SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: NALOXONE HYDROCHLORIDE, USP (Dihydrate)

PRODUCT CODE: 0757

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: Narcotic antagonist.

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION:
Acute Toxicity - Oral (Category 4)
Eye Irritation (Category 2A)

PICTOGRAM:
⚠️

SIGNAL WORD: Warning

HAZARD STATEMENT(S):
Harmful if swallowed. Causes serious eye irritation. Causes respiratory irritation.

AUSTRALIA-ONLY HAZARDS:
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.

**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.

HMIS CLASSIFICATION:
<table>
<thead>
<tr>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Reactivity</th>
<th>Personal Protection</th>
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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Last Revision: 07/2015

NALOXONE HYDROCHLORIDE, USP (Dihydrate)
SAFETY DATA SHEET

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
Not applicable

COMPOSITION

<table>
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<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
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<tr>
<td>NALOXONE HYDROCHLORIDE</td>
<td>51481-60-8</td>
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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
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.

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.
SAFETY DATA SHEET

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

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool 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.

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

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

<table>
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<tr>
<th></th>
<th>TWA</th>
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<th>REL</th>
<th>IDLH</th>
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<tr>
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</table>

N/L = Not Listed

Consult local authorities for provincial or state exposure limits

EXPOSURE GUIDELINES

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 respiratory 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.

PERSONAL PROTECTIVE EQUIPMENT

SPECIFIC ENGINEERING CONTROLS

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: Solid

DESCRIPTION: White to slightly off-white powder. Hygroscopic.

SOLUBILITY: Soluble in water, in dilute acids, and in strong alkali; slightly soluble in alcohol; practically insoluble in ether and in chloroform.

ODOR: Not available.

FLAMMABILITY: May be combustible at high temperature.
### SAFETY DATA SHEET

**ODOR THRESHOLD**  | Not available  | **PH**  | 5  | **MELTING POINT**  | 127 °C, 260.6 °F  
**BOILING POINT**  | Not available  | **FREEZING POINT**  | Not available  | **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**  | Not available  
**VAPOR DENSITY (AIR = 1)**  | Not available  | **RELATIVE DENSITY (WATER = 1)**  | Not available  | **LOG P (OCTANOL-WATER)**  | 3.46 (20 °C)  
**AUTO-IGNITION TEMPERATURE**  | Not available  | **DECOMPOSITION TEMPERATURE**  | Not available  | **VISCOSITY**  | Not available  

**SECTION 10: STABILITY AND REACTIVITY**

**REACTIVITY**  | Not established  
**STABILITY**  | Stable under recommended storage conditions  
**MATERIALS TO AVOID**  | 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**

**ACUTE TOXICITY**  | Oral: Rat: LD50: 660 mg/kg  
**SKIN CORROSION/IRRITATION**  | Not available  
**SERIOUS EYE DAMAGE/EYE IRRITATION**  | Causes eye irritation  
**RESPIRATORY OR SKIN SENSITIZATION**  | Not available  
**GERM CELL MUTAGENICITY**  | Not available  
**CARCINOGENICITY**  | OSHA: NALOXONE HYDROCHLORIDE is not listed  
**OSHA**  | NALOXONE HYDROCHLORIDE is not listed  
**NTP**  | NALOXONE HYDROCHLORIDE is not listed  
**IARC**  | NALOXONE HYDROCHLORIDE is not evaluated.
This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

California Proposition 65

REPRODUCTIVE TOXICITY
Not available

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
Not available

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
Not available

ASPIRATION HAZARDS
Not available

SIGNS AND SYMPTOMS OF EXPOSURE
May cause nausea and vomiting; hypotension, hypertension, cardiac arrhythmias, pulmonary oedema and seizures.

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
Daphnia 1: EC50: 90 mg/l (48 hr)

PERSISTENCE AND DEGRADABILITY
Not available

BIOACCUMULATIVE POTENTIAL
3.46 (20 °C)

MOBILITY IN SOIL
Not available

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
SAFETY DATA SHEET

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>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
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<tbody>
<tr>
<td>NALOXONE HYDROCHLORIDE, USP (Dihydrate) 51481-60-8</td>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</table>

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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<tbody>
<tr>
<td>NALOXONE HYDROCHLORIDE, USP (Dihydrate) 51481-60-8</td>
<td>Not Listed</td>
<td>Listed as Schedule 4</td>
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</tr>
</tbody>
</table>

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
07/2015

SUPERSEDES
04/2014

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.