SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME
NALTREXONE HYDROCHLORIDE, USP

PRODUCT CODE
0887

SUPPLIER
MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.880.5855
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)
Specific Target Organ Toxicity - Repeated Exposure (Category 2) - (Liver)

PICTOGRAM

SIGNAL WORD
Warning

HAZARD STATEMENT(S)
Harmful if swallowed.
May cause respiratory tract irritation.
May cause damage to organs (liver) through prolonged or repeated exposure.
Exposure may produce an allergic reaction.

AUSTRALIA-ONLY HAZARDS
Not Applicable.

PRECAUTIONARY STATEMENT(S)

Prevention
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
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.
Do not breathe dust/fume/gas/mist/vapors/spray.

Response
IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth.
IF EXPOSED OR CONCERNED: Get medical advice/attention.

Storage
Store locked up.

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

HMIS CLASSIFICATION

<table>
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<tr>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Reactivity</th>
<th>Personal Protection</th>
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<td>0</td>
<td>0</td>
<td>E</td>
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**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

- **CHEMICAL NAME**: Morphinan-6-one, 17-(cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxy-, hydrochloride, (5a)- dihydrate
- **BOTANICAL NAME**: Not applicable
- **SYNONYM**: Not applicable
- **CHEMICAL FORMULA**: C_{20}H_{23}NO_4\cdot HCl \cdot 2H_2O
- **CAS NUMBER**: 16676-29-2 (General)
- **ALTERNATE CAS NUMBER**: 850808-02-5 (Dihydrate)
- **MOLECULAR WEIGHT**: 413.8952

<table>
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<th>COMPOSITION</th>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
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<tr>
<td>NALTREXONE HYDROCHLORIDE (Dihydrate)</td>
<td>16676-29-2</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: Oxymorphone. Opioid receptor antagonist.

**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, CO\textsubscript{2} or water spray. Large fire: dry chemical, CO\textsubscript{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.

**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.
On land, sweep or shovel into suitable containers. Minimize generation of dust.

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.

PRECAUTIONS FOR SAFE HANDLING

Store in original container, tightly sealed, 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. Recommended storage temperature: controlled room temperature. Preserve in tight, light-resistant containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: NALTREXONE HYDROCHLORIDE    CAS #: 16676-29-2

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<th></th>
<th>TWA</th>
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<td>N/L</td>
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<td>NIOSH</td>
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N/L = Not Listed

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m3.

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 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.

PERSONAL PROTECTIVE EQUIPMENT

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

SPECIFIC ENGINEERING CONTROLS

NOTES

Occupational exposure guidelines: 8-hour TWA: 50 ug/m3
Short Term Exposure guidelines: 15-min: 500 ug/m3

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid
Description: White crystalline powder. Very hygroscopic.
SOLUBILITY
Very soluble in water; slightly soluble in alcohol; practically insoluble in dichloromethane and methylene chloride.

ODOR
Odorless

FLAMMABILITY
May be combustible at high temperature

ODOR THRESHOLD
Not available

PH
4.5 - 5.5 (2%) (Anhydrous)

MELTING POINT
(274 - 276)°C, (525.2-528.8)°F

BOILING POINT
Not available

FREEZING POINT
(274 - 276)°C, (525.2-528.8)°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
Not available

VAPOR DENSITY
Not available

RELATIVE DENSITY (WATER = 1)
Not available

log P (OCTANOL-WATER)
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, bases and acids.

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. Light Sensitive.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY
Oral: Rat: LD50: (mg/kg): 1450
Dermal: Rabbit: LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION
Due to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE IRRITATION
Due to lack of data the classification is not possible.

RESPIRATORY OR SKIN SENSITIZATION
Possible hypersensitization.
Due to lack of data the classification is not possible.
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GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible.
Laboratory experiments have shown mutagenic effects.
Genotoxicity in vitro - Equivocal evidence.
Histidine reversion (Ames)
Genotoxicity in vitro - Human - fibroblast
Unscheduled DNA synthesis

CARCINOGENICITY

OSHA
NALTREXONE HYDROCHLORIDE is not listed.

NTP
NALTREXONE HYDROCHLORIDE is not listed.

IARC
NALTREXONE 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

In two-year studies in rats given naltrexone, there were small increases in the numbers of testicular mesotheliomas in males and tumors of vascular origin in both sexes. Only the incidence of vascular tumors in males (4%) exceeded the maximum (2%) reported in historical control groups. No evidence of carcinogenicity was observed in several other two-year studies in mice or rats receiving naltrexone.

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

REPRODUCTIVE TOXICITY

Reduced weight in neonates.
Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Inhalation of dust can irritate the respiratory tract.
Based on available data, the classification criteria are not met.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Repeated ingestion may cause liver damage. Repeated exposure may cause hepatitis and liver disease.

ASPIRATION HAZARDS

Due to lack of data the classification is not possible.

SIGNS AND SYMPTOMS OF EXPOSURE

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


Delayed and immediate effects of exposure: Fast heartbeat. Liver damage.

Medical conditions aggravated by exposure: Heart problems. Impaired kidney function. Impaired liver function. Opioid dependence.

POTENTIAL HEALTH EFFECTS

Inhalation
May be harmful if inhaled. May cause 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: Daphnia magna: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
IC50: 72 Hr: Algae: (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

Not available

MOBILITY IN SOIL

Very soluble in water. (> 100 mg/L)

OTHER ADVERSE EFFECTS

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS
SAFETY DATA SHEET

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

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N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

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<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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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

02/2016

SUPERSEDES

08/2013

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.