

1. Identification

Product identifier	Amantadine Hydrochloride		
Other means of identification			
Chemical name	Tricyclo[3.3.1.1(3,7)]decan-1-amine, hydrochloride		
Company name	Triova Pharmaceuticals, LLC		
Address	115 W 3rd Street Suite 720 Tulsa, OK 74103		
Telephone	539.770.0720		
Website	www.triovarx.com		
E-mail	quality@triovarx.com		
Emergency phone number	INFOTRAC within US & Canada	1-800-535-5053	

2. Hazard(s) identification

Physical hazards	Not classified.		
Health hazards	Acute toxicity, oral	Category 4	
	Skin corrosion/irritation	Category 1B	
	Serious eye damage/eye irritation	Category 1	
	Reproductive toxicity	Category 2	
OSHA hazard(s)	Not classified.		
Label elements			



Signal word	Danger		
Hazard statement	Harmful if swallowed. Causes severe skin burns and eye damage. Suspected of damaging fertility or the unborn child.		
Precautionary statement			
Prevention	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. Wash thoroughly after handling.		
Response	If swallowed: Rinse mouth. Do NOT induce vomiting. Call a poison center/doctor if you feel unwell. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If exposed or concerned: Get medical advice/attention.		
Storage	Store locked up.		
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.		
Hazard(s) not otherwise classified (HNOC)	Not classified.		

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Amantadine Hydrochloride		665-66-7	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Corrosive effects.
Indication of immediate medical attention and special treatment needed	Overdose treatment should be symptomatic and supportive and may include the following: To decrease absorption, perform gastric lavage if ingestion was recent and administer activated charcoal for gastric contamination. Do NOT induce vomiting. Slowly administer intravenous physostigmine to control central nervous system toxicities. Monitor blood electrolytes, blood pressure, pulse, respiration, temperature, urinary pH, and urinary output. If there is no record of recent voiding, catheterization should be done. Increase acidity of urine to increase elimination. Administer appropriate anticonvulsant, antiarrhythmic, or antihypertensive therapy as required. Use care when administering adrenergic agents such as isoproterenol since the dopaminergic activity of amantadine may induce malignant arrhythmias. [USP DI 2003; PDR 2009]
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.

Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White or practically white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	3 - 5.5 (1 in 5 solution)
Melting point/freezing point	680 °F (360 °C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	> 338.00 °F (> 170.00 °C) Open Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Freely soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Tricyclic amine.
Molecular formula	C10H17N . HCl
Molecular weight	187.71

Solubility (other) Soluble in ethanol and in chloroform; practically insoluble in ether.

10. Stability and reactivity

Reactivity No reactivity hazards known.
Chemical stability Material is stable under normal conditions.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid None known.
Incompatible materials Strong oxidizing agents.
Hazardous decomposition products Cl-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion Harmful if swallowed.
Inhalation Due to lack of data the classification is not possible.
Skin contact Causes severe skin burns.
Eye contact Causes severe eye burns.

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.

Delayed and immediate effects of exposure Coma. Cardiac toxicity. Respiratory toxicity. Kidney toxicity. Central nervous system effects.

Medical conditions aggravated by exposure Active alcoholism. Peripheral edema. Congestive heart failure. Epilepsy, or history of epilepsy. History of seizures. Impaired kidney function.

Acute toxicity Causes severe skin burns and eye damage. Harmful if swallowed.

Product	Species	Test Results
Amantadine Hydrochloride (CAS 665-66-7)		
<i>Oral</i>		
LD50	Mouse	1275 mg/kg
		700 mg/kg
	Rat	800 mg/kg

Skin corrosion/irritation Causes severe skin burns and eye damage.

Serious eye damage/eye irritation 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 Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

Reproductive toxicity Suspected of damaging fertility or the unborn child. Reproductivity studies in animals administered a related material have yielded mixed results.

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

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Not available.
Hazardous waste code	Not available.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	Not Regulated
IATA	Not Regulated

15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable. All components are on the U.S. EPA TSCA Inventory List.
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Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 01-01-2017

Revision date 01-01-2017

Version # 00

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