



RE: **Eplerenone Tablets 25mg, 50mg**

25mg (30s) NDC # 51991-877-33
25mg (90s) NDC # 51991-877-90

50mg (30s) NDC # 51991-878-33
50mg (90s) NDC # 51991-878-90

To Whom It May Concern:

The purpose of the OSHA Hazard Communication Standard (HCS) is to ensure that hazards of all chemicals produced by a manufacturer are classified and these classified hazards are communicated to employers and employees through a Safety Data Sheet (SDS).

As per 29 CFR 1910.1200(b)(6)(vii) Occupational Safety and Health Administration (OSHA), any food or drug, as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act), is exempt from the HCS and does not require a SDS if it is in its final solid dosage form and/or it is packaged by the chemical manufacturer for sale to the consumers in a retail establishment.

“Any drug as that term is defined in the Federal Food Drug and Cosmetic Act (21 U.S.C. 301 et seq.) when it is in solid, final form for direct administration to the patient (e.g., tablets or pills): drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs): and drug intended for personal consumption by employees while in the workplace (e.g., first aid supplies):”

Breckenridge Pharmaceutical Inc.’s products are regulated by the FD&C Act and are subject to the labeling requirements as governed by the Act and the FDA. Breckenridge Pharmaceutical Inc.’s products are manufactured to their final dosage forms and are packaged for sale to consumers.

Breckenridge Pharmaceutical Inc. is exempt from OSHA requirements for an SDS for the product mentioned above, However the SDS for the Active Ingredient for this product is attached as a service to our customers, to help them to comply with the regulations depending on how the product is used.

Please contact us if you have any further questions.

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SAFETY DATA SHEET

Product Name

Eplerenone Tablets 25 mg and 50 mg

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1. Identification of the substance/mixture and the company/undertaking**Product Name:** Eplerenone Tablets 25 mg and 50 mg**Chemical Family:** Mixture**Intended use:** Pharmaceutical product used as cardiovascular drug**Details of the manufacturer:**

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +91 40 3044 9200

2. Hazards Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients Moderate to severe irritant to the skin and eyes.

3. Composition/Information on Ingredients

C.A.S. No : 107724-20-9

Molecular Formula : $C_{24}H_{30}N_6$

Molecular Weight : 414.49

Chemical Name : (7 α .,11 α ,17 α)-9,11-epoxy-17-hydroxy-3-oxopregn-4-ene-7, 21-dicarboxylic acid
 γ -lactone methyl ester**4. First Aid Measures****Eye Contact:** Check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.**Skin Contact:** flush with copious amounts of water; remove contaminated clothing and shoes; call a physician.**Ingestion:** If swallowed, wash out mouth with copious amounts of water; call a physician.**Inhalation:** If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration.

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5. Fire Fighting Measures

Extinguishing media: Extinguish fire with carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds

Fire Fighting Procedures: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. 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.

7. Handling and Storage

General Handling: Minimize dust generation and accumulation. 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. Wash hands and any exposed skin after removal of PPE. Refer to Section 13 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

Storage Conditions: Store below 25°C

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8. Exposure Controls/Personal Protection

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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: 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.

Ireland OEL - TWAs = 10 mg/m³ TWA = 4 mg/m³

9. Physical and Chemical Properties**Appearance:**

25 mg : Yellowish red color diamond shaped biconvex film coated tablets, debossed with "E" on one side and "25" on other side.

50 mg : Yellowish red color diamond shaped biconvex film coated tablets, debossed with "E" on one side and "50" on other side.

10. Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

11. Toxicological Information

- Eplerenone
- Rat Oral Minimum Lethal Dose > 2000 mg/kg Rat Oral LD50 > 7500 mg/kg
Mouse Oral Minimum Symptomatic Dose > 300 mg/kg
Dog Oral Minimum Symptomatic Dose 500 mg/kg

12. Ecological Information

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

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

14. Transport Information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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15. Regulatory Information

D.O.T. Proper Shipping Name: Not Regulated

Hazard Class: N/A

Identification Number: N/A

Packing Group: N/A

Label: N/A

Emergency Response Guide Book: N/A

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.