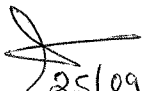


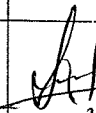



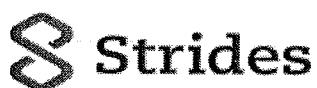
CERTIFICATE FOR SAFETY DATA SHEET

Name of the product: Potassium chloride Extended Release Tablets USP 8 mEq (600 mg) & 10 mEq (750 mg)

Product Code: 2002245, 2002246

SDS Number: SDS/D1-051-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	G. SIVAKUMAR REDDY	 25/09/18
Reviewed By (FD)	FD	Fazila	 25/09/18
Reviewed By (RA)	RA	K-S. PAVAN KUMAR	 25/09/18
Approved By (FD)	FD	Sudarshan Nimbaliker	 26/09/18
Authorized By (TSGQA/DQA)	DQ	S. GOPALNATH	 26/09/18



Safety data Sheet		
Company Name:	Strides Pharma Science Limited	SDS Number : SDS/D1-051-00
Section 1: Identification		
Product Identifier		
Product name:	Potassium chloride Extended Release Tablets USP 8 mEq (600 mg) & 10 mEq (750 mg)	
Trade name:	Not applicable	
Product Code No.:	2002245, 2002246	
Relevant identified use of the substance or mixture and use advised against		
Recommended Use:	For the therapeutic use of patients with hypokalemia, with or without metabolic alkalosis; in digitalis intoxication; and in patients with hypokalemic familial periodic paralysis. For the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop, e.g., digitalized patients or patients with significant cardiac arrhythmias.	
Restrictions on Use:	Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest.	
Details of the supplier of the safety data sheet:		
Manufacturer name:	Strides Pharma Science Limited	
Address:	Strides Pharma Science Limited No 36/7, Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bengaluru, Karnataka, India. 562106	
Telephone Number-General:	91 8067 840307/309	
Emergency Telephone Number:	91 8067 840307/309	
Note: <i>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).</i>		
Section 2: Hazard Identification:		
Hazard Classification of the chemical mixture:	Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.	
Signal Word:	Not classified	
Hazard Statement:	Not determined	
Label elements		
Precautionary statements	Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.	
Storage/Disposal:		
EU Classification:	Not classified	

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US GHS Classification:	Not available		
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 Chloride	7447-40-7	**	Not available
Hydrogenated Vegetable Oil	928771-01-1	**	Not available
Ethylcellulose	9004-57-3	**	Not available
Silicon Dioxide	14808-60-7	**	Not available
Talc	14807-96-6	**	Not available
Magnesium Stearate	557-04-0	**	Not available
Note: Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
General Information:			
Inhalation:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.		
Skin:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.		
Eye:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.		
Ingestion:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.		
Most important symptoms and effects both acute and delayed:			
Symptoms:	Ingestion may result in the following: gastrointestinal upset, alterations in blood chemistry, cardiac arrest.		
Other hazards	Not available		
UN GHS/ EU EINECS:			
Effects:	Not available		
Indication of any immediate medical attention and special treatment needed:			
Notes for the doctor:	Treat symptomatically		
Special treatment:	Not available		
Other information	Not available		

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Section 5: Fire Fighting Measures	
Extinguishing media	
Suitable Extinguishing Media:	Use extinguishing agent suitable for type of surrounding fire
Unsuitable Extinguishing Media:	Not determined
Firefighting Procedures:	As in any fire, wear self-contained breathing apparatus and full protective gear.
Unusual Fire and Explosion Hazards:	Not determined
Hazardous Combustion Products:	Not available
Additional information:	Not available
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
Personal Precautions:	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits. Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
Emergency Procedures:	Not applicable
Methods and material for containment and cleaning up	
Containment/Cleanup Measures:	Recover product and place in an appropriate container for disposal.
Prohibited Materials:	Not applicable
Section 7: Handling and Storage	
Precautions for safe handling	
Protective measures:	
Safe Handling:	Handle in accordance with good industrial hygiene and safety practice.
Fire prevention:	Not available
Dust generation preventions:	Not available
Environmental precautions:	Contain material and prevent release to waterways or soil.
Conditions for safe storage, including any incompatibilities:	Store according to label instructions.
Technical measures and storage conditions:	Not available
Special Packaging	Not available

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Materials:			
Requirement for storage rooms and assembly: Not available			
Incompatible Materials or Ignition Sources: Not available			
Section 8: Exposure Controls and personal protection			
Control Parameters:			
National limit values, Occupational exposure limit values (Workplace Exposure Limits), Relevant DNELs/DMELs/PNECs and other threshold levels			
Exposure Limits/ Guidelines: Refer to the occupational exposure limits / guidelines for the individual product components.			
Exposure Limits			
Component Name	TWAs/STELs/ WEEL Result	OSHA	Other agency information
Potassium Chloride	Not available	Not available	Not available
Hydrogenated Vegetable Oil	Not available	Not available	Not available
Ethylcellulose	Not available	Not available	Not available
Silicon Dioxide	Not available	Not available	Not available
Talc	2 (mg/m ³) from ACGIH (TLV) [United States] Respirable	2 (mg/m ³) from OSHA (PEL) [United States] Respirable	2 (mg/m ³) from NIOSH [United States] Respirable. 1 (mg/m ³) [United Kingdom (UK)] Respirable.
Magnesium Stearate	10 from ACGIH (TLV) [United States]	15 mg/m ³ , total dust; 5 mg/m ³ , respirable fraction	10 from ACGIH (TLV) [United States]
Exposure Controls			
Engineering Controls:	No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.		
Personal Protective Equipment:			
Hands:	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.		
Eyes:	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.		
Skin:	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.		
Respiratory protection:	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable		



	limits.		
Special requirements for PPE :	Not needed during normal product use.		
Section 9: Physical and Chemical properties			
Information on physical and chemical Properties			
Material Description:			
Physical form	Tablet		
Color	Blue color (600 mg) & Yellow color (750 mg)		
Odor	Not determined		
General Properties:			
Boiling Point	Not determined	Melting Point	Not determined
Water Solubility	Not determined	Solvent solubility	Not determined
Specific Gravity/Relative Density	Not determined	pH	Not determined
Decomposition Temperature	Not determined	Viscosity	Not determined
Density	Not determined	Partition co - efficient	Not determined
Volatility and Flammability:			
Vapor Pressure	Not available	Vapor Density	Not available
Evaporation Rate	Not available	UEL (Upper exposure Limit)	Not available
Flash Point	Not available	LEL (Lower Exposure Limit)	Not available
Flammability (Solid, Gas)	Not available		
Section 10: Stability and Reactivity			
Reactivity:	Not determined		
Chemical Stability under normal ambient temperature:	Stable under normal conditions		
Possibility of Hazardous Reactions:	Not determined.		
Any stabilizer requirement on storage:	Not available		
Conditions to Avoid:	Not determined.		
Incompatible materials:	Not determined.		
Hazardous decomposition products:	Not determined.		

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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 Chloride	7447-40-7	LD50, Rat Guinea Pigs, Mice 1500-2600 mg/kg
Hydrogenated Vegetable Oil	928771-01-1	Oral = Low toxicity: LD50 > 5000 mg/kg , Rat Skin = Expected to be of low toxicity: LD50 >2000 mg/kg , Rabbit
Ethylcellulose	9004-57-3	Not available
Silicon Dioxide	14808-60-7	LD50, Rat > 3160 mg/kg
Talc	14807-96-6	LD50, Rat > 1600 mg/kg
Magnesium Stearate	557-04-0	LD50, Rat > 10 g/kg
Potential Health Effects		
Inhalation		
Acute (Immediate):	Not determined.	
Chronic (Delayed):	Not determined.	
Skin		
Acute (Immediate):	Practically non-irritating in an eye irritation test	
Chronic (Delayed):	Not determined.	
Eye		
Acute (Immediate):	Not determined.	
Chronic (Delayed):	Not determined.	
Ingestion		
Acute (Immediate):	Not determined.	
Chronic (Delayed):	Not determined.	
Section 12: Ecological Information		
Toxicity:	Not determined.	
Persistence and degradability:	Not determined.	
Bio accumulative potential:	Not determined.	
Mobility in Soil:	Not determined.	
Other adverse effects:	Not determined.	

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Section 13: Disposal Considerations		
Product Waste:	Disposal should be made in accordance with country, federal, state and local regulations.	
Packaging Waste:	Not available	
Section 14: Transport information		
UN Number	Not applicable	
UN Shipper Name	Not applicable	
Transport Hazard Class	Not applicable	
Environmental Hazards	Not applicable	
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable	
Section 15: Regulatory Information		
Safety, health and environmental regulations/legislation specific for the substance or mixture		
Component	CAS No.:	CERCLA/SARA Emission Reporting
Potassium Chloride	7447-40-7	Not listed
Hydrogenated Vegetable Oil	928771-01-1	Not listed
Ethylcellulose	9004-57-3	Not listed
Silicon Dioxide	14808-60-7	Not listed
Talc	14807-96-6	Not listed
Magnesium Stearate	557-04-0	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		
Reason for revision: (Include Change control number)	New safety data sheet prepared.	
Revision date :	25/09/2018	
Version Number:	00	