

SAFETY DATA SHEET

Section 1: Identification	
Material	Eplerenone Tablets, 25 mg and 50 mg
Recommended use	Pharmaceutical product used as, cardiovascular drug
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	
Statement of Hazard	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information: Short Term	May cause eye and skin irritation if tablets are crushed or broken (based on components). Accidental ingestion may cause effects similar to those seen in clinical use.
Known Clinical Effects	Effects reported during clinical use include headache, dizziness, decrease in blood pressure (hypotension), increased potassium, nausea, diarrhea, and insomnia
Australian Hazard Classification (NOHSC):	Non-Hazardous Substance. Non-Dangerous Goods
Section 3: Composition/Information on Ingredients	
Ingredient	CAS
Eplerenone	107724-20-9
Croscarmellose Sodium	74811-65-7
Hypromellose	9004-65-3
Lactose Monohydrate	10039-26-6
Magnesium Stearate	557-04-0
Microcrystalline Cellulose	9004-34-6
Opadry Yellow	NA
Sodium Lauryl Sulfate	151-21-3
Talc	14807-96-6
Section 4: First-Aid Measures	
Eye Contact	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention

Skin Contact	Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately
Section 5: Fire-Fighting Measures	
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray
Hazardous Combustion Products	Not determined
Fire Fighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards	Not applicable
Section 6: Accidental Release Measures	
Health and Safety Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
Section 7: Handling and Storage	
General Handling	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Minimize dust generation and accumulation.
Storage Conditions	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. Exposure controls / personal protection	
Analytical Method	An analytical method may be available for the compound(s) listed above (Contact Greenstone for additional details)
Engineering Controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep
Personal Protective Equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes	Wear safety glasses or goggles if eye contact is possible
Skin	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations
Respiratory protection	Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
Section 9: Physical and Chemical Properties	
Physical State	Tablet
Description	<p>Eplerenone Tablets 25 mg are light yellow, round, biconvex, film coated tablets debossed with “V” on one side and “68” on the other side.</p> <p>Bottle of 30 NDC 31722-049-30 Bottle of 90 NDC 31722-049-90</p> <p>Eplerenone Tablets 50 mg are light yellow, round, biconvex, film coated tablets debossed with “V” on one side and “67” on the other side.</p> <p>Bottle of 30 NDC 31722-050-30 Bottle of 90 NDC 31722-050-90</p>
Section 10: Stability and Reactivity	
Stability	Stable at normal conditions
Conditions to Avoid	None known
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers

Section 11: Toxicological Information	
General Information	The information included in this section describes the potential hazards of the individual ingredients
<u>Acute Toxicity: (Species, Route, End Point, Dose)</u>	
Eplerenone Rat Oral Minimum Lethal Dose > 2000 mg/kg Mouse Oral Minimum Symptomatic Dose > 300mg/kg Dog Oral Minimum Symptomatic Dose 500mg/kg	
<u>Irritation / Sensitization: (Study Type, Species, Severity)</u>	
Eplerenone Eye Irritation Rabbit Minimal Skin Irritation Rabbit Mild Skin Sensitization - GPMT Guinea Pig Negative	
<u>Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)</u>	
Eplerenone 13 Week(s) Rat Oral 500 mg/kg/day LOAEL Kidney 13 Week(s) Dog Oral 1.5 mg/kg/day NOEL Male reproductive system	
<u>Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))</u>	
Eplerenone Reproductive & Fertility-Males Rat Oral 1000 mg/kg/day LOAEL Fertility Embryo/ Fetal Development Rat Oral 1000 mg/kg/day LOAEL Maternal Toxicity, Fetotoxicity Embryo / Fetal Development Rabbit Oral 300 mg/kg/day LOAEL Maternal Toxicity, Fetotoxicity Embryo / Fetal Development Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose	
<u>Genetic Toxicity: (Study Type, Cell Type/Organism, Result)</u>	
Eplerenone Bacterial Mutagenicity (Ames) Negative Mammalian Cell Mutagenicity Mouse Lymphoma Negative Chromosome Aberration Negative Unscheduled DNA Synthesis Negative In Vitro Micronucleus Negative	
<u>Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))</u>	
Eplerenone 6 Month(s) Mouse Oral 1000 mg/kg/day NOEL Not carcinogenic 2 Year(s) Male Rat Oral 75 mg/kg/day LOEL Benign tumors, Thyroid 2 Year(s) Female Rat Oral 250 LOEL Benign tumors, Thyroid	

Section 12: Ecological Information	
Environmental Overview	Environmental properties have not been investigated. Releases to the environment should be avoided.
Section 13: Disposal Considerations	
Disposal Procedures	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
Section 14: Transport Information	
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.	
Section 15: Regulatory Information	
<p>EU Indication of danger: Not classified</p> <p>OSHA Label: Non-hazardous in accordance with international standards for workplace safety.</p> <p>Canada - WHMIS: Classifications</p> <p>WHMIS hazard class: None required</p> <p>This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.</p> <p>Eplerenone</p> <p>Standard for the Uniform Scheduling Schedule 4</p>	

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

Issue Date: 29-08-2023

Version: 00

Further information

Revision date: NA

Revision note: NA

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