Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Potassium Chloride Oral Solution
Product Use:	Potassium Chloride is indicated for the treatment and prophylaxis of hypokalemia in patients for whom dietary management with potassium-rich foods or diuretic dose reduction are insufficient.
Manufacturer's Name:	VistaPharm, Inc.
Address:	7265 Ulmerton Road Largo, FL 33771
Phone Number:	727-530-1633

In Case of Emergency Call National Poison Control: 800-222-1222

2. HAZARDS IDENTIFICATION

Emergency Overview	Physical State: Liquid solution administered orally. Orange color containing potassium chloride. Odor: No data available.
Primary Route of Entry:	Ingestion / Not hazardous
Potential Health Effects	Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form. Eye Contact: Not expected to be a hazard to the eye. Contact with eye may cause irritation, burning and redness. Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. Ingestion: Most common adverse reactions are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea.
Overdoseage:	The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly potentially fatal hyperkalemia can result. Hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration (6.5–8.0 mEq/L) and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest (9–12 mEq/L).

Treatment

Treatment measures for hyperkalemia include the following:

1. Monitor closely for arrhythmias and electrolyte changes.
2. Eliminate foods and medications containing potassium and of any agents with potassium-sparing properties such as potassium-sparing diuretics, ARBS, ACE inhibitors, NSAIDS, certain nutritional supplements and many others.
3. Administer intravenous calcium gluconate if the patient is at no risk or low risk of developing digitalis toxicity.
4. Administer intravenously 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1000 mL.
5. Correct acidosis, if present, with intravenous sodium bicarbonate.
6. Use exchange resins, hemodialysis, or peritoneal dialysis.

In patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Composition:	Potassium Chloride
CAS No:	7447-40-7
Chemical Name:	Potassium Chloride

Please refer to current package insert for other components.

4. FIRST AID MEASURES

Eye Exposure:	Immediately flush eyes with water and continue washing for several minutes. Obtain medical attention if discomfort persists.
Skin Exposure:	Remove contaminated clothing and shoes immediately. Wash affected area with soap and large amounts of water.
Inhalation:	Move to fresh air.
Ingestion:	If taken not as prescribed obtain medical attention or contact poison control center.

Special Protection Information

Ventilation:	Not required under normal conditions of therapeutic use.
Respiratory Protection:	Not required under normal conditions of therapeutic use.
Protective Gloves and Clothing:	Not required under normal conditions of therapeutic use.
Eye Protection:	Safety glasses recommended.

5. FIRE AND EXPLOSION HAZARD

This product does not pose a fire hazard.

Flash Point:	Not determined.

Extinguishing Media:	Water spray, multipurpose dry chemical, carbon dioxide or foam as appropriate for the surrounding fire or material.
Fire Fighting Procedures:	Use self contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

If Material is Spilled or Released:	Use proper personal protective equipment to avoid overexposure. Small spills can be absorbed with appropriate material, e.g. rags, paper towels. Large spills should be contained and vacuumed and placed in a suitable container. Dispose of the spilled material in compliance with federal, state and local regulations.

7. HANDLING AND STORAGE

Handling:	Observe good industrial hygiene practices.
Storage:	Store at Controlled Room Temperature, 25°C (77°F); excursions are permitted to 15° - 30°C (59° - 86°F). Dispense in a tight, light-resistant container as defined in the USP PROTECT from LIGHT.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

OSHA Exposure Limits:	None
Engineering Controls:	Not required when handling liquid or containers. Good ventilation should be use. Ventilation should be matched to conditions.
Respiratory Protection:	Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.
Personal Protection:	Not required when handling final product. If containers are compromised or exposure is likely wear: goggles, lab coat, and gloves.
Recommended Facilities:	Eye wash, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor:	Yellow-colored, Orange-flavor
Melting Point (deg. C):	Not determined.
Boiling Point (deg. C):	Not determined.
Solubility:	Soluble

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable
Conditions to Avoid:	Direct sunlight, extremely high or low temperatures
Incompatibility:	Strong acids, silver nitrate, strong oxidizers
Hazardous Decomposition:	Hydrogen chloride, potassium oxide

11. TOXICOLOGICAL INFORMATION

Acute Studies:

Oral LD50 (rat):	2600 mg/kg
Oral LD50 (mouse):	1500 mg/kg

Other Studies:

Pregnancy:	Pregnancy Category C: Animal reproduction studies have not been conducted with potassium chloride. It is unlikely that potassium supplementation that does not lead to hyperkalemia would have an adverse effect on the fetus or would affect reproductive capacity.
Nursing Mother:	The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.
Pediatric Use:	The safety and effectiveness of potassium chloride have been demonstrated in children with diarrhea and malnutrition from birth to18 years.
Geriatric Use:	Clinical studies of Potassium Chloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

12. ECOLOGICAL INFORMATION

Environmental Effects:	Not determined.

13. WASTE DISPOSAL INFORMATION

Waste Disposal Considerations:	Dispose of this material in accordance with applicable international, national, state and local waste disposal regulations.
At Home:	Discard away from children’s reach.

14. TRANSPORTATION INFORMATION

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.

15. REGULATORY INFORMATION

FDA:	Potassium Chloride is an approved prescription medication.
Inventory Status:	The material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use. This material is not listed on the DSL Inventory but is exempt.

16. DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for it particular purpose. VistaPharm, Inc. assumes no responsibility for the use of this information.

Date: November 2015

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION