

## SAFETY DATA SHEET

### 1. Identification

<b>Product identifier:</b>	Prednisone
<b>Chemical name:</b>	Pregna-1,4-diene-3,11,20-trione, 17,21-dihydroxy-1-Dehydrocortisone
<b>Synonym(s):</b>	1-Dehydrocortisone
<b>Recommended use of the chemical and restrictions on use:</b>	Drug substance: 1) for R&D purpose (analytical testing &) formulation studies. 2) for further manufacturing, process or repacking
<b>Manufacturer information:</b>	
<b>Company name:</b>	Taizhou Xianju Pharmaceutical Co., Ltd
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### 2. Hazard(s) identification

#### Classification of the substance or mixture

<b>Physical hazards:</b>	Not classified
<b>Health hazards:</b>	Reproductive toxicity Category 2 Specific target organ toxicity, repeated exposure Category 1 (endocrine system)
<b>OSHA hazard(s):</b>	Not classified
<b>Hazard statement:</b>	Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure.

#### Label elements

##### Pictograms:



**Signal word:** Danger

##### Precautionary statements:

**Prevention:** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

<b>Response:</b>	If exposed or concerned: Get medical advice/attention.
<b>Storage:</b>	Preserve in tightly closed containers, protected from light. Store at 0°C to 30°C.
<b>Disposal:</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Other hazards which do not result in classification:</b>	Not classified.

### 3. Composition/information on ingredients

<b>Molecular formula:</b>	C <sub>21</sub> H <sub>26</sub> O <sub>5</sub>
<b>Molecular weight:</b>	358.44
<b>Chemical name:</b>	Prednisone
<b>CAS number:</b>	53-03-2
<b>Concentration:</b>	100%

### 4. First-aid measures

<b>Inhalation:</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact:</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact:</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion:</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms /effects, acute and delayed:</b>	Fluid and electrolyte disturbances. Mood or mental changes.
<b>General information:</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
<b>Indication of immediate medical attention and special treatment needed:</b>	Treatment of corticosteroid overdose should be symptomatic and supportive and may include the following: Toxicity is low after acute ingestion. Gastrointestinal decontamination is generally not necessary. (Poisindex)

### 5. Fire-fighting measures

<b>Suitable extinguishing media:</b>	Use fire-extinguishing media appropriate for surrounding materials. Foam. Dry chemical or CO <sub>2</sub> .
<b>Unsuitable extinguishing</b>	None known.

**media:**

**Specific hazards arising from the chemical:** No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters:** Wear suitable protective equipment.

**Fire-fighting equipment/instructions:** Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods:** Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

**Methods and materials for containment and cleaning up:** Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

## 7. Handling and storage

**Precautions for safe handling:** As a general rule, when handling, 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. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

**Conditions for safe storage, including any incompatibilities:** Preserve in tightly closed containers, protected from light. Store at 0°C to 30°C.

## 8. Exposure controls/personal protection

### Exposure limit values

#### Industrial Use

Material	Type	Value
Prednisone (CAS 53-03-2)	STEL	40 micrograms/m <sup>3</sup>
	TWA	5 micrograms/m <sup>3</sup>

**Biological limit values:** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering** Airborne exposure should be controlled primarily by engineering controls

**controls:** such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

**Individual protection measures, such as personal protective equipment:**

**Eye/face protection:** Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection is preferred. Maintain eyewash facilities in the work area.

**Skin protection:**

**Hand protection:** Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact.

Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

**Other:** For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

**Respiratory protection:** Where respirators are deemed necessary to reduce or control occupational exposures.

**Thermal hazards:** Not available.

**General hygiene considerations:** Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

**Appearance:** White or almost white crystalline powder.

**Physical state:** Solid.

**Form:** Powder.

**Odor:** Odorless

**Odor threshold:** Not available



<b>pH:</b>	Not available
<b>Melting point/ freezing point:</b>	446-455 °F (230-235 °C)
<b>Initial boiling point and boiling:</b>	Not available.
<b>Flash point:</b>	Not available.
<b>Evaporation rate:</b>	Not available.
<b>Flammability (solid, gas):</b>	Not available.
<b>Upper/lower flammability or explosive limits:</b>	
<b>Flammability limit - lower(%):</b>	Not available.
<b>Flammability limit - upper(%):</b>	Not available.
<b>Explosive limit - lower (%):</b>	Not available.
<b>Explosive limit - upper (%):</b>	Not available.
<b>Vapor density:</b>	Not available.
<b>Relative density:</b>	Not available.
<b>Solubility in water:</b>	Very slightly soluble.
<b>Partition coefficient (n-octanol/water):</b>	1.46
<b>Auto-ignition temperature:</b>	Not available.
<b>Decomposition temperature:</b>	Not available.
<b>Viscosity:</b>	Not available.
<b>Other information:</b>	
<b>Chemical family:</b>	Corticosteroid.
<b>Solubility (other):</b>	Slightly soluble in ethanol, in chloroform, in dioxane, and in methanol.

## 10. Stability and reactivity

<b>Reactivity:</b>	No reactivity hazards known.
<b>Chemical stability:</b>	Stable at normal conditions.
<b>Possibility of hazardous reactions:</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid:</b>	None known
<b>Incompatible materials:</b>	Strong oxidizing agents
<b>Hazardous decomposition products:</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

Information on likely routes of exposure:

<b>Ingestion:</b>	Due to lack of data the classification is not possible.
<b>Inhalation:</b>	Due to lack of data the classification is not possible.
<b>Skin contact:</b>	Due to lack of data the classification is not possible.
<b>Eye contact:</b>	Due to lack of data the classification is not possible.
<b>Symptoms related to the physical, chemical, and toxicological characteristics:</b>	Mineralocorticoid effects: Swelling. Confusion. Lightheadedness. Nausea. Vomiting. Numbness. Tremors. Glucocorticoid effects: Bone fractures. Back pain. Joint pain or stiffness. Weakness. Increased appetite. Infection. Delayed wound healing. Thinning skin. Bruising. Purple lines on skin. Increased hair growth. Acne. Redistribution of body fat. Menstrual irregularities. Impotence. Headache. Increased sweating. Eye pain. Change in vision. Mental or behavioral changes. Withdrawal effects: Fever. Muscle pain. Joint pain. Malaise.
<b>Delayed and immediate effects of exposure</b>	Corticosteroids: Fluid and electrolyte imbalance. Cushing's syndrome. Adrenal suppression. Immune system depression. Withdrawal.
<b>Cross sensitivity</b>	Persons sensitive to one corticosteroid may be sensitive to this material also.
<b>Medical conditions aggravated by exposure:</b>	Corticosteroids: Heart disease. High blood pressure. Diabetes. Epilepsy. Glaucoma. Hypothyroidism. Osteoporosis. Peptic ulcer. Systemic fungal infection. Mental disorders. Impaired liver or kidney function.

**Acute toxicity:**

<b>Product</b>	<b>Species</b>	<b>Test Results</b>
Prednisone (CAS 53-03-2)		
<b>Acute</b>		
<i>Oral</i>	Mouse	101 mg/kg

**Skin corrosion/irritation:** Due to lack of data the classification is not possible.

**Serious eye damage/eye irritation:** Due to lack of data the classification is not possible.

**Respiratory sensitization:** Due to lack of data the classification is not possible.

**Skin sensitization:** Due to lack of data the classification is not possible.

**Germ cell mutagenicity:** Due to lack of data the classification is not possible.

**Mutagenicity**

Data from germ cell mutagenicity tests were not found.  
Ames test in Salmonella, with and without activation  
Result: Negative  
In vivo chromosome aberration studies in rat bone marrow  
Result: Negative  
In vivo human studies  
Result: Negative; no chromosome damage to peripheral lymphocytes.  
Mouse lymphoma studies, without activation  
Result: Negative

<b>Carcinogenicity:</b>	Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA. 5 mg/kg/day Long-term carcinogenicity study, Result: Negative. Species: Mouse
<b>Reproductive toxicity:</b>	Suspected of damaging fertility or the unborn child. Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in the incidence of cleft palate was seen in some human studies. Infants born to mothers who received substantial doses of corticosteroids during pregnancy should be observed for signs of hypoadrenalism.
<b>Reproductivity</b>	10 mg/day Epidemiological study Result: Statistically significant decrease in birth weights of term infants. Species: Human
<b>Specific target organ toxicity-single exposure:</b>	Based on available data, the classification criteria are not met.
<b>Specific target organ toxicity-repeated exposure:</b>	Causes damage to organs (endocrine system) through prolonged or repeated exposure.
<b>Aspiration hazard:</b>	Based on available data, the classification criteria are not met.

## 12. Ecological information

### Ecotoxicity:

Product	Species	Test Results
Prednisone (CAS 53-03-2)		
Aquatic		
Acute		
Algae	IC50	Algae 31 mg/l, 72 hours

**Persistence and degradability:** No data is available on the degradability of this product.

**Bioaccumulative potential:** Not available.

**Mobility in soil:** Not available.

**Other adverse effects:** Not available.

## 13. Disposal considerations

**Disposal instructions:** Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

**Local disposal** Dispose of in accordance with local regulations.

**regulations:**

<b>Hazardous waste code:</b>	Not available.
<b>Waste from residues/ unused products:</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging:</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information**

<b>DOT:</b>	Not regulated as a hazardous material by DOT.
<b>IATA:</b>	Not regulated as a dangerous good.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:</b>	No information available.

**15. Regulatory information**

<b>US federal regulations:</b>	CERCLA/SARA Hazardous Substances - Not applicable. All components are on the U.S. EPA TSCA Inventory List.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA):</b>	
<b>Hazard categories:</b>	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance:</b>	No
<b>SARA 311/312 Hazardous chemical:</b>	No
<b>Other federal regulations:</b>	
<b>Safe Drinking Water Act (SDWA):</b>	Not regulated.
<b>Food and Drug Administration (FDA):</b>	Not regulated.
<b>US state regulations:</b>	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**16. Other information, including date of preparation or last revision**



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