### SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>NALOXONE HYDROCHLORIDE, USP/EP (Dihydrate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT CODE</td>
<td>0767</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>SUPPLIER</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>SUPPLIER</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>SUPPLIER</td>
<td>MEDISCA UK Limited</td>
</tr>
<tr>
<td></td>
<td>Tel.: 0800.029.4641</td>
</tr>
<tr>
<td></td>
<td>33 St. James's Square, London, United Kingdom SW1Y 4JS</td>
</tr>
</tbody>
</table>

**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

**USES**
- Narcotic antagonist.

### SECTION 2: HAZARDS IDENTIFICATION

**GHS CLASSIFICATION**
- Acute Toxicity - Oral (Category 4)
- Eye Irritation (Category 2A)
- Chronic Aquatic Toxicity (Category 3)

**PICTOGRAM**

![Warning symbol]

**SIGNAL WORD**
- Warning

**HAZARD STATEMENT(S)**
- Harmful if swallowed.
- Causes serious eye irritation.
- Harmful to aquatic life with long lasting effects.

**ADVERSE PHYSICOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS**
- Not applicable.

**PRECAUTIONARY STATEMENT(S)**

**Prevention**
- Wash thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Wear eye and face protection protection.
- 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.

Storage
Not applicable.

Disposal
Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION
Health Hazard 1
Flammability 0
Reactivity 0
Personal Protection G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME
Morphinan-6-one, 4, 5-epoxy-3, 14-dihydroxy-17-(2-propenyl)-, hydrochloride, (5α)-

BOTANICAL NAME
Not applicable

SYNONYM
Not applicable

CHEMICAL FORMULA
C₁₉H₂₁NO₄·HCl·2H₂O

CAS NUMBER
51481-60-8

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
399.8684

COMPOSITION

<table>
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<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>EC NUMBER</th>
<th>% BY WEIGHT</th>
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<tbody>
<tr>
<td>NALOXONE HCl (Dihydrate)</td>
<td>51481-60-8</td>
<td>206-611-0</td>
<td>100</td>
</tr>
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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: Morphinan derivative.

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

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL
Not applicable.

FLAMMABLE PROPERTIES
May be combustible at high temperature.

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.

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. Preserve in tight, light-resistant containers. Store at 25°C, excursions permitted between 15° and 30°C.

SPECIFIC END USE(S)

See Section 1

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Chemical Name: NALOXONE HYDROCHLORIDE (Dihydrate)  CAS #: 51481-60-8

<table>
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<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
</tr>
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<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<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>
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<tr>
<td>AIHA WEEL</td>
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<td>N/L</td>
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<td>Safe Work Australia HSIS</td>
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<td>HSE</td>
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<td>N/L</td>
<td>N/L</td>
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<tr>
<td>GESTIS</td>
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<td>N/L</td>
<td>N/L</td>
<td>-</td>
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<td>-</td>
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</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.

Last Revision: 06/2019
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. Fume hood, eye wash station, and safety shower.

NOTES

Manufacturer: LTEL (8hr TWA): 100 µg/m³.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PHYSICAL STATE</th>
<th>Solid</th>
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<tbody>
<tr>
<td>DESCRIPTION</td>
<td>White to slightly off-white powder. Hygroscopic.</td>
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<tr>
<td>SOLUBILITY</td>
<td>Soluble in water, in dilute acids, and in strong alkali; slightly soluble in alcohol; practically insoluble in ether and in chloroform.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Not available.</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td>AUTO-IGNITION TEMPERATURE</td>
<td>Not available</td>
</tr>
<tr>
<td>BOILING POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>DECOMPOSITION TEMPERATURE</td>
<td>127 °C, 260.6 °F</td>
</tr>
<tr>
<td>EVAPORATION RATE</td>
<td>Not available</td>
</tr>
<tr>
<td>EXPLOSIVE LIMIT</td>
<td>Not available</td>
</tr>
<tr>
<td>FLASH POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>log P (OCTANOL-WATER)</td>
<td>3.46 (20°C)</td>
</tr>
<tr>
<td>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
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</tr>
<tr>
<td>MELTING/FREEZING POINT</td>
<td>127 °C, 260.6 °F (decomposes)</td>
</tr>
<tr>
<td>ODOR THRSHOLD</td>
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<td>OXIDIZING PROPERTY</td>
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<tr>
<td>pH</td>
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<td>RELATIVE DENSITY (WATER = 1)</td>
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<tr>
<td>SPECIFIC GRAVITY</td>
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<tr>
<td>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
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</tr>
<tr>
<td>VAPOR DENSITY (AIR = 1)</td>
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<tr>
<td>VAPOR PRESSURE</td>
<td>&lt; 0.0000001 kPa (25°C)</td>
</tr>
<tr>
<td>VISCOSITY</td>
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</table>

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 oxidants.

**HAZARDOUS DECOMPOSITION PRODUCTS**
Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.

**HAZARDOUS POLYMERIZATION**
Will not occur.
POSSIBILITY OF HAZARDOUS REACTION  
Not established.

CONDITIONS TO AVOID  
Moisture, sunlight and extreme temperatures. Sensitive to light.

SECTION 11: TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>ACUTE TOXICITY</th>
<th>Oral: Rat: LD50: (mg/kg): 660</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Dermal: Rabbit LD50: (mg/kg): Not available</td>
</tr>
<tr>
<td></td>
<td>Inhalation: Rat: LC50: (mg/L/4hr): Not available</td>
</tr>
</tbody>
</table>

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

SERIOUS EYE DAMAGE/EYE IRRITATION  
Causes eye irritation. (pH 5)

RESPIRATORY SENSITIZATION  
Due to lack of data the classification is not possible.

SKIN SENSITIZATION  
Based on available data, the classification criteria are not met. Suspected skin sensitizer: CEASAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability).

GERM CELL MUTAGENICITY  
Due to lack of data the classification is not possible.

CARCINOGENICITY  
OSHA: NALOXONE HYDROCHLORIDE is not listed. 
NTP: NALOXONE HYDROCHLORIDE is not listed. 
IARC: NALOXONE 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  
Due to lack of data the classification is not possible.

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; Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value).

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  
Symptoms related to the physical, chemical, and toxicological characteristics: 

Delayed and immediate effects of exposure: 
Change in blood pressure.

Medical conditions aggravated by exposure: 

SIGNS AND SYMPTOMS OF EXPOSURE

POTENTIAL HEALTH EFFECTS  
Inhalation  
May be harmful if inhaled. Causes respiratory tract irritation.

Ingestion  
Harmful if swallowed.

Skin  
May be harmful if absorbed through skin. May cause skin irritation.

Eyes  
Causes serious eye irritation.
SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
EC50: 48 Hr: Crustacea: Daphnia (mg/L): 2.62**
LC50: 96 Hr: Fish: (mg/L): 0.0606* - 34.04**
EC50: 96 Hr: Green Algae: (mg/L): 14.5**

PERSISTENCE AND DEGRADABILITY
Suspected persistent in the environment: Ready biodegradability model (IRFMN) in VEGA (Q)SAR platform predicts that the chemical is NON Readily Biodegradable (moderate reliability); The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

BIOACCUMULATIVE POTENTIAL
LogPow: 3.46 (20 °C)

MOBILITY IN SOIL
Soluble in water.

OTHER ADVERSE EFFECTS
Suspected hazardous to the aquatic environment: Fish toxicity classification (SarPy/IRFMN) model in VEGA (Q)SAR platform predicts that the chemical is Toxic-1 (less than 1 mg/l) (moderate reliability).

This product is not intended to be released into the environment.

NOTES
*Fish Acute Toxicity model (KNN/Read-Across) in VEGA (Q)SAR platform prediction (moderate 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

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
SAFETY DATA SHEET

Chemical Name & CAS | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR Part 372.85 | EPA 40 CFR Part 355 Appendix A | Appendix B | Pennsylvania | Right-to-know | New Jersey | Massachusetts | California Prop 65
---|---|---|---|---|---|---|---|---|---|---
NALOXONE HCl (Dihydrate) 51481-60-8 | N/L | N/L | N/L | N/L | N/L | N/L | N/L | N/L | N/L

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>
</tr>
</thead>
<tbody>
<tr>
<td>NALOXONE HCl (Dihydrate) 51481-60-8</td>
<td>N/L</td>
<td>Listed as Schedule 4*</td>
<td>N/L</td>
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</table>

N/L = Not Listed

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

NOTES

*Listed as the base

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS


LAST REVISION

06/2019

SUPERSEDES

06/2019

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.