

Safety data Sheet

Company Name: Stides Shasun Limited

Section 1: Identification

Product Identifier

Product name: Potassium citrate ER Tablets USP 5,10 and 15mEq

Trade name: Not Applicable

Product Code No.: 3007817 / 3007818 / 3007819

Relevant identified use of the substance or mixture and use advised against

Recommended Use: Finished pharmaceutical product as Urinary Alkalinizing 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

Details of the supplier of the safety data sheet: Strides Shasun Limited

Manufacturer name: Strides Shasun Limited

Address: Strides Shasun Ltd

Formulation Division

RS No: 32 -34, PIMS Road

Periyakalpet

Puducherry, India

Telephone Number- General: 91 0413 2655946

Emergency Telephone Number: : 0413-2655154 / 1-800-222-1222

Note: This safety data sheet is written to provide safety, health and environmental information for people handling the formulated product in the work place. It is not intended to provide information relevant to consumer use of the product (PIL will be applicable for consumer).

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Section 2: Hazard Identification:

Hazard Classification of the chemical mixture: No data Available

Signal Word: No data available

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

Label elements

Precautionary statements : Obtain special instructions before use

Storage/Disposal: Store at 20° to 25°C (68° to 77°F), Dispense in a tight container

EU Classification: This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

US GHS Classification: The product contains no substances which at their given concentration, are considered to be hazardous to health.

Section 3: Composition/Information on Ingredients

Mixtures: Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and EU EINECS.

Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Potassium Citrate (as monohydrate)	6100-05-6	540mg/1080/ 1620 mg	
Carnauba wax	8015-86-9	-	Not classified
Stearic acid	57-11-4	-	Not classified
Magnesium stearate	577-04-0	-	Not classified

Note: Percentage composition for in actives is not captured due to trade secret.

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Section 4: First aid measures

General Information:

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 conscious. 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.

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UN GHS/ EU EINECS:

Effects: Not applicable

Indication of any immediate medical attention and special treatment needed:

Notes for the doctor: Treat symptomatically.

Special treatment: No data available

Other information: no Data available

Section 5: Fire Fighting Measures

Extinguishing media

Suitable Extinguishing Media: Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

Unsuitable Extinguishing Media: No data reported

Firefighting Procedures: No data available

Unusual Fire and Explosion Hazards: No data available

Hazardous Combustion Products: In case of fire and/or explosion do not breathe fumes. Can be released in case of fire:, Carbon oxides, nitrogen oxides, hydrogen chloride, Sulphur oxides

Additional information: no data available

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation.

Emergency Procedures: No data available

Methods and material for containment and cleaning up

Containment/Cleanup Measures:

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.

Prohibited Materials: not known

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Section 7: Handling and Storage

Precautions for safe handling

Protective measures:

Safe Handling: use Glass, gloves and respirators.

Fire prevention: no data available

Dust generation preventions: No data available

Environmental precautions: Do not discharge into drains/surface waters/groundwater

Conditions for safe storage, including any incompatibilities: No data available

Technical measures and storage conditions: Requirements for storage rooms and vessels : Store in original container. Protect from heat and direct sunlight. Joint less smooth floor Keep container tightly closed. Advice on storage compatibility: Keep away from food, drink and animal feedingstuffs. Advice on Segregation Storage class according to VCI : 11 Combustible Solids

Special Packaging Materials: No data available

Requirement for storage rooms and assembly: No data available

Incompatible Materials or Ignition Sources: No data Available

Section 8: Exposure Controls and personal protection

Control Parameters:

Exposure Limits/ Guidelines: Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits			
Component Name	Result	OSHA	Other agency information
Potassium Citrate (as monohydrate)	TWAs/STELs	No Data	No data
Carnauba wax	PEL/TWA	No Data	No data
Stearic acid	TWA	No Data	No data
Magnesium stearate	PEL	Permissible Exposure Limits For Chemical Contaminants	10 mg/m3

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Exposure Controls

Engineering Controls:

Personal Protective Equipment:

Hands: Chemical resistant protective gloves (EN 374)

Eyes: Safety glasses with side-shields (frame goggles) (EN 166)

Skin: Laboratory: laboratory coat; factory: disposable Overall.

Respiratory protection: Use breathing apparatus if exposed to vapours/dust/aerosol. half mask (EN 140) particle filter P1 (EN 143)

Special requirements for PPE: Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.

Section 9: Physical and Chemical properties

Information on physical and chemical Properties

Material Description:

Physical form	Solid
Color	White
Odor	Odorless
Description	Crystalline powder

General Properties:

Boiling Point	Decompose below boiling point	Melting Point	230°C
Water Solubility	Soluble in cold water, hot water.	Solvent solubility	Water:1.780 g/ l
Specific Gravity/Relative Density	Not available	pH	7.5 – 9.0 (concentration :5g/l)
Decomposition Temperature	230°C	Viscosity	Not available
Density	900 Kg/m ³	Partition co -efficient	Not available

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Volatility and Flammability:

Vapor Pressure	Not Applicable	Vapor Density	1.98 (20° C)
Evaporation Rate	Not Applicable	UEL (Upper exposure Limit)	Not Applicable
Flash Point	Not Applicable	LEL (Lower Exposure Limit)	Not Applicable
Flammability (Solid, Gas)	Product is not flammable		

Section 10: Stability and Reactivity

Reactivity: No decomposition is stored and applied as directed.

Chemical Stability under normal ambient temperature: Stable under recommended storage conditions

Possibility of Hazardous Reactions: No data available

Any stabilizer requirement on storage: No data available

Conditions to Avoid: No data available

Incompatible materials: No data Available

Hazardous decomposition products: No data available

Section 11: Toxicological information

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual Ingredients.

Components		
Components	CAS No	Acute toxicity
Potassium Citrate (as monohydrate)	6100-05-6	ORAL (LD50): Acute: 11.700 mg/kg [Rat]
Carnauba wax	8015-86-9	Not available
Stearic acid	57-11-4	ORAL LD50: 4640 mg/kg (Rat)
Magnesium stearate	577-04-0	Not available

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Potential Health Effects

Inhalation

Acute (Immediate): Dust may cause respiratory tract irritation

Chronic (Delayed): No data available

Skin

Acute (Immediate): May cause skin irritation

Chronic (Delayed): No data available

Eye

Acute (Immediate): Dust may cause eye irritation

Chronic (Delayed): No data available

Ingestion

Acute (Immediate): No data available

Chronic (Delayed): No data available

Section 12: Ecological Information

Toxicity: No data Available

Persistence and degradability: No data Available

Bio accumulative potential: No data Available

Mobility in Soil: No data Available

Other adverse effects: No data Available

Section 13: Disposal Considerations

Product Waste: Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Packaging Waste: No data available

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Section 14: Transport information

UN Number	(Four digit number)
UN Shipper Name	No data Available
Transport Hazard Class	No data Available
Environmental Hazards	No data Available
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No data Available

Section 15: Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS No.:	CERCLA/SARA Reporting	Emission
Potassium Citrate (as monohydrate)	6100-05-6	Not listed	
Carnauba wax	8015-86-9	Not listed	
Stearic acid	57-11-4	Not listed	
Magnesium stearate	577-04-0	Not listed	

Note: Superfund Amendments and Reauthorization Act

Or Superfund or Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)

Section 16: Other information

MSDS was revised into new SDS format as per the Guidance of OSHA and GHS.

Reason for revision: Not Applicable

Revision date: Not Applicable

Revision No: Not Applicable