

SAFETY DATA SHEET

Section 1: Identification	
Product Name	Spironolactone Oral Suspension, 25 mg/5 mL
Recommended use	Treatment of heart failure and hypertension and management of edema
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Health Hazards	May cause damage to organs through prolonged or repeated exposure. May damage fertility or the unborn child. May cause harm to breast-fed children
Precautionary Statements	Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash hands and face thoroughly after handling. Keep away from heat, sparks and open flames. Do not eat, drink, or smoke when using this product. Do not breathe dust/fume/gas/mist/vapors/spray
Hazards not otherwise classified	None classified
Section 3: Composition/Information on Ingredients	
Active Ingredient	CAS
Spironolactone	52-01-7
Microcrystalline Cellulose & Carboxy methyl cellulose sodium	NA
Glycerine	56-81-5
Saccharin Sodium	128-44-9
Simethicone Emulsion	8050-81-5
Sorbic acid	110-44-1
Potassium sorbate	24634-61-5
Ammonium Glycyrrhizate	53956-04-0
Malic Acid	6915-15-7
Dibasic sodium phosphate anhydrous	7558-79-4

Banana FL ART	NA
Section 4: First-Aid Measures	
Eye Contact	Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately
Skin Contact	Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention
Ingestion	Do not induce vomiting. Wash out mouth with copious amounts of water. Seek medical attention immediately
Inhalation	Remove affected person to fresh air and keep patient at rest. Seek medical attention immediately
Most Important Symptoms/Effects Acute or delayed	Repeated or prolonged exposure may cause hypercalcaemia, hyponatremia and other renal dysfunction.
Notes to physicians or First Aid providers	This product should only be given to patients by medical professionals educated in the therapy intended for this product. Treat any symptoms and eliminate exposure.
Section 5: Fire-Fighting Measures	
Suitable Extinguishing Media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials
Unsuitable Extinguishing Media	None known
Unusual Fire and Explosion Hazards	May form sulfur and/or carbon oxides under combustion
Special Fire Fighting Procedures	Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.
Section 6: Accidental Release Measures	
Personal Precautions	Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Minimize the generation of aerosols. Remove all sources of heat and ignition.

Methods/Materials Used for containment & cleaning	Use an inert absorbent material to remove and collect spillage. Minimize the generation of aerosols. Dampen remaining residue with water, then clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labelled container for disposal. Observe all applicable regulations when disposing of this substance
Section 7: Handling and Storage	
Handling Precautions	Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. Wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse.
Storage Precautions	Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Shake well before use. Dispense in a tight container as defined in the USP
8. Exposure controls / personal protection	
Engineering controls	In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit
PERSONAL PROTECTIVE EQUIPMENT (PPE)	
Eye Protection	Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur
Skin Protection	Avoid unintended skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

Respiratory Protection	<p>If exposure limits are exceeded, approved respiratory protection should be worn.</p> <p>Seek professional assistance for proper selection of respiratory protection</p>				
Section 9: Physical and Chemical Properties					
Physical State	Suspension				
Description	<p>Spironolactone oral suspension 25 mg/5 mL is a white to off-white, banana flavored suspension.</p> <p>It is available in a</p> <table> <tr> <td>118 mL bottle</td><td>NDC 31722-691-11</td></tr> <tr> <td>473 mL bottle</td><td>NDC 31722-691-47</td></tr> </table>	118 mL bottle	NDC 31722-691-11	473 mL bottle	NDC 31722-691-47
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Section 10: Stability and Reactivity					
Reactivity	No available data				
Chemical stability	Material is stable under normal conditions				
Possibility of Hazardous Reactions	Danger of dust explosion when handling solid drug substance				
Conditions to avoid	Intense heat				
Incompatible materials	Strong oxidizing agents				
Hazardous Decomposition Products	Under fire conditions, thermal decomposition may generate sulfur and/or carbon oxides				
Section 11: Toxicological Information					
Ingestion	In an occupational setting, ingestion of this product is unlikely. Ingestion may cause irritation				
Inhalation	Although unlikely due to product form, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon exposure to fresh air				
Skin contact	May be absorbed through the skin. Active ingredient has blood pressure lowering effects				
Eye contact	Avoid contact with eyes. May cause irritation of the eyes				
Signs and symptoms of overexposure	Possible gastrointestinal discomfort, dizziness, and/or headache				

Chronic effects	May include possible hypersensitivity, gastrointestinal discomfort, or effects on blood and blood forming organs
Acute toxicity Values	LD 50 for active ingredient (oral, rat) = > 1 g/kg
Section 12: Ecological Information	
Ecological Information	This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility. Care should be taken to avoid environmental release.
Section 13: Disposal Considerations	
Waste disposal method	It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials
Waste disposal Containers	Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations
Section 14: Transport Information	
U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101	
Section 15: Regulatory Information	
U.S. FEDERAL REGULATIONS TOXIC SUBSTANCE CONTROL ACT (TSCA): All components of this product are included on the TSCA inventory	

Section 16: Other Information, including date of preparation or last revision

Issue Date: 13-12-2024

Version: 00

Further information : NA

Revision date: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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