

**Attach 2: Material Safety Data Sheet****Section 1. Product And Company Identification**

*Product name:* Spironolactone

*Chemical name:* 17-Hydroxy-7 $\alpha$ -mercapto-3-oxo-17 $\alpha$ -pregn-4-ene-21-carboxylic acid  $\gamma$ -lactone acetate

*Molecular formula:* C<sub>24</sub>H<sub>32</sub>O<sub>4</sub>S *Molecular weight:* 416.57

*CAS No.:* 52-01-7

*RTECS No.:* TU4725000

*Chemical family:* Synthetic steroid

*Therapeutic category:* Diuretic; aldosterone antagonist

*Manufacturer:* Zhejiang Xinhua Pharmaceutical Co., Ltd.

*Address of corporate head quarters and Manufacturing facility:*

Zhejiang provincial chemical and medical materials base Linhai zone, Linhai,  
Zhejiang, China

*Fax:* 86-576-5588368;

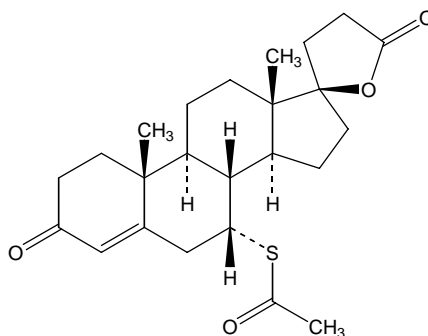
*Tel:* 86-576-5588341

**Section 2. Composition / Information on Ingredients**

*Product name:* Spironolactone

*Chemical name:* 17-Hydroxy-7 $\alpha$ -mercapto-3-oxo-17 $\alpha$ -pregn-4-ene-21-carboxylic acid  $\gamma$ -lactone acetate

*Structure:*



*Molecular formula:* C<sub>24</sub>H<sub>32</sub>O<sub>4</sub>S *Molecular weight:* 416.57

*CAS No.:* 52-01-7

**Section 3. Hazards Identification**

*Usual adult dose:* The usual oral adult dose of spironolactone is 25 to 400 mg a day in two to four divided doses.

*Adverse effects:* Adverse effects may include increased urination; confusion; irregular heartbeat; nervousness; numbness or tingling in hands, feet, or lips; difficulty breathing; unusual tiredness; weakness in legs; clumsiness; headache; decreased sexual ability; dizziness; nausea or vomiting; stomach cramps; diarrhea; drowsiness; dry mouth; increased thirst; and sweating. Females may experience breast tenderness, deepening of voice, increased hair growth, and menstrual irregularities. Males may experience enlargement of breasts and impotence. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

*Overdose effects:* n/f.

*Acute:* Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

*Chronic:* Possible hypersensitization.

*Inhalation:* May cause irritation. Avoid inhalation. Remove to fresh air.

*Eye:* may cause irritation. Flush with copious quantities of water.

*Skin:* May cause irritation. Flush with copious quantities of water.

*Ingestion:* May cause irritation. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.

*Medical Conditions Aggravated by Exposure:* Hypersensitivity to the material, hyperkalemia, anuria, kidney or liver function impairment and diabetic nephropathy.

*Cross sensitivity:* n/f

*Pregnancy comments:* Pregnancy problems in humans have not been documented.

*Pregnancy category:* C

#### **Section 4. First Aid Measures**

*General:* Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

*Overdose treatment:* Overdose should be treated by immediate evacuation of the stomach followed by supportive, symptomatic treatment and monitoring of serum electrolyte concentrations and renal functions.

#### **Section 5: Firefighting Measures**

*Flash point:* n/f; *Auto-Ignition temperature:* n/f;

*Upper flammable limit:* n/f; *Lower flammable limit:* n/f

*Extinguisher Media:* Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

*Fire and explosion hazards:* This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

*Firefighting Procedures:* As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

#### **Section 6: Accidental release measures**

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

#### **Section 7: Handling and storage**

*Handling:* As a general rule, when handling chemical substances avoid all contact and inhalation of dust, mist, and/or vapors associated with the material. Wash thoroughly after handling.

*Storage:* Store in tight containers as defined in USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

*Spill Response:* Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

*Disposal:* Dispose of waste in accordance with all applicable Federal, State and local laws.

#### **Section 8: Exposure controls, personal Protection**

*Respiratory Protection:* When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

*Ventilation:* No special ventilation requirements.

*Gloves:* Rubber.

*Eye Protection:* Safety Goggles.

*Protective Clothing:* Protect exposed skin.

#### **Section 9. Physical and Chemical Properties**

*Appearance and odor:* White or off-white crystalline powder; faint mercaptan-like odor.

*Melting Point:* 198~209 °C (decompose)

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| <p><i>Solubility in water:</i> Practically insoluble.</p> <p>Vapor density: n/f; Evaporation rate: n/f; Boiling point: n/f; Specific Gravity: n/f</p> <p>Reactivity in Water: n/f; Vapor pressure: n/f; % Volatile by volume: n/f</p>  |
| <p style="text-align: center;"><b>Section 10. Stability and Reactivity</b></p> <p><i>Conditions to Avoid:</i> Avoid exposure to light</p> <p><i>Incompatibilities:</i> acid, alkali, oxidant</p> <p><i>Decomposition Products:</i> When heated to decomposition material emits foxic fumes of Sox.</p> <p>Emits toxic fumes under fire conditions.</p> <p><i>Stable:</i> yes      <i>Hazardous Polymerization?</i> No</p>  |
| <p style="text-align: center;"><b>Section 11. Toxicological properties</b></p> <p><i>Oral Rat:</i> LD50:&gt;1000mg/kg</p> <p><i>Oral Mouse:</i> LD50:&gt;1000mg/kg</p> <p><i>Irritancy Data:</i> n/f</p> <p><i>Target Organ (s):</i> n/f</p> <p>Listed as a Carcinogen? NTP: No IARC: No OSHA: No</p> <p><i>Other:</i> this material is not classifiable as to its carcinogenicity in humans. Breast carcinoma has been reported in men and women taking this medication, but a direct causal relationship has not yet been established. Spironolactone has been found to be tumoring.</p> |
| <p style="text-align: center;"><b>Section 12. Ecological in formation</b></p> <p>n/f</p>   |
| <p style="text-align: center;"><b>Section 13. Disposal Considerations</b></p> <p>Incinerate in an approval facility.</p> <p>Observe related environmental regulations.</p>   |
| <p style="text-align: center;"><b>Section 14. Transport Information</b></p> <p>n/f</p>   |
| <p style="text-align: center;"><b>Section 15. Regulatory Information</b></p> <p>n/f</p>  |
| <p style="text-align: center;"><b>Section 16. Other Information</b></p> <p>n/f</p>   |