Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Amantadine Hydrochloride USP
Commercial Name Midantane, Mydantane, Symmetrel, Virasol, Virofral
Product Use Not available.
Restrictions On Use Not available.

Product Code 30-1754

Company
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2 Repr. 2 Lact. STOT RE 2

Signal Word WARNING

Hazard Statement(s) May cause irritation of skin and eyes. May cause damage to fertility or unborn child. Prolonged/repeated exposure causes organ damage. Harmful to aquatic life with long lasting effects.

Pictogram(s) or Symbol(s)

Precautionary Statement(s):

Prevention P201 Obtain special instructions before use. P263 Avoid contact during pregnancy/while nursing. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response P308 + P313 IF exposed or concerned: Get medical advice/attention. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Storage Not available.

Disposal Not available.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components 1-Adamantanamine hydrochloride
% By Weight 100
CAS# 665-66-7
Molecular Weight 187.71 g/mole
Chemical Formula C10-H17-N.HCl
Synonym(s) 1-Adamantanamine hydrochloride; 1-Adamantylamine hydrochloride; 1-Aminoadamantene hydrochloride; Adamantanamine hydrochloride Adamantylamine hydrochloride; Aminoadamantane hydrochloride

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
1-Adamantanamine hydrochloride	665-66-7	100		

Section 4: First-Aid Measures

Inhalation If breathed in, move person into fresh air. Give water to drink. If not breathing, give artificial respiration.

Skin Contact Wash off with plenty of water at least for 20 minutes. Contaminated clothing should be laundered before reuse.

Eye Contact Flush eyes with water as a precaution at least for 20 minutes.

Ingestion Never give anything by mouth to an unconscious person. Rinse mouth with water. If ingestion of a large amount does occur, call the ambulance or provide medical attention immediately.

Symptoms/Effects

Acute Symptoms appear after exposure may include fever, anxiety, severe headache, confusion, hallucinations, agitation, aggression, personality changes, tremor, problems with balance or walking, fast or uneven heart rate, urinating less than usual or not at all, trouble breathing, seizure (convulsion), or fainting. An overdose of amantadine hydrochloride can be fatal (deaths have been reported from overdose with amantadine hydrochloride). The lowest reported acute lethal dose was 1 gram. Other serious side effects include: feeling short of breath, even with mild exertion; • swelling, rapid weight gain; • feeling depressed, agitated, or aggressive; • behaviour changes, hallucinations, thoughts of hurting yourself; • urinating less than usual or not at all; • high fever, stiff muscles, confusion, sweating, fast or uneven heartbeats, rapid breathing, feeling like you might pass out; • restless muscle movements in your eyes, tongue, jaw, or neck; • or tremor (uncontrolled shaking). Less serious side effects may include: • dizziness, drowsiness, headache; • sleep problems (insomnia), strange dreams; • feeling nervous; nausea, diarrhea, constipation, loss of appetite; • dry mouth, dry nose; • or loss of balance or coordination. Chronic effects. Amantadine hydrochloride can cause side effects that may impair vision, thinking, or reactions. Be carefulif you drive or do anything that requires you to be alert and able to see clearly. Please note, that some people taking medicines for Parkinson’s disease have developed skin cancer (melanoma). However, people with Parkinson's disease may have a higher risk than most people for developing melanoma.

Delayed Symptoms appear after exposure may include fever, anxiety, severe headache, confusion, hallucinations, agitation, aggression, personality changes, tremor, problems with balance or walking, fast or uneven heart rate, urinating less than usual or not at all, trouble breathing, seizure (convulsion), or fainting. An overdose of amantadine hydrochloride can be fatal (deaths have been reported from overdose with amantadine hydrochloride). The lowest reported acute lethal dose was 1 gram. Other serious side effects include: feeling short of breath, even with mild exertion; • swelling, rapid weight gain; • feeling depressed, agitated, or aggressive; • behaviour changes, hallucinations, thoughts of hurting yourself; • urinating less than usual or not at all; • high fever, stiff muscles, confusion, sweating, fast or uneven heartbeats, rapid breathing, feeling like you might pass out; • restless muscle movements in your eyes, tongue, jaw, or neck; • or tremor (uncontrolled shaking). Less serious side effects may include: • dizziness, drowsiness, headache; • sleep problems (insomnia), strange dreams; • feeling nervous; nausea, diarrhea, constipation, loss of appetite; • dry mouth, dry nose; • or loss of balance or coordination. Chronic effects. Amantadine hydrochloride can cause side effects that may impair vision, thinking, or reactions. Be carefulif you drive or do anything that requires you to be alert and able to see clearly. Please note, that some people taking medicines for Parkinson’s disease have developed skin cancer (melanoma). However, people with Parkinson's disease may have a higher risk than most people for developing melanoma.

Immediate Medical Attention

Attention! Making the "mouth to mouth" artificial respiration may be dangerous. Make a contactless artificial respiration. Qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Water spray. Carbon dioxide (COi). Dry chemical. Chemical foam.

Unsuitable Extinguishing Media

Not avaialble.

Products of Combustion

Thermal decomposition can lead to release of acrid smoke or irritating gases and vapours. Emits toxic fumes under fire conditions: carbon monoxide (CO), carbon dioxide (CO2), hydrogen chloride gas (HC1), phosgene and other pyrolysis products typical of burning organic material. May emit corrosive fumes.

Firefighters Special Equipment and Precautions

Fire fighter's clothing conforming to European standard EN469 provides a basic level of protection for chemical incidents and includes helmets, protective boots and gloves. Clothing not conforming to EN469 may not be suitable in any chemical incident, Use water delivered as a fine spray to control fire and cool adjacent area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment: wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. For non-emergency personnel: Protective equipment: Use personal protective equipment. Emergency procedures: Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. For emergency responders: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Environmental precautions - do not let product enter drains. Methods and material for containment and cleaning up For containment: Remove all ignition sources. Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact by using protective equipment. In case of major spills alert Emergency Responders and tell them location and nature of hazard. Prevent, by any means available, spillage from entering drains or watercourses. For cleaning up: Use dry clean up procedures and avoid generating dust. Place in a suitable, labelled container for waste disposal. Recover product wherever possible. Wash area down with large amounts of water. If contamination of drains or waterways occurs, advise emergency services.

Section 7: Handling and Storage

Precautions for safe handling Protective measures: Measures to prevent fire: Avoid contact with incompatible materials, heat, direct sunlight, water and moisture. Keep away from sources of ignition. .. Measures to prevent aerosol and dust generation: Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. Avoid all personal contact, including inhalation. Measures to protect the environment: Wear protective clothing when risk of exposure occurs. Keep containers securely sealed when not in use. Avoid physical damage to containers. Advice on general occupational hygiene: Use good occupational work practice. Observe manufacturer's storing and handling recommendations. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Launder contaminated clothing before re-use. Conditions for safe storage, including any incompatibilities Technical measures and storage conditions: Store in original containers at dark and dry place. Protect from moisture and light. Keep container tightly closed when not in use. Check that all containers are clearly labelled. Protect containers against physical damage and check regularly for leaks. Packing materials: Tied polyethylene bag, which is placed into polyethylene vat or other polymer container with a tight-fitting and sealable cover. Requirements for storage rooms and vessels: For quality assurance store at temperature below 25 °C. Protect from light and humidity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	Not available.
Engineering Controls	Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction. Exhaust ventilation should be designed to prevent recirculation of particulates and accumulation in the workplace.

Personal Protection

Eye I face protection - For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs - chemical goggles. Full-face shield may be required for supplementary but never for primary protection of eyes. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. DO NOT wear contact lenses. Skin protection - Choose body protection according to the amount and concentration of the dangerous substance at the work place. Hand protection: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 and US F739. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include such as frequencyi and duration of contact, chemical resistance of glove material, glove thickness and dexterity. When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended. When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended. Contaminated gloves should be replaced. Respiratory protection - Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type PI (EN 143) respirator, Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or-CEN (EU). Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures. The decision to use respiratory protection should be based on professional judgmentthat takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option). Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program. Use approved positive flow mask if significant quantities of dust becomes airborne. Environmental exposure controls: Contact a licensed professional waste disposal service to dispose of this material. Do not let product enter drains.

Section 9: Physical and Chemical Properties

Appearance	Solid. Crystalline powder. White or practically white
Odor	Odourless
Odor Threshold	Not available.

Melting Point	255 °C; 300 - 360 °C (lit.)	**pH**	4.9 - 5.1 (20 % solution, exp.) satu
Freezing Point	Not available.	**Vapor Pressure**	0.13 mm Hg at 25 °C (est., lit.)
Boiling Point/Range	225.7 ± 8.0 °C at 760 mmHg	**Vapor Density**	Not available.
Decomposition temperature	>310 °C (lit.)'	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	-1.64 at 23 °C and pH 6.3 (e	**Evaporation Rate**	Not available.
Flash Point	96 °C (exp., lit.)	**Autoignition temperature**	No self-heating detected
Flammability	214 °C (lit.)	**Flammability or Explosive Limits:**	
		Lower	lower flammability limits -17,5 g/m3 at dispersion 50 -
		Upper	Not available.

Solubility(ies)	Very soluble in water (100 g/100 mL) in water at 23°C and at 20.0 °C is = 35.0 g/100 g <39.8 g/100 g, pH 4.2 -4.4 Very soluble in 96. % ethanol Slightly soluble in chloroform Practically insoluble in ether 2.22 - 2.44 (est., lit.)
Other	Not available.

Section 10: Stability and Reactivity

Reactivity	No dangerous reactions known.
Chemical Stability	Stable in light and air.
Hazardous Polymerization	Hazardous polymerization products are unknown.
Conditions to Avoid	Sources of ignition, exposure to moist air or water, and exposure to light,
Incompatible Materials	Strong oxidizing agents, acids, acid anhydrides, and acid chlorides.
Hazardous Decomposition Products	Not available.

Section 11: Toxicological Information

RTECS AU4375000

Acute Toxicity

Acute toxicity may be attributable to the anticholinergic effects of amantadine hydrochloride. Drug overdose has resulted in cardiac, respiratory, renal or central nervous system toxicity. Cardiac dysfunction includes arrhythmia, tachycardia and hypertension. Pulmonary edema and respiratory distress (including adult respiratory distress syndrome - ARDS) have been reported; renal dysfunction including increased BUN, decreased creatinine clearance and renal insufficiency can occur. Central nervous system effects that have been reported include insomnia, anxiety, agitation, aggressive behaviour, hypertonia, hyperkinesia, ataxia, gait abnormality, tremor, confusion, disorientation, depersonalization, fear, delirium, hallucinations, psychotic reactions, lethargy, somnolence and coma. Seizures may be exacerbated in patients with prior history of seizure disorders. Hyperthermia has also been observed in cases where a drug overdose has occurred.

Skin Corrosion/Irritation

cause skin irritation

Serious Eye Damage/Irritation

cause eye irritation

Respiratory or Skin Sensitization

Not available.

Germ Cell Mutagenicity

Not available.

Carcinogenicity
Not available.

Reproductive Toxicity
Not available.

Routes of Entry
Inhalation. Ingestion.

Symptoms Related to Exposure
Not available.

Potential Health Effects
Not available.

Target Organ(s) Specific target organ toxicity, repeated exposure, Central nervous system, cardiovascular system, Hazard Categor

Section 12: Ecological Information

Ecotoxicity
Amantadine hydrochloride: Short-term toxicity to fish: LC50 = 25 mg/L (4 days) ; Short-term toxicity to aquatic invertebrates: EC50 = 24.4 mg/L (48 h) Toxicity to aquatic algae and cyanobacteria: EC50 = 62.1 mg/L (72 h); EC10 = 30.8 mg/L (72 h) Toxicity to microorganisms: EC50 = 300 mg/L (3 h); EC10 = 32 mg/L (3 h)

Persistance and Degradability
Not available.

Bioaccumulative Potential
Not available.

Mobility in Soil
substance less likely to move unless soil erosion occurs.

Other Adverse Effects
Not available.

Section 13: Disposal Considerations

Waste Disposal
Contact a licensed professional waste disposal service to dispose of this material. All waste must be handled in accordance with local, state and federal regulations. Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area.

Disposal of Container
Decontaminate empty containers

Other Considerations
Not available.

Section 14: Transport Information

DOT Classification
Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information

Regulations

Safety, health and environmental regulations/legislation specific for the substance or mixture Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Commission regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). ¦ , .> Regulation (EC) No 286/2011 of the European Parliament and of the Council of 10 March 2011 on amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Commission regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Commission regulation (EU) 2016/918 of 19 May 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the; European Parliament and of the Council on classification, labelling and packaging of substances and mixtures,

Other
Not available.

Section 16: Other Information

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.