


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	AMANTADINE HYDROCHLORIDE, USP
PRODUCT CODE	0411
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 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 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Manufacturing and Compounding
RESTRICTIONS ON USE	Not applicable

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 Causes severe skin burns and eye damage. Harmful to aquatic life.
ADVERSE PHYSIOCHEMICAL, 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. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection Avoid release to the environment.

Response IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth.
 IF EXPOSED OR CONCERNED: Get medical advice.
 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
CHEMICAL FAMILY Tricyclic amine
CAS NUMBER 665-66-7
ALTERNATE CAS NUMBER Not applicable
MOLECULAR WEIGHT 187.71

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
AMANTADINE HYDROCHLORIDE	665-66-7	211-560-2	100

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 Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

MEDICAL ATTENTION AND SPECIAL TREATMENT Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE 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, CO ₂ or water spray. Large fire: dry chemical, CO 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.
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. Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40 °C are acceptable

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

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.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

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				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	360 °C, 680 °F
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	170 °C, 338 °F (Open Cup)
log P (OCTANOL-WATER)	1.9	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	360 °C, 680 °F (decomposes)
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	3 - 5.5 (1 in 5 solution)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	0.0000001 kPa (25°C)	VISCOSITY	Not available

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

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 800 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. Toxic for reproduction: unborn child: Substances which cause concern for humans owing to possible developmental toxic effects.

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
ROUTES OF EXPOSURE:

Oral, Dermal

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Coma. Cardiac toxicity. Respiratory toxicity. Kidney toxicity. Central nervous system effects.

Symptoms related to the physical, chemical, and toxicological characteristics

Burning pain and severe corrosive skin damage. Permanent eye damage including blindness could result. Blurred vision. Hallucinations. Fainting. Confusion. Anxiety. Difficulty concentrating. Dizziness. Disorientation. Headache. Insomnia. Nervousness. Irritability. Drowsiness. Weakness. Slurred speech. Painful or difficult urination. Swelling of feet or lower legs. Dry mouth, nose, or throat. Loss of appetite. Nausea. Constipation. Diarrhea. Red spots on skin. Nervous system disorders. Gastrointestinal disorders. May produce irregular heart beat and nervous symptoms. Reduced blood pressure. Loss of coordination. Psychiatric disorders.

Medical conditions aggravated by exposure

Active alcoholism. Peripheral edema. Congestive heart failure. Epilepsy, or history of epilepsy. History of seizures. Impaired kidney function.

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. Causes severe skin burns.

Eyes

May cause eye irritation. Causes severe eye burns.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

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

DISPOSAL METHODS

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

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
AMANTADINE HCl, 665-66-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
AMANTADINE HCl, 665-66-7	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
AMANTADINE HCl, 665-66-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

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

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

04/2024

SUPERSEDES

01/2023

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.