Safety Data Sheet
Potassium Citrate Extended- Release Tablets

Strength: 5 mEq, 10 mEq, 15 mEq **Pack Size:** 30/90/100/500/1000 Tablets per bottle **Revision No.:** 02
Unit dose blisters of 10X10 Tablets

EMERGENCY OVERVIEW

Each Potassium Citrate Extended-release Tablets intended for oral administration contains Potassium Citrate and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

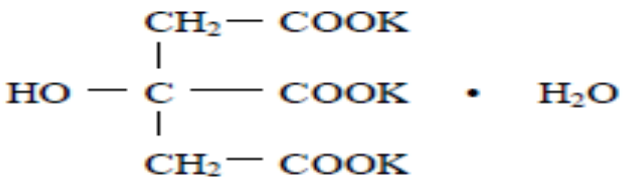
Section 1. Identification

Identification of the product

Product name: Potassium Citrate Extended-release Tablets

Formula : $K_3C_6H_5O_7 \cdot H_2O$

Chemical Name: 1, 2, 3-propanetricarboxylic acid, 2- hydroxy-, tripotassium salt, monohydrate



Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd. Ahmedabad, India**

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand.
Dist. Ahmedabad – 382210. State: Gujarat. India

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Recommended use / Therapeutic Category Urinary alkanizing agent

Restriction on Use / Contraindications: 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).

Section 2. Hazard(s) Information

Dose and Administration

Severe hypocitraturia (urinary citrate < 150 mg/day): therapy should be initiated at 60 mEq per day; a dose of 30 mEq two times per day or 20 mEq three times per day with meals or within 30 minutes after meals or bedtime snack.

Mild to moderate hypocitraturia (urinary citrate > 150 mg/day): therapy should be initiated at 30 mEq per day; a dose of 15 mEq two times per day or 10 mEq three times per day with meals or within 30 minutes after meals or bedtime snack.

Adverse Effects

Some patients may develop minor gastrointestinal complaints such as abdominal discomfort, vomiting, diarrhea, loose bowel movements or nausea. These may be alleviated by taking the dose with meals or snacks or by reducing the dosage.

Over Dose Effect

The administration of potassium salts to persons without predisposing conditions for hyperkalemia rarely causes serious hyperkalemia at recommended dosages. It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-wave, loss of P-wave, depression of S-T segment and prolongation of the QT interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest.

Medical Conditions

NA

Contraindications

- 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).

Pregnancy Comments It is also not known whether potassium citrate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium citrate should be given to a pregnant woman only if clearly needed.

Pregnancy Category C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Potassium citrate	Not Found	6100-05-6
Inactive Ingredients :		
Carnauba wax	Not Found	8015-86-9
Magnesium stearate	Not Found	577-04-0

Section 4. First - aid measures

General

Inhalation

Remove to fresh air. If not breathing give artificial respiration.
If breathing is difficult, give oxygen. Seek medical attention.

Contact with skin

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Contact with eyes

Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

Ingestion

If swallowed, wash out mouth with water, provided person is concious. Seek medical advice.

Remove and wash/dispose of contaminated clothing promptly.

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.

Section 5. Fire - fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	Not Found

Fire Fighting Procedure As with all fires, evacuate personnel to a safe area. Fire fighter 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 high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage Store at 20° to 25°C (68° to 77°F)
Dispense in a tight container.

Incompatibilities: No data available.

Section 8. Exposure controls / personal protection

Respiratory Protection Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing Protective clothing is not normally necessary, however it is good practice to use apron.

Engineering Control Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Section 9. Physical and chemical properties

Appearance Potassium Citrate Extended-release Tablets, 5 mEq are tan to yellowish color, round shaped, biconvex uncoated tablets debossed with “536” on one side and plain on the other side.

Potassium Citrate Extended-release Tablets, 10 mEq are tan to yellowish color, oval shaped, biconvex uncoated tablets debossed with “537” on one side and plain on the other side.

Potassium Citrate Extended-release Tablets, 15 mEq are tan to yellowish color, oblong shaped, biconvex uncoated tablets debossed with “538” on one side and plain on the other side.

Solubility in water	No Data Available	**Odour**	Odourless
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
% Volatile by volume	No Data Available	**Specific gravity**	No Data Available
		Vapour pressure	No Data Available

Other information Not available.

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities:	No data available.		

Section 11. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
Other	Not Available

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 203546

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.