

## TIANJIN JINJIN PHARMACEUTICAL CO., LTD

Industrial Zone of Zhangjiawo Town, Xiqing District Economic and Development Area, Tianjin, China Tel: 0086-22-87982602 Fax: 0086-22-87982950 Postcode: 300380

E-mail: qa@jinjinpharm.com http://www.jinjinpharm.com

### **SECTION 1-IDENTIFICATION**

#### 1.1 Product identifier

**Product: SPIRONOLACTONE** 

**CAS No:** 52-01-7

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Main use category: API or manufacture of substance.

1.2.2 Uses advised against

No additional information available

1.3 Details of the supplier of the safety data sheet

Company: Tianjin Jinjin Pharmaceutical Co.,Ltd.

**Telephone / Fax :** 0086-022-87982602 / 0086-022-87982950

### **SECTION 2- HAZARDS IDENTIFICATION**

#### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Repr. 1A H360F Repr. 2 H351 STOTRE 2 H373

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Carc.Cat.3; R40 Repr.Cat.1; R60 Xn; R48/22

Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP): GHS08 Signal word (CLP): Warning



### **Hazard statements (CLP):**

H351 - Suspected of causing cancer

H360F - May damage fertility

H373 - May cause damage to organs through prolonged or repeated exposure

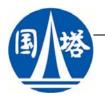
### **Precautionary statements (CLP):**

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P281 - Use personal protective equipment as required



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P314 - Get medical advice/attention if you feel unwell

P501 - Dispose of contents/container to: Hazardous waste. Comply with applicable regulations

#### 2.3 Other hazards

Other hazards not contributing to the classification: Exposure may produce an allergic reaction.

## SECTION 3- COMPOSITION/INFROMATION ON INGREDIENT

ComponentsCAS NumberPercent by weightSPIRONOLACTONE52-01-797%-103%(HPLC)

**Chemical Name:** 

7-(Acetylthio)-17-hydroxy-3-oxopregn-4-ene-21-carboxylic acid gamma-lactone

### **SECTION 4-FIRST AID MEASURES**

### 4.1 Description of first aid measures

**First-aid measures general:** If you feel unwell, seek medical advice (show the label where possible). Delayed adverse effects possible. Active component. Pharmaceuticals. For further information refer to Summary of Product Characteristics.

**First-aid measures after inhalation:** Move to fresh air in case of accidental inhalation. Assure fresh air breathing. Obtain medical attention if breathing difficulty persists.

**First-aid measures after skin contact:** Rinse skin with water/shower. Wash with plenty of soap and water.

**First-aid measures after eye contact:** Rinse with water while holding the eyes wide open. Contact lenses should be removed. Obtain medical attention if pain, blinking or redness persist.

**First-aid measures after ingestion:** Rinse mouth out with water. The following symptoms may occur: (see section(s): 2, 4.2). If you feel unwell, seek medical advice. Prolonged medical observation may be indicated. (see section(s): 4.3). The affected person must rest and be kept under medical observation..

### 4.2 Most important symptoms and effects, both acute and delayed

**Symptoms/injuries:** See Heading 2. Cardiac disorders. Disturbances of heart rate. cardiac arrhythmias. Chest pain. Vascular disorders. May cause headache and dizziness. Sweating.

### 4.3 Indication of any immediate medical attention and special treatment needed

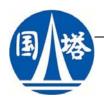
In all cases of doubt, or when symptoms persist, seek medical attention. If possible show this sheet, if not available show packaging or label. If the occupational exposure limit is exceeded: Specific medical surveillance. Cardiac arrest: perform resuscitation.

### **SECTION 5- FIRE FIGHTING MEASURES**

### 5.1 Extinguishing media

**Suitable extinguishing media:** Small amounts: Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder. Large amounts: Not applicable.

Unsuitable extinguishing media: Water may be ineffective in firefighting due to low



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solubility.

### 5.2 Special hazards arising from the substance or mixture

### No additional information available

#### **5.3** Advice for firefighters

**Precautionary measures fire:** Small amounts: Use normal individual fire protective equipment. Large amounts: Not applicable.

### SECTION 6- ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

**General measures:** Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Avoid any direct contact with the product. Evacuate unnecessary personnel. Large amounts: Not applicable.

### **6.1.1 For non-emergency personnel**

**Protective equipment:** See Headings 7 and 8.

**Emergency procedures:** Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Wear suitable protective clothing and gloves.

### **6.1.2** For emergency responders

### No additional information available

### **6.2 Environmental precautions**

No additional information available

### 6.3 Methods and material for containment and cleaning up

**Methods for cleaning up:** Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents. Collect all waste in suitable and labelled containers and dispose according to local legislation. Wash the non-recoverable remainder with: Sodium hypochlorite solution.

### **6.4 Reference to other sections**

See section(s): 8, 13

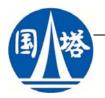
### **SECTION 7- HANDLING AND STORAGE**

### 7.1 Precautions for safe handling

Additional hazards when processed: Small amounts: See Heading 1. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended. Avoid contact during pregnancy/while nursing.

**Precautions for safe handling:** Handle and open container with care. See Heading 8. Do not handle until all safety precautions have been read and understood. Avoid any direct contact with the product. Obtain special instructions before use.

**Hygiene measures:** Handle in accordance with good industrial hygiene and safety procedures. Small amounts: Material should be handled in a laboratory hood whenever possible Handle in accordance with good industrial hygiene and safety procedures.



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### 7.2 Conditions for safe storage, including any incompatibilities

Technical measures: Comply with applicable regulations.

Storage conditions: Protected from light.

Incompatible products: Strong oxidizing agents.

### 7.3 Specific end use(s)

See Heading 1.

### **SECTION 8- EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

No additional information available

### 8.2 Exposure controls

**Appropriate engineering controls:** Material should be handled in a laboratory hood whenever possible.

**Personal protective equipment:** Gloves. Safety glasses. Protective clothing. Dust production: dust mask with filter type P3.

**Hand protection:** Gloves. Chemical resistant PVC gloves (to European standard EN 374 or equivalent).

**Eye protection:** Wear eye protection. DIN EN 166.

Skin and body protection: Lab coat. Wear suitable protective clothing. DIN EN 13034.

**Respiratory protection:** Quarter mask (DIN EN 140). Wear appropriate breathing apparatus if air renewal not sufficient to maintain dust/vapour under TLV.

### **SECTION 9-PHYSICAL AND CHEMICAL PROPERTIES**

### 9.1 Information on basic physical and chemical properties

Physical state: Solid

**Appearance:** White or yellowish - white powder.

### 9.2 Other information

No additional information available

### SECTION 10- STABILITY AND REACTIVITY

- 10.1 Reactivity: Stable under normal conditions.
- 10.2 Chemical stability: No additional information available
- 10.3 Possibility of hazardous reactions

Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

Large amounts: Not applicable.

10.4 Conditions to avoid: No additional information available

### 10.5 Incompatible materials

Small amounts: None under normal use. Large amounts: Not applicable.

### 10.6 Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. Large amounts: Not applicable.



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### SECTION 11- TOXICOLOGICAL INFORMATION

## 11.1 Information on toxicological effects

**Acute toxicity:** Not classified **LD50 oral rat:** 4121 mg/kg

Skin corrosion/irritation: Not classified Serious eye damage/irritation: Not classified Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Suspected of causing cancer Reproductive toxicity: May damage fertility.

Specific target organ toxicity (single exposure): Not classified

**Specific target organ toxicity (repeated exposure):** May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Not classified

**Potential Adverse human health effects and symptoms:** Avoid any direct contact with the product. Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: Not applicable.

### **SECTION 12- ECOLOGICAL INFORMATION**

### 12.1 Toxicity

**Ecology - general:** Small amounts: See Heading 2. Poorly soluble in water. No data available on ecotoxicity. Hazardous waste. Use suitable disposal containers. Large amounts: Not applicable.

- 12.2 Persistence and degradability: No additional information available
- 12.3 Bioaccumulative potential: Log Pow 3,56 at 20°C
- 12.4 Mobility in soil: No additional information available
- 12.5 Results of PBT and vPvB assessment: No additional information available
- 12.6 Other adverse effects: No additional information available

### SECTION 13 DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

**Regional legislation (waste):** Dispose in a safe manner in accordance with local/national regulations.

**Waste disposal recommendations:** Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

### **SECTION 14 TRANSPORT INFORMATION**

In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA

- **14.1 UN number:** No dangerous good in sense of transport regulations
- 14.2 UN proper shipping name: Not applicable
- 14.3 Transport hazard class(es): Not applicable
- 14.4 Packing group: Not applicable
- 14.5 Environmental hazards: Other information: No supplementary information available.



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### 14.6 Special precautions for user

**14.6.1 Overland transport:** No additional information available **14.6.2 Transport by sea:** No additional information available **14.6.3 Air transport:** No additional information available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

### **SECTION 15 REGULATORY INFORMATION**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1 EU-Regulations: No REACH Annex XVII restrictions 15.1.2 National regulations: No additional information available 15.2 Chemical safety assessment: No additional information available

### **SECTION 16 OTHER INFORMATION**

### Full text of R-, H- and EUH-phrases::

Carc. 2: Carcinogenicity, Category 2

Repr. 1A: Reproductive toxicity, Category 1A

**STOTRE 2:** Specific target organ toxicity — Repeated exposure, Category 2

H351: Suspected of causing cancer

**H360F:** May damage fertility

H373: May cause damage to organs through prolonged or repeated exposure

**R40:** Limited evidence of a carcinogenic effect

R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed

**R60:** May impair fertility

Xn: Harmful