



# SAFETY DATA SHEET

## Potassium Citrate Extended-Release Tablets USP

### 1. IDENTIFICATION

**Manufacturer:**

Ascent Pharmaceuticals Inc  
400 S. Technology Drive  
Central Islip, NY 11722  
USP

**Emergency Phone:**

1-855-221-1622

**Common Name:** Potassium Citrate Extended-Release Tablets, USP

**Synonym(s):** Not Applicable

**Trade Name(s):** Potassium Citrate Extended-Release Tablets, USP 5 mEq, 10 mEq, 15 mEq.

**Recommended Use:** Finished pharmaceutical product as Urinary Alkalizing agent.

**Restrictions on Use:** Patients with hyperkalemia (or who have conditions predisposing them to hyperkalemia) Such conditions include chronic renal failure, uncontrolled diabetes mellitus, acute dehydration, strenuous physical exercise in unconditioned individuals, adrenal insufficiency, extensive tissue breakdown.

Patients for whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract such as those suffering from delayed gastric emptying, esophageal compression, intestinal obstruction or stricture

Patients with peptic ulcer disease.

Patients with active urinary tract infection.

Patients with renal insufficiency (glomerular filtration rate of less than 0.7 ml/kg/min)

### 2. HAZARDS IDENTIFICATION

Handling of this product in its final form presents minimal occupational exposure risk

**Classification:** Not classified

**Signal Word:** No data available

**Hazard Statement:** Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

### 3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration*</u>
Potassium Citrate	6100-05-6	≈ 89 %
Excipients	NA	≈ 11%

\* All Concentrations are percent by weight.

### 4. FIRST AID MEASURES

**Inhalation:** If breathing is difficult, move to fresh air, if not breathing give artificial respiration. Get medical attention immediately.

**Skin Contact:** Wash with soap and water for at least 15 minutes. Get medical attention if symptoms occur.

**Eye Contact:** Any material that contacts the eye should be washed out immediately with water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.

**Ingestion:** In case of accidental ingestion, give the victim several glasses of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Do not force an unconscious or convulsing person to drink liquids or to vomit. Seek medical attention immediately.

#### Overdose Treatment

Treatment measures for hyperkalemia include the following:

- Patients should be closely monitored for arrhythmias and electrolyte changes.
- Elimination of medications containing potassium and of agents with potassium sparing properties such as potassium-sparing diuretics, ARBs, ACE inhibitors, NSAIDs, certain nutritional supplements and many others.
- Elimination of foods containing high levels of potassium such as almonds, apricots, bananas, beans (lima, pinto, white), cantaloupe, carrot juice (canned), figs, grapefruit juice, halibut, milk, oat bran, potato (with skin), salmon, spinach, tuna and many others.
- Intravenous calcium gluconate if the patient is at no risk or low risk of developing



- digitalis toxicity.
- Intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1,000 mL.
  - Correction of acidosis, if present, with intravenous sodium bicarbonate.
  - Hemodialysis or peritoneal dialysis.
  - Exchange resins may be used. However, this measure alone is not sufficient for the acute treatment of hyperkalemia.
  - Lowering potassium levels too rapidly in patients taking digitalis can produce digitalis toxicity.

## 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area

**Unusual Fire & Explosion Hazards:** Not Applicable.

**Special Fire Fighting Procedures:** Wear full protective clothing and self-contained breathing apparatus.

**Protective Measures:** Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

**Environmental precautions:** Do not release in to the environment.

**Spill Cleanup methods:** Sweep up or vacuum up spillage and collect in suitable container for disposal. Should not be released into the environment. Do not flush to sewer. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. See section 13 of the SDS.

## 7. HANDLING AND STORAGE

**Handling:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's direction



**Storage:** Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light at USP Controlled Room Temperature: 20° to 25° C (68° to 77° F).

## 8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

**Protective Measures:** Not required when handling tablets or containers. Ventilation should be matched to conditions.

**Respiratory Protection:** Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

**Hand Protection:** Chemical resistant gloves.

**Eye Protection:** Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and Body Protection:** Not required when handling tablets. If containers are compromised or exposure is likely wear: Goggles, Lab Coat and Gloves

**Hygiene Measures:** Wash skin thoroughly with soap and water.

## 9.PHYSICAL AND CHEMICAL PROPERTIES

### **Physical Properties:**

**Physical State:** Solid

**Form:** Tablets

### **Appearance:**

**Potassium Citrate Extended-Release Tablets, USP 5 mEq K (540mg):** Off white to tan yellowish color round shaped uncoated tablet, de-bossed with “T” on one side and “399” on the other.

**Potassium Citrate Extended-Release Tablets, USP 10 mEq K (1080mg):** Off white to tan yellowish color capsule shaped uncoated tablet, de-bossed with” T400” on one side and “plain” on the other side.



**Potassium Citrate Extended-Release Tablets, USP 15 mEq K (1620mg):** Off white to tan yellowish color oval shaped uncoated tablet, de-bossed with T on one side and 401 on the other side.

## 10. STABILITY AND REACTIVITY

**Possibility of hazardous reactions:** Stable under ordinary conditions of use and storage.

**Conditions to avoid:** Excessive heat & Moisture.

**Incompatible materials:** Alkalis.

**Hazardous Decomposition products:** May produce Carbon oxides, Nitrogen oxides (NO<sub>x</sub>) & Hydrogen Citrate.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity:**

Active Ingredient:

LD50 Oral: 11.7 mg/kg

## 12. ECOLOGICAL INFORMATION

**General information:** The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

**Ecotoxicity:** No data available.

**Acute toxicity (Aquatic invertebrates):** No data available.

**Bioaccumulation:** No data available.

**Mobility:** No data available.

## 13. DISPOSAL CONSIDERATIONS

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



## **14. TRANSPORT INFORMATION**

**DOT:** Not Regulated

**IATA:** Not Regulated

## **15. REGULATORY INFORMATION**

Stated regulatory information chosen primarily for possible usage of Ascent Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

### **U.S. Regulatory Information**

**CERLA Hazardous Substance List:** None

**Superfund Amendments and Reauthorization Act (SARA):** None

## **16. OTHER INFORMATION**

SDS Sections Revised: New



## GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration
DEA	Drug Enforcement Administration

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