

## 1. Identification

Product identifier	Amiloride Hydrochloride		
Other means of identification			
Catalog number	1019701		
CAS number	17440-83-4		
Chemical name	Pyrazinecarboxamide, 3,5-diamino-N-(aminoiminomethyl)-6-chloro-, monohydrochloride, dihydrate		
Recommended use	Specified quality tests and assay use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States		
Telephone	RS Technical Services	301-816-8129	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300	
	CHEMTREC outside US & Canada	+1 703-527-3887	

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 2
	Serious eye damage/eye irritation	Category 2A
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger		
<b>Hazard statement</b>	Fatal if swallowed. Causes serious eye irritation.		
<b>Precautionary statement</b>			
<b>Prevention</b>	Wash thoroughly after handling. Wear eye protection/face protection.		
<b>Response</b>	If swallowed: Immediately call a poison center/doctor. Rinse mouth. 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.		
<b>Storage</b>	Store locked up.		
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.		
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.		
<b>Supplemental information</b>	Potent pharmacologically active material.		

## 3. Composition/information on ingredients

<b>Substance</b>			
<b>Chemical name</b>	<b>Common name and synonyms</b>	<b>CAS number</b>	<b>%</b>
Amiloride Hydrochloride		17440-83-4	100

## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	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.
<b>Ingestion</b>	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
<b>Most important symptoms/effects, acute and delayed</b>	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Treatment of potassium sparing diuretic overdose may include the following: Administer activated charcoal as a slurry. Monitor serum potassium concentration in symptomatic patients. Treat severe hyperkalemia (associated with dysrhythmias and QRS widening) aggressively. Administer intravenous calcium chloride, intravenous sodium bicarbonate, intravenous insulin/dextrose, and sodium polystyrene sulfonate by nasogastric tube or rectal enema, as needed. Monitor ECG continuously during and after therapy. Dialysis may remove potassium if hyperkalemia persists. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. For bradycardia, include correction of hyperkalemia in initial treatment.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP Reference Standards, 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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
<b>Conditions for safe storage, including any incompatibilities</b>	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

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**Exposure limit values**

Industrial Use Material	Type	Value	Form
Amiloride Hydrochloride (CAS 17440-83-4)	TWA	0.1 mg/m3	anhydrous

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection****Hand protection**

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

**Other**

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection**

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

**9. Physical and chemical properties****Appearance**

Appearance descriptions are general information and not specific to any USP lot.

**Physical state**

Solid.

**Form**

Powder.

**Color**

Pale yellow. Yellow green.

**Odor**

Almost odorless

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

545 - 550.4 °F (285 - 288 °C) (decomposes)

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

**Evaporation rate**

Not available.

**Flammability (solid, gas)**

Not available.

**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**

Not available.

**Vapor density**

Not available.

**Relative density**

Not available.

**Solubility(ies)****Solubility (water)**

Slightly soluble.

**Solubility (other)**

Dimethylsulfoxide: Freely soluble.  
Methanol: Sparingly soluble.  
Isopropanol: Slightly soluble.

	Ethanol: Slightly soluble. Ether: Insoluble. Ethyl acetate: Insoluble. Acetone: Insoluble. Chloroform: Insoluble.
<b>Partition coefficient (n-octanol/water)</b>	-1.245
<b>Auto-ignition temperature</b>	> 1020 °F (> 548.89 °C)
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Pyrazinoylguanidine derivative.
<b>Molecular formula</b>	C <sub>6</sub> H <sub>8</sub> CIN <sub>7</sub> O . HCl . 2H <sub>2</sub> O
<b>Molecular weight</b>	302.12

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	NO <sub>x</sub> , HCl. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Causes serious eye irritation.
<b>Ingestion</b>	Fatal if swallowed.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Headache. Dizziness. Fatigue. Nervousness. Gastrointestinal disturbances. Loss of appetite. Numbness, pain, tingling, or weakness in hands or feet. Muscle weakness. Muscle pain. Skin rash. Impotence. Cough. Shortness of breath. Irregular heartbeat. Pounding heartbeat.

### Information on toxicological effects

<b>Acute toxicity</b>	Fatal if swallowed. The base of this material was highly toxic when administered orally to animals.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Causes serious eye irritation.

#### Local effects

Eye irritation test  
Result: Severe irritatant  
Species: Rabbit  
Skin irritation test  
Result: Slightly irritating.  
Species: Rabbit

### Respiratory or skin sensitization

<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.
<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met. 10 mg/kg/day Carcinogenicity, administered orally. Result: Not carcinogenic Species: Mouse Test Duration: 92 weeks 6 - 8 mg/kg/day Carcinogenicity, administered orally. Result: Not carcinogenic Species: Rat Test Duration: 104 weeks

## IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

## OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

## US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

**Reproductive toxicity** Based on available data, the classification criteria are not met.

### Reproductivity

2 - 8 mg/kg/day Fertility study, administered orally.

Result: No adverse effects on fertility.

Species: Rat

2 - 8 mg/kg/day Reproductivity / Developmental, administered orally during gestation.

Result: Not teratogenic. Maternally toxic at high dose.

Species: Rabbit

2.5 - 10 mg/kg/day Reproductivity / Developmental, administered orally during gestation.

Result: Not teratogenic. Maternally toxic at high dose.

Species: Mouse

**Specific target organ toxicity - single exposure** Knowledge about health hazard is incomplete.

**Specific target organ toxicity - repeated exposure** Knowledge about health hazard is incomplete.

**Aspiration hazard** Knowledge about health hazard is incomplete.

**Further information** Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

## 12. Ecological information

### Ecotoxicity

Product	Species	Test Results
Amiloride Hydrochloride (CAS 17440-83-4)		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	LC50 Daphnia magna	56.3 mg/l

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

### Bioaccumulative potential

**Octanol/water partition coefficient log Kow**  
-1.245

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 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** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** 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** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Amiloride Hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	II

## IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Amiloride Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

DOT; IATA



### General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

### 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

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**SARA 313 (TRI reporting)**  
Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations** California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
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)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

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

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date	12-05-2006
Revision date	04-12-2018
Version #	04
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