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

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION
Acute Toxicity - Oral (Category 3)
Sensitization - Skin (Category 1)
Sensitization - Respiratory (Category 1)
Carcinogenicity (Category 2)

PICTOGRAM

SIGNAL WORD
Danger

HAZARD STATEMENT(S)
Toxic if swallowed.
May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of causing cancer.
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
Repeated exposure may cause skin dryness or cracking.

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, and spray. Contaminated work clothing must not be allowed out of the workplace.
Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye protection, face protection.

Response
IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
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 EXPOSED OR CONCERNED: Get medical advice/attention.
SAFETY DATA SHEET

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

ALTENATE CAS NUMBER: Not applicable

MOLECULAR WEIGHT: 288.81

COMPOSITION:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIDOCAINE HYDROCHLORIDE</td>
<td>6108-05-0</td>
<td>100</td>
</tr>
</tbody>
</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.

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: May cause irritation and numbness.

SYMPTOMS AND EFFECTS:

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.
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.

STORAGE CONDITIONS
Store in original container, tightly sealed container, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

Controlled room temperature indicates a temperature 20° to 25° (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°; and that allows for excursions between 15° and 30° (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>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
<tr>
<td>AIHA WEL</td>
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<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
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<td>-</td>
<td>-</td>
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</tr>
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<td>HSE</td>
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<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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.
## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL STATE</strong></td>
<td>Solid</td>
</tr>
<tr>
<td><strong>DESCRIPTION</strong></td>
<td>White, odorless, crystalline powder</td>
</tr>
<tr>
<td><strong>SOLUBILITY</strong></td>
<td>Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.</td>
</tr>
<tr>
<td><strong>ODOR</strong></td>
<td>Odorless or characteristic odor</td>
</tr>
<tr>
<td><strong>FLAMMABILITY</strong></td>
<td>This material is assumed to be combustible</td>
</tr>
<tr>
<td><strong>ODOR THRESHOLD</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>4.0 - 5.5 (5 g/L)</td>
</tr>
<tr>
<td><strong>MELTING POINT</strong></td>
<td>(74-79)°C, (165.2-174.2)°F</td>
</tr>
<tr>
<td><strong>BOILING POINT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>FREEZING POINT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>FLASH POINT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>SPECIFIC GRAVITY</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>EVAPORATION RATE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>EXPLOSIVE LIMIT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
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</tr>
<tr>
<td><strong>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>VAPOR PRESSURE</strong></td>
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</tr>
<tr>
<td><strong>VAPOR DENSITY (AIR = 1)</strong></td>
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</tr>
<tr>
<td><strong>RELATIVE DENSITY (WATER = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>log P (OCTANOL-WATER)</strong></td>
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</tr>
<tr>
<td><strong>AUTO-IGNITION TEMPERATURE</strong></td>
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</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
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</tr>
<tr>
<td><strong>VISCOSITY</strong></td>
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</tr>
</tbody>
</table>

## SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REACTIVITY</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>STABILITY</strong></td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td><strong>MATERIALS TO AVOID</strong></td>
<td>Strong oxidizing agents and strong mineral acids.</td>
</tr>
<tr>
<td><strong>HAZARDOUS DECOMPOSITION PRODUCTS</strong></td>
<td>When heated to decomposition, material emits toxic fumes of NO</td>
</tr>
<tr>
<td><strong>HAZARDOUS POLYMERIZATION</strong></td>
<td>Will not occur</td>
</tr>
<tr>
<td><strong>POSSIBILITY OF HAZARDOUS REACTION</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>CONDITIONS TO AVOID</strong></td>
<td>Moisture, Sunlight and extreme temperatures</td>
</tr>
</tbody>
</table>

## SECTION 11: TOXICOLOGICAL INFORMATION
SAFETY DATA SHEET

ACUTE TOXICITY
Oral: Rat: LD50: (mg/kg): 220 - 317
Dermal: Rabbit: LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION
Based on available data, the classification criteria are not met.

SERIOUS EYE DAMAGE/EYE IRRITATION
Based on available data, the classification criteria are not met.

REPRODUCTORY OR 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.

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

CARCINOGENICITY
OSHAl LIDOCAINE HYDROCHLORIDE is not listed.
NTP LIDOCAINE HYDROCHLORIDE is not listed.
IARC LIDOCAINE HYDROCHLORIDE is not evaluated.

ADDITIONAL CARCINOGENICITY INFORMATION
Metabolites of lidocaine have been shown to be carcinogenic in laboratory animals.

REPRODUCTIVE TOXICITY
Studies in animals have not shown that lidocaine causes adverse effects on the fetus. It is used as a local anesthetic during delivery. 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.

APSEIRATION HAZARDS
Not expected to present a significant hazard under anticipated conditions of normal use.

SIGNES AND SYMPTOMS OF EXPOSURE
Lidocaine is an amide type anesthetic, it is readily absorbed from the gastrointestinal tract, from mucous membranes, and through damaged skin. Adverse effects may include numbness, burning, stinging or swelling of skin, drowsiness or excitement, nervousness, dizziness, blurred vision, tremors, convulsions, unconsciousness, and possible cardiac arrest. When taken orally, lidocaine may cause nausea, vomiting or abdominal discomfort. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

The substance is a powerful local anaesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion. 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.
Ingestion Toxic if swallowed.
Skin Harmful if absorbed through skin. Causes skin irritation. May cause allergic skin reaction. May cause erythema or pigmentation.
Eyes May cause eye irritation.

NOTES

SECTION 12: ECOLOGICAL INFORMATION
SAFETY DATA SHEET

TOXICITY
- LC₅₀: 96 Hr: Fish: (mg/L): 106
- IC₅₀: 72 Hr: Algae: (mg/L): Not available
- EC₅₀: 48 Hr: Daphnia magna: (mg/L): 112

PERSISTENCE AND DEGRADABILITY
- Not available

BIOACCUMULATIVE POTENTIAL
- Not available

MOBILITY IN SOIL
- Very soluble in water

OTHER ADVERSE EFFECTS
- Not available
- This product is not intended to be released into the environment

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
- 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

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIDOCAINE HYDROCHLORIDE 6108-05-0</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Last Revision: 05/2016
SAFETY DATA SHEET

<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>
</tr>
</thead>
<tbody>
<tr>
<td>LIDOCAINE HYDROCHLORIDE 6108-05-0</td>
<td>N/L</td>
<td>Listed as Schedule 4*</td>
<td>N/L</td>
</tr>
</tbody>
</table>

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

05/2016

SUPERSEDES

08/2015

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.