   | Not available      |
| SPECIAL SHIPPING INFORMATION | Not applicable    |
## SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.85</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Pennsylvania Right-to-know</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
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</thead>
<tbody>
<tr>
<td>LIDOCAINE HCl, 6108-05-0</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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N/L = Not Listed; X = Listed

### AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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<tr>
<td>LIDOCAINE HCl, 6108-05-0</td>
<td>N/L</td>
<td>Listed as Schedule 4*</td>
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</table>

*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.