

Amantadine Hydrochloride Oral Solution,
USP 50 mg/5 mL
Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name. : Amantadine Hydrochloride Oral Solution, USP 50 mg/5 mL

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical Use

1.3. Details of the supplier of the safety data sheet

Xttrium Laboratories, Inc.
1200 East Business Center Drive
Mt. Prospect, IL 60056

1.4. Emergency telephone number

Emergency number : 773-268-5800

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Physical Hazard: Combustible liquid Category 4

Health Hazard: Not classified

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) : None
Signal word (GHS-US) : Warning.
Hazard statements (GHS-US) : H227 - combustible liquid.

Precautionary statements (GHS-US) P210 - Keep away from flames and hot surfaces. No smoking.
P280 - Wear protective gloves/ eye protection/ face protection.
P370 + P378 - In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary to extinguish.
P403 + P235 - Store in a well-ventilated place. Keep cool.
P501 - Dispose of contents/container in accordance with local/regional/national/ international regulations.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : 1-Adamantanamine hydrochloride

3.2. Mixture

Name	CAS Number	%	
Amantadine Hydrochloride, USP	665-66-7	Trade Secret	
Saccharin Sodium, USP	6155-57-3	Trade Secret	
Sodium Citrate Dihydrate, USP	6132-04-3	Trade Secret	
Purified Water	7732-18-5	Trade Secret	
Propylene Glycol, USP	57-55-6	Trade Secret	
Methylparaben, NF	99-76-3	Trade Secret	
Propylparaben, NF	94-13-3	Trade Secret	
Sorbitol Solution, USP	50-70-4	Trade Secret	
Anhydrous Citric Acid, USP	77-92-9	Trade Secret	
Artificial Raspberry Flavor (F-1784)	N/A	Trade Secret	

Full text of H-phrases: see section 16

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SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Move to fresh air. Call a physician if symptoms develop or persist.
- First-aid measures after skin contact : Wash off with soap and water. Get medical attention if irritation develops and persists.
- First-aid measures after eye contact : Flush eyes thoroughly with water, taking care to rinse under eyelids. If irritation persists, continue flushing for 15 minutes, rinsing from time to time under eyelids. If discomfort continues, consult a physician.
- First-aid measures after ingestion : Rinse mouth. If ingestion of a large amount occurs, seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after skin contact : Prolonged skin contact may cause temporary irritation.
- Symptoms/injuries after eye contact : Direct contact with eyes may cause temporary irritation.
- Symptoms/injuries after ingestion : In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

4.3. Indication of any immediate medical attention and special treatment needed

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Can form explosive mixtures with air.
- Hazard decomposition products in case of fire : Carbon dioxide. Carbon monoxide. Nitrogen oxide. Toxic fumes may be released.

5.3. Advice for firefighters

- Protection during firefighting : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection. Stop leak if safe to do so. Ventilate area.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Large spills: stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Flush area with water. Small spills: wipe up with absorbent material (e.g. cloth, fleece).
- Methods for cleaning up

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Handle in accordance with product label and/or product insert information.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Stored at 20° to 25°C (68° to 77°F), excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. KEEP TIGHTLY CLOSED.

7.3. Specific end use(s)

Pharmaceutical Use.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional information : Ingredients with workplace control parameters: Contains no substances with occupational exposure limit values.

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Hand protection : Handle with gloves. For prolonged or repeated contact use protective gloves.
Eye protection : Chemical goggles or face shield.

Skin and body protection : Wear suitable protective clothing.
Respiratory protection : Wear appropriate mask.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Colorless to pale yellow liquid.
Color : Colorless to pale yellow.
Odor : Raspberry flavor
Odor threshold : No data available
pH : 2.0 - 3.0
Relative evaporation rate (butylacetate=1) : No data available
Melting point : No data available
Freezing point : No data available
Boiling point : No data available
Flash point : >140.0 °F
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Flammability (solid, gas) : No data available
Vapour pressure : No data available
Relative vapour density at 20 °C : No data available
Specific gravity : 1.1440 - 1.1560
Solubility : Water: Soluble
Log Pow : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is stable and non-reactive under normal conditions of use, storage, and transport.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong oxidizing agent.

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10.6. Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Amantadine Hydrochloride (665-66-7)

LD50 oral rat	800 mg/kg
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Skin corrosion/irritation : Causes severe skin irritation and eye damage.
Serious eye damage/irritation : Causes serious eye damage.
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified
Potential adverse human health effects and symptoms : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - water : No data available
Acute aquatic toxicity : Not data available
Chronic aquatic toxicity : No data available

12.2. Persistence and degradability

May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Disposal Instructions : Dispose of all waste in accordance with Federal, State and Local regulations.

SECTION 14: Transport information

In accordance with DOT / IMDG / IATA

14.1. UN number

Not applicable

14.2. UN proper shipping name

DOT Proper Shipping Name : No additional information available.

SECTION 15: Regulatory information**15.1. US Federal regulations****Water (7732-18-5)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Amantadine Hydrochloride, USP (665-66-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Saccharin Sodium, USP (6155-57-3)

Not Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium Citrate Dihydrate, USP (6132-04-3)

Not Listed on the United States TSCA (Toxic Substances Control Act) inventory

Propylene Glycol, USP (57-55-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Methylparaben, NF (99-76-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Propylparaben, NF (94-13-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sorbitol Solution, USP (50-70-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Anhydrous Citric Acid, USP (77-92-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Artificial Raspberry Flavor (F-1784)

Not Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations**Amantadine Hydrochloride (CAS 665-66-7)**

U.S. - California - Proposition 65 - Carcinogens or Reproductive Toxicity (CRT): Listed substance

SECTION 16: Other information

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

End of Safety Data Sheet