

SAFETY DATA SHEET

Potassium Chloride Extended-Release Tablets USP

1. IDENTIFICATION

Manufacturer:

Emergency Phone:

Ascent Pharmaceuticals Inc 400 S. Technology Drive Central Islip, NY 11722 USP 1-855-221-1622

Common Name: Potassium Chloride Extended-Release Tablets, USP **Synonym(s):** Not Applicable

Trade Name(s): Potassium Chloride Extended-Release Tablets, USP 10 mEq, 15 mEq, 20 mEq.

2.HAZARDS IDENTIFICATION

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

Classification: Not classified

Label elements: Not classified

Other Hazards: No information available.

Unknown acute toxicity: No information available.



3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	CAS	Concentration*
Potassium Chloride	7447-40-7	<u>≈</u> 75 %
Excipients	NA	<u>≈</u> 25%

* 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

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 Chloride Extended-Release Tablets, USP 10mEq K (750mg): White modified capsules shaped biconvex tablets debossed with "A10" on one side and plain on other. Potassium Chloride Extended-Release Tablets, USP 15mEq K (1125mg): White modified capsules shaped biconvex tablets debossed with "A15" on one side and bisect on other.

Potassium Chloride Extended-Release Tablets, USP 20mEq K (1500mg): White modified capsules shaped biconvex tablets debossed with "A20" on one side and **bisect** on other.

10. STABILITY AND REACTIVITY

Stability/Incompatibility: The mixture is stable under normal conditions of use.

11.TOXICOLOGICAL INFORMATION

Carcinogenesis, mutagenesis, impairment of fertility: Carcinogenicity, mutagenicity and fertility studies in animals have not been performed. Potassium is a normal dietary constituent

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

Based on available data this drug product has been determined non-hazardous according

to USDOT/IATA criteria

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.

Toxic Substance Control Act (TSCA): Potassium chloride and Hydrogenated cottonseed oil are included on the TSCA inventory.

Clean Water Act (CWA): There are no ingredients in this mixture listed in the Clean Water Act.

Clean Air Act (CAA): There are no ingredients in this mixture listed under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information: There are no ingredients in this mixture listed under SARA.

16.OTHER INFORMATION

NFPA ratings Health: 1 Flammability: 0 Reactivity: 0 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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