# SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>AMANTADINE HYDROCHLORIDE, USP</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT CODE</td>
<td>0411</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></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>
<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></td>
<td>National Chemical Emergency Centre 44(0)1235239670</td>
</tr>
<tr>
<td>USES</td>
<td>Antiviral (Influenza A); antiparkinsonian</td>
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</table>

# SECTION 2: HAZARDS IDENTIFICATION

<table>
<thead>
<tr>
<th>GHS CLASSIFICATION</th>
<th>Acute Toxicity - Oral (Category 4)</th>
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<tbody>
<tr>
<td></td>
<td>Toxic to Reproduction (Category 1A)</td>
</tr>
<tr>
<td></td>
<td>Acute Aquatic Toxicity (Category 3)</td>
</tr>
<tr>
<td>PICTOGRAM</td>
<td>![Safety Hazard Symbol]</td>
</tr>
<tr>
<td>SIGNAL WORD</td>
<td>Danger</td>
</tr>
<tr>
<td>HAZARD STATEMENT(S)</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td></td>
<td>May damage fertility or the unborn child</td>
</tr>
<tr>
<td></td>
<td>Causes severe skin burns and eye damage.</td>
</tr>
<tr>
<td></td>
<td>Harmful to aquatic life.</td>
</tr>
<tr>
<td>ADVERSE PHYSICOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</td>
<td>Not Applicable.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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.
Avoid release to the environment.

Response
IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
IF EXPOSED OR CONCERNED: Get medical advice/attention.
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 ON SKIN (OR HAIR): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Storage
Store locked up.

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

HMIS CLASSIFICATION

Health Hazard 1
Flammability 1
Reactivity 0
Personal Protection E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME
1-Adamantanamine, hydrochloride

BOTANICAL NAME
Not applicable

SYNONYM
Tricyclo[3.3.1.1(3,7)]decan-1-amine, hydrochloride

CHEMICAL FORMULA
C₁₀H₁₇N•HCl

CAS NUMBER
665-66-7

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
187.71

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>EC NUMBER</th>
<th>% BY WEIGHT</th>
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</thead>
<tbody>
<tr>
<td>AMANTADINE HYDROCHLORIDE</td>
<td>665-66-7</td>
<td>101-560-2</td>
<td>100</td>
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</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.

NOTES
Chemical family: Tricyclic amine.

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
SAFETY DATA SHEET

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.

SUITE & 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 well-closed containers.

SPECIFIC END USE(S)

See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: AMANTADINE HYDROCHLORIDE CAS #: 665-66-7

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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</thead>
<tbody>
<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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<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 WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

Last Revision: 09/2019

AMANTADINE HYDROCHLORIDE, USP
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. Thermal Hazards: For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICAL STATE</td>
<td>Solid</td>
</tr>
<tr>
<td>DESCRIPTION</td>
<td>White or practically white, crystalline powder.</td>
</tr>
<tr>
<td>SOLUBILITY</td>
<td>Freely soluble in water; soluble in alcohol and in chloroform.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Odorless</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>360 °C, 680 °F</td>
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<tr>
<td>EVAPORATION RATE</td>
<td>Not available</td>
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<tr>
<td>EXPLOSIVE LIMIT</td>
<td>Not available</td>
</tr>
<tr>
<td>FLASH POINT</td>
<td>170 °C, 338 °F (Open Cup)</td>
</tr>
<tr>
<td>log P (OCTANOL-WATER)</td>
<td>1.9</td>
</tr>
<tr>
<td>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>MELTING/FREEZING POINT</td>
<td>360 °C, 680 °F (decomposes)</td>
</tr>
<tr>
<td>ODOR THRESHOLD</td>
<td>Not available</td>
</tr>
<tr>
<td>OXIDIZING PROPERTY</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>3 - 5.5 (1 in 5 solution)</td>
</tr>
<tr>
<td>RELATIVE DENSITY (WATER = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY</td>
<td>Not available</td>
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<tr>
<td>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>VAPOR DENSITY (AIR = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>VAPOR PRESSURE</td>
<td>0.0000001 kPa (25°C)</td>
</tr>
<tr>
<td>VISCOSITY</td>
<td>Not available</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
### SECTION 11: TOXICOLOGICAL INFORMATION

#### ACUTE TOXICITY
- Oral: Rat: LD50: (mg/kg): 300 - 2000
- 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.
- Causes severe skin burns and eye damage.

#### SERIOUS EYE DAMAGE/EYE IRRITATION
- Based on available data, the classification criteria are not met.
- Causes severe eye burns.

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

#### SKIN SENSITIZATION
- Due to lack of data the classification is not possible.

#### GERM CELL MUTAGENICITY
- Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found. A related material tested negative in mutagenicity studies.

#### CARCINOGENICITY
- OSHA: AMANTADINE HYDROCHLORIDE is not listed.
- NTP: AMANTADINE HYDROCHLORIDE is not listed.
- IARC: AMANTADINE HYDROCHLORIDE is not listed.
- California Proposition 65: This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: AMANTADINE HYDROCHLORIDE.

#### ADDITIONAL CARCINOGENICITY INFORMATION
- Due to lack of data the classification is not possible.

#### REPRODUCTIVE TOXICITY
- An oral dose of 182 mg/kg in a women from 1-91 days of pregnancy produced specific developmental abnormalities in the cardiovascular system. An oral dose in a women of 14mg/kg at 4-6 weeks of pregnancy produced abnormalities in the musculoskeletal system and cardiovascular system.
- Suspected of damaging fertility or the unborn child. Reproductivity studies in animals administered a related material have yielded mixed results.
- Amantadine is distributed into breast milk and licensed product information states that adverse effects have occurred in infants being breast fed by mothers taking amantadine.

#### 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
- Based on available data, the classification criteria are not met.
SAFETY DATA SHEET

SIGNS AND SYMPTOMS OF EXPOSURE
Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms related to the physical, chemical, and toxicological characteristics
Burning pain and severe corrosive skin damage. Permanent eye damage including blindness could result.
Diarrhea. Red spots on skin.

Delayed and immediate effects of exposure

Medical conditions aggravated by exposure

POTENTIAL HEALTH EFFECTS

<table>
<thead>
<tr>
<th>Exposure Path</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May be harmful if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Harmful if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>May be harmful if absorbed through skin. May cause skin irritation. Causes severe skin burns.</td>
</tr>
<tr>
<td>Eyes</td>
<td>May cause eye irritation. Causes severe eye burns.</td>
</tr>
</tbody>
</table>

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
EC50: 48 Hr: Crustacea: (mg/L): 24.4
LC50: 96 Hr: Fish: (mg/L): 51 - 55
EC50: 72 Hr: Fresh water algae: (mg/L): 62.1

PERSISTENCE AND DEGRADABILITY
Not available

BIOACCUMULATIVE POTENTIAL
LogPow: 1.9

MOBILITY IN SOIL
Freely soluble in water
Solubility: 100 - 1000 g/L

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

UN PROPER SHIPPING NAME
Not dangerous good

UN NUMBER
Not applicable

CLASS
Not applicable

PACKING GROUP
Not applicable

AUSTRALIA
Not Applicable

HAZCHEM
SAFETY DATA SHEET

EU
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

ENVIRONMENTAL HAZARDS Not available
SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.66</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
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</thead>
<tbody>
<tr>
<td>AMANTADINE HYDROCHLORIDE, USP 665-66-7</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>X</td>
</tr>
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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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</thead>
<tbody>
<tr>
<td>AMANTADINE HYDROCHLORIDE, USP 665-66-7</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
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</table>

N/L = Not Listed

EU REGULATIONS

<table>
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<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AMANTADINE HYDROCHLORIDE, USP 665-66-7</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</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

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

SECTION 16: OTHER INFORMATION

REFERENCES Available upon request
ABBREVIATIONS AND ACRONYMS


LAST REVISION

09/2019

SUPERSEDES

03/2016

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.