Material Safety Data Sheet

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AMILORIDE HYDROCHLORIDE
Catalog Number: 1019701
Revision Date: December 5, 2006

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Amiloride Hydrochloride
Manufacturer: U. S. Pharmacopeia
Responsible Party: Reference Standards Technical Services
Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA
Phone: 301-816-8129
Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.
Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW - Poison. Irritant.

Adverse Effects: Adverse effects may include confusion; irregular heartbeat; nervousness; numbness or tingling in hands, feet, or lips; troubled breathing; unusual tiredness; weakness in legs; headache; constipation; decreased sexual ability; dizziness; nausea or vomiting; stomach cramps; diarrhea; drowsiness; dry mouth; thirst; loss of appetite; and muscle cramps. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, hyperkalemia, diabetic nephropathy, anuria, medical conditions involving small urine output, and impaired kidney or liver function.

Cross Sensitivity: Persons sensitive to sulfonamides may be sensitive to this material also.

Target Organs: Kidney

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Amiloride Hydrochloride
Formula: C6H8ClN7O.HCl.2H2O
Synonym: n/f

Chemical Name: Pyrazinecarboxamide, 3,5-diamino-N-(aminoiminoethyl)-6-chloro-, monohydrochloride, dihydrate

CAS: 17440-83-4; 2016-88-8 (anhydrous); 2609-46-3 (base)

RTECS Number: UQ2275500 (anhydrous); UQ2278200 (base)

Chemical Family: Pyrazinoylguanidine derivative

Therapeutic Category: Diuretic

Composition: Pure Material

**SECTION 4 - FIRST AID MEASURES**

**Inhalation:** May cause irritation. Remove to fresh air. Material may be absorbed through inhalation.

**Eye:** Causes irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

**Skin:** Causes irritation. Avoid contact. Flush with copious quantities of soap and water.

**Ingestion:** May cause irritation. Flush out mouth with water. This material is incompletely absorbed from the gastrointestinal tract. Effects begin within 2 hours and last up to 24 hours.

**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

**Note to Physicians**

**Overdose Treatment:** Treatment of potassium sparing diuretic overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as a slurry.
2. Monitor serum potassium concentration in symptomatic patients.
3. 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.
4. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine.
5. For bradycardia, include correction of hyperkalemia in initial treatment. [Meditext 2006]

**SECTION 5 - FIREFIGHTING MEASURES**

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**SECTION 6 - ACCIDENTAL RELEASE MEASURES**

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

**SECTION 7 - HANDLING AND STORAGE**

**Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

**Storage:** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: Industry: 0.1 mg/m³ (anhydrous)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: Pale yellow to yellowish-green crystalline powder; odorless or nearly odorless.

Odor Threshold: n/f

pH: n/f

Melting Range: 285 - 288° C (decomposes)

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Slightly soluble

Fat Solubility: n/f

Other Solubility: Freely soluble in dimethyl sulfoxide; sparingly soluble in methanol; insoluble in ether, in ethyl acetate, in acetone, and in chloroform

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C₆H₈ClN₇O . HCl . 2H₂O

Molecular Weight: 302.12
SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: n/f

Incompatibilities: Strong oxidizing agents

Decomposition Products: When heated to decomposition material emits toxic fumes of NOx and Cl-. Emits toxic fumes under fire conditions.

Stable? Yes Hazardous Polymerization? No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 36 to 86 mg/kg (base)
Oral Mouse: LD50: 56 mg/kg (base)

Other Toxicity Data: Oral Dog: LD50: 40 mg/kg (base)

Irritancy Data: Rabbit/eye: severe (anhydrous); Rabbit/skin: slight (anhydrous)
Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: NTP: No IARC: No OSHA: No

Other Carcinogenicity Data: There was no evidence of tumorigenicity when amiloride hydrochloride was administered to mice at doses up to 10 mg/kg/day for 92 weeks or carcinogenicity when administered to male and female rats at doses up to 6 and 8 mg/kg/day for 104 weeks.

Mutagenicity Data: Amiloride hydrochloride was negative for mutagenicity in the Ames test, with and without activation, in all strains of Salmonella, except for TA1537; which tested positive, with and without activation.

Reproductive and Developmental Effects: Studies in rats given amiloride at 20 times the expected maximum daily dose for humans showed no evidence of impaired fertility. However, some toxicity in adult rats and rabbits and a decrease in rat pup growth and survival were seen at doses 5 or more times the expected maximum daily human dose. No evidence of harm to the fetus was seen in rabbits and mice given 20 and 25 times the maximum human dose, respectively. The maximum daily human dose of amiloride hydrochloride is 20 mg.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: This material is harmful to aquatic organisms.
Daphnia magna: LC50: 56.3 ppm

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: Toxic solid, organic, n.o.s. (Amiloride Hydrochloride)
Class: 6.1
UN Number: UN2811
Packing Group: III
Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f
AMILORIDE HYDROCHLORIDE

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International Regulatory Information:
- EINECS # 217-958-2 (anhydrous); EINECS # 220-024-7 (base)
- Hazard Code: T, Xi
- Risk Phrases: R23/24/25, R36/38
- Safety Phrases: S24/25, S26, S36/37
- Canada: WHMIS Classification D1A

SECTION 16 - OTHER INFORMATION

Revision: 05-Dec-06
Previous Revision Date: 08-Dec-03