## 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>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>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>
</tbody>
</table>

## SECTION 2: HAZARDS IDENTIFICATION

### GHS CLASSIFICATION
- Acute Toxicity - Oral (Category 4)
- Toxic to Reproduction (Category 1A)
- Acute Aquatic Toxicity (Category 3)

### PICTOGRAM

### SIGNAL WORD
Danger

### HAZARD STATEMENT(S)
- Harmful if swallowed
- May damage fertility or the unborn child
- Can cause severe skin burns and eye damage
- Harmful to aquatic life.

### 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.
- 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.

#### Storage
- Store locked up.

#### Disposal
- Dispose of contents and/or container in accordance with local regulations.
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>% BY WEIGHT</th>
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</thead>
<tbody>
<tr>
<td>AMANTADINE HYDROCHLORIDE</td>
<td>665-66-7</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: 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
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
SAFETY DATA SHEET

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. Preserve in well-closed containers.

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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<tr>
<td>OSHA PEL</td>
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<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>
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<td>-</td>
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<tr>
<td>AIHA WEEL</td>
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<td>N/L</td>
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<td>-</td>
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<tr>
<td>Safe Work Australia HSIS</td>
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<td>HSE</td>
<td>N/L</td>
<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.

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE Solid
DESCRIPTION White or practically white, crystalline powder.
### SOLUBILITY
Freely soluble in water; soluble in alcohol and in chloroform.

### ODOR
Odorless

### FLAMMABILITY
May be combustible at high temperature

<table>
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<tr>
<th>Property</th>
<th>Value</th>
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<tr>
<td><strong>Odor Threshold</strong></td>
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<tr>
<td><strong>pH</strong></td>
<td>3 - 5.5 (1 in 5 solution)</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>360 °C, 680 °F (decomposes)</td>
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<tr>
<td><strong>Boiling Point</strong></td>
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</tr>
<tr>
<td><strong>Freezing Point</strong></td>
<td>360 °C, 680 °F</td>
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<tr>
<td><strong>Flash Point</strong></td>
<td>170 °C, 338 °F (Open Cup)</td>
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<tr>
<td><strong>Specific Gravity</strong></td>
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<tr>
<td><strong>Evaporation Rate</strong></td>
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<td><strong>Explosive Limit</strong></td>
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</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>
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<tr>
<td><strong>Vapor Density (Air = 1)</strong></td>
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</tr>
<tr>
<td><strong>Relative Density (Water = 1)</strong></td>
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</tr>
<tr>
<td><strong>Relative Density</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Log P (Octanol-Water)</strong></td>
<td>2.44 (20°C)</td>
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<tr>
<td><strong>Auto-Ignition Temperature</strong></td>
<td>Not available</td>
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<tr>
<td><strong>Decomposition Temperature</strong></td>
<td>360 °C, 680 °F</td>
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<tr>
<td><strong>Viscosity</strong></td>
<td>Not available</td>
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</tbody>
</table>

### 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

### SECTION 11: TOXICOLOGICAL INFORMATION

- **Acute Toxicity**
  - Oral: Rat: LD50: (mg/kg): 800
  - Dermal: Rabbit: LD50: (mg/kg): Not available
  - Inhalation: Rat: LD50: (mg/L/4hr): Not available

- **Skin Corrosion/Irritation**: Causes severe skin burns and eye damage. Based on available data, the classification criteria are not met.
- **Serious Eye Damage/Eye Irritation**: Causes severe eye burns. Based on available data, the classification criteria are not met.
- **Respiratory or 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

<table>
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<tr>
<th>OSHA</th>
<th>AMANTADINE HYDROCHLORIDE is not listed.</th>
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</thead>
<tbody>
<tr>
<td>NTP</td>
<td>AMANTADINE HYDROCHLORIDE is not listed.</td>
</tr>
<tr>
<td>IARC</td>
<td>AMANTADINE HYDROCHLORIDE is not listed.</td>
</tr>
</tbody>
</table>

### Additional Carcinogenicity Information

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

Due to lack of data the classification is not possible.

### Reproductive Toxicity

An oral dose of 182mg/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.

### Signs and Symptoms of Exposure

Symptoms related to the physical, chemical, and toxicological characteristics:
- Burning pain and severe corrosive skin damage. Permanent eye damage including blindness could result.

Delayed and immediate effects of exposure:

Medical conditions aggravated by exposure:

### Potential Health Effects

<table>
<thead>
<tr>
<th>Route</th>
<th>Description</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 and eye damage.</td>
</tr>
<tr>
<td>Eyes</td>
<td>May cause eye irritation. Causes severe eye burns.</td>
</tr>
</tbody>
</table>

### Section 12: Ecological Information

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>LC50: 96 Hr: Fish: (mg/L): 95</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IC50: 72 Hr: Algae: (mg/L): Not available</td>
</tr>
<tr>
<td></td>
<td>EC50: 48 Hr: Daphnia magna: (mg/L): Not available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Persistence and Degradability</th>
<th>Biodegradation: 100</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Bioaccumulative Potential</th>
<th>LogPow: 2.44 (20°C)</th>
</tr>
</thead>
</table>

| Mobility in Soil              | Freely 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>
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<tbody>
<tr>
<td>AMANTADINE HYDROCHLORIDE, USP 665-66-7</td>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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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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<tbody>
<tr>
<td>AMANTADINE HYDROCHLORIDE, USP 665-66-7</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
<td>N/L</td>
</tr>
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</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
03/2016

SUPERSEDES
07/2014

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.