

Safety data sheet

In compliance with Regulation (CE) n. 1907/2006 and (UE) n. 453/2010 (Annex I)

SECTION 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY/ UNDERTAKING

1.1. Product identifier

Commercial name:	PREDNISOLONE
Synonyms:	1,4-pregnadiene-3,20-dione-11 β ,17 α ,21-triol 1,4-pregnadiene-11 β ,17 α ,21-triol-3,20-dione 3,20-dioxo-11 β ,17 α ,21-trihydroxy-1,4-pregnadiene
CLP Classification and Labelling Inventory name:	
CAS:	50-24-8
EINECS:	200-021-7
Chemical name:	11-beta,17-alpha,21-trihydroxypregna-1,4-diene-3,20-dione
REACH Registration number:	No.

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

Identified uses:	For Manufacturing, processing or repacking.
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1.3. Details of the supplier of the safety data sheet

Company name:	HENAN LIHUA PHARMACEUTICAL CO., LTD.
Address:	MIDDLE OF HUANGHE STREET, ANYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE, HENAN, CHINA
Telephone number:	+86-372-2595136
E-mail address of the competent person responsible for safety data sheet:	henanlihua@vip.sina.com

1.4. Emergency telephone number

Mr. Li Bin (9:00 AM to 17:30 PM) at Henan Lihua Pharmaceutical Co., Ltd. Tel. +86-372-2595136

SECTION 2 HAZARD IDENTIFICATION

2.1 Classification of the substance

- According to Directive 67/548/CEE:

Classification	Risk phrases
GHS07/08	

- According to n. 1272/2008 (CE) Regulation:

Hazard class and category	Hazard statements
GHS07/08	H332: Harmful if inhaled.

	<p>H312: Harmful in contact with skin. H302 Harmful if swallowed. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H315 Causes skin burns. H361d Suspected of damaging the unborn child.</p>
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Rif. Section 16 for full text.

- Most important adverse effects:

See sections from 9 to 12.

2.2 Label elements

- Labelling according to n. 1272/2008 (CE) Regulation:

Hazard pictogram	
Signal Word	Warning
Hazard statements	H332 - 312 - 302 - 319 - 335 - 315 - 361d
Precautionary statements	No

2.3 Other hazards

None.

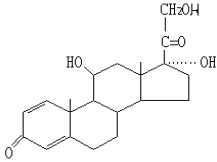
The substance is:

- PBT
- vPvB

YES	NO
	x
	x

**SECTION 3
COMPOSITION / INFORMATION ON INGREDIENTS**

Substances :

<i>Name:</i>	Prednisolone
<i>Structure:</i>	
<i>Formula:</i>	C ₂₁ H ₂₈ O ₅
<i>Molecular mass:</i>	360.44
<i>CAS name:</i>	(11β)-11,17,21-Trihydroxypregna-1,4-diene-3,20-dione
<i>CAS number:</i>	50-24-8
<i>EC number:</i>	200-021-7
<i>REACH Registration number:</i>	No.
<i>Impurities</i>	97.0-103%

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

- *Eye contact:* Flush with copious amounts of water for at least 15 minutes. Get medical attention in case of adverse reactions.
- *Skin contact:* Remove contaminated clothing and shoes. Wash with water and soap. Get medical attention in case of adverse reactions.
- *Ingestion:* Flush out mouth with water provided is conscious. Get medical attention in case of adverse reactions.
- *Inhalation:* Remove from exposure. If not breathing give artificial respiration. If breathing is difficult give oxygen. Get medical attention in case of adverse reactions.

4.2 Most important symptoms and effects, both acute and delayed

- *Acute effects:* Not available.
- *Delayed effects:* Not available.

4.3 Indication of any immediate medical attention and special treatment needed

- *Clinical testing and medical monitoring for delayed effects:* Not available.
- *Antidotes and contraindications:* Not Available.

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

- *Suitable extinguishing media:* Water spray, carbon dioxide, dry chemical powder or appropriate foam.
- *Unsuitable extinguishing media:* Not known

5.2 Special hazards arising from the substance or mixture

- *Hazardous combustion products:* Emits toxic fumes when heated to decomposition or under fire conditions. Do not breathe fumes or dust.

5.3 Advice for fire-fighters

- *Advices on protective actions:* Keep containers cool with water spray.
- *Special protective equipment for fire-fighters:* Wear boots, overall, gloves, eye and face protection and breathing apparatus in compliance with law.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- Protective equipment
- *Eye:* Wear approved safety goggles
- *Skin:* Wear approved clothing
- *Respiration:* Wear approved full face respirator P3

6.2 Environmental precautions

In case of accidental release or spill, keep away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up

- *Methods to contain spill and to clean-up spillage:* Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). If emergency, enforce internal emergency plan.

6.4 Reference to other sections

Consult sections 8 and 13

SECTION 7 HANDLING AND STORAGE

7.1. Precautions for safe handling

- *Handling:* Keep away from heat and flames. Avoid powder dispersion. Avoid contact with incompatible substances. Avoid: direct contact with skin and eyes; inhalation of vapours and fumes. Wear appropriate PPE (See section 8).
- *Occupational hygiene:* Do not eat, drink or smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Store at room temperature.
Keep away from heat, sparks and ignition sources. Keep in well- sealed labelled containers away from light.
Keep in a ventilated place. Avoid direct sun light. Avoid static discharges formation.
Store in accordance with all current regulations and standards.

7.3. Specific end uses

None.

	YES	NO
- Exposure scenario		X

- Chemical Safety Report		X
- Other risk evaluations available		X

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

- | | |
|--|---|
| - National limit values: | Not available. |
| - Other limit values: | Not available. |
| - National biological limit value (BEI): | Not available. |
| - Monitoring procedures: | Monitoring of substances in work environment shall be done with standard methods or with appropriate methods and in compliance with national law. |

8.2. Exposure controls

Provide adequate exposition controls.

8.2.1. Appropriate engineering controls

Provide adequate engineering control measures in confined plants or with local exhaust ventilation systems, to avoid powder dispersion.

8.2.2. Individual protection measures, such as personal protective equipment

- | | |
|----------------------------|---------------------------|
| a) Eye/face protection: | Wear eye protection. |
| b) Skin protection | |
| - <i>Hand protection:</i> | Wear protective gloves. |
| - <i>Body protection:</i> | Wear Protective clothing. |
| c) Respiratory protection: | Wear face protection. |

8.2.3 Environmental exposure controls

If exposed or concerned: Get medical advice/attention.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

- | | |
|---|--|
| Appearance: | White or almost white, crystalline, hygroscopic powder |
| Odor: | Not available |
| Odor threshold: | Not available |
| pH | About 7.0 |
| Melting point/freezing point: | Not available |
| Initial boiling point and boiling range: | Not available |
| Evaporation rate: | Not available |
| Flash point: | Not available |
| Upper/lower flammability or explosive limits: | Not available |

Vapor pressure:	Not available
Vapor density:	Not available
Relative density:	Not available
Water solubility:	Very slightly sol in water
Partition coefficient: n-octanol/water:	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity:	Not available
Explosive properties:	Not available
Oxidizing properties:	Not available

9.2. Other Information

Not available for data lacking.

SECTION 10 STABILITY AND REACTIVITY

10.1. Reactivity

The substance is an organic compound, may create in particular conditions (ex. temperature, pressure, powder granulometry, humidity, oxygen concentration) explosive mixtures with air. In case of accidental release remove all sources of ignition and ventilate gradually the area.

10.2. Chemical stability

The substance is stable in normal conditions of temperature and pressure and if stocked in closed containers in cold and ventilated area.

10.3. Possibility of hazardous reactions

The substance is an organic compound, may create in particular conditions (ex. temperature, pressure, powder granulometry, humidity, oxygen concentration) explosive mixtures with air. In case of accidental release, remove all sources of ignition and ventilate gradually the area.

10.4. Conditions to avoid

Keep away from heat, flames, sources of ignition and static discharges.

10.5. Incompatible materials

Strong oxidizing agents, acids and bases.

10.6. Hazardous decomposition products

When heated to decomposition or under fire conditions material emits toxic fumes of carbon monoxide and carbon dioxide gas.

SECTION 11 TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

- **Acute toxicity:** Not available
- *LD50 Oral rat:*
- *LD50 Subcutaneous rat:*
- *LD50 Intra-peritoneal rat:*

- **Corrosion/irritation:**
 - Skin:* Causes skin burns
 - Eyes:* Causes serious eye irritation.
 - Inhalation:* May cause respiratory irritation

- **Sensitization:** Not applicable.
- *Skin:*
- *Respiratory:*

- **CMR effects:** Not applicable.
- Germ cell mutagenicity:
- Carcinogenicity:
- Reproductive toxicity:

- **STOT-single exposure:**
Not available for data lacking.

- **STOT-repeated exposure:**
Not available for data lacking.

SECTION 12 ECOLOGICAL INFORMATION

12.1. Toxicity

Acute toxicity for Daphnia Magna: Not available
Acute toxicity for algae: Not available

12.2. Persistence and degradability

Not available for data lacking.

12.3. Bioaccumulative potential

Not available for data lacking.

12.4. Mobility in soil

Not available for data lacking.

12.5. Results of PBT and vPvB assessment

No Chemical Safety Report done.

12.6. Other adverse effects

None.

**SECTION 13
DISPOSAL CONSIDERATIONS**

13.1. Waste treatment methods

Dispose of in accordance with local regulations.

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

**SECTION 14
TRANSPORT INFORMATION**

- UN Number: not applicable.
- UN proper shipping name: not applicable.
- Transport hazard classes: not applicable.
 - ADR/RID/ADN: not applicable.
 - IMDG code: not applicable.
 - IATA/ICAO: not applicable.
- Packing group: not applicable.
- Environmental hazards
 - ADR/RID: not applicable.
 - Marine pollutant: not applicable.
- Special precautions for users
 - EMS code: not applicable
 - ADR/RID-hazard number: not applicable.
- 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

- Dir. 67/548/CE and modifies: n. 1907/2006/CE (REACH) Regulation, n. 1272/2008/CE (CLP) Regulation, n. 790/2009/CE Regulation.
- D.Lgs. 81/2008 and modifies and Dir. 2009/161/UE.
- D.Lgs. 334/1999 and modifies.

15.2. Chemical Safety Assessment

	YES	NO
- Exposure scenario		X
- Chemical Safety Report		X

**SECTION 16
OTHER INFORMATION**

Revision:

- **Revision n. date** : Version 001/ Dec. 21, 2010

Sections modified: N/A

- **Full text of classification phrases:**

H-PHRASES:

H332: Harmful if inhaled.

H312: Harmful in contact with skin.

H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H315 Causes skin burns.
H361d Suspected of damaging the unborn child.

P-PHRASES: None

R-PHRASES: None

- Abbreviations and acronyms

- ACGIH: American Conference of Governmental Industrial Hygienists
- BEI: Biological Exposure Indices
- CAS: Chemical Abstract Service (division of the American Chemical Society)
- CLP: Classification, Labeling and Packaging
- CMR: (substances) Carcinogenic, mutagens or toxic for reproduction
- PPE: Personal Protective Equipment
- EINECS: European Inventory of Existing Commercial Chemical Substances
- GHS: Global Harmonized System
- IARC: International Agency for Research on Cancer
- IUPAC: International Union of Pure and Applied Chemistry
- OSHA: Occupational Safety and Health Administration
- PBT: Persistent, Bioaccumulative and Toxic substances
- TLV/TWA: Threshold Limit Value (a level to which it is believed a worker can be exposed day after day for a working lifetime without adverse health effects)
- vPvB: very Persistent and very Bioaccumulative
- NIOSH: The National Institute for Occupational Safety and Health

NOTICE TO USERS

This document is intended to provide guidance on appropriate handling and precaution of this substance by qualified personnel or working under the supervision of personnel trained in handling chemicals. The substance should not be used for purposes other than those mentioned in Section 1, unless they have been given adequate written information on how to handle the material. The head of this document can not provide any warnings about the dangers arising from the use or interaction with other chemicals or materials. The safe use of the substance, the adequacy of the substance for the purpose for which it is applied and proper disposal are under user's responsibility. The information below should not be considered a representation or warranty, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS is in accordance with Annex I of Regulation No 453/2010/EU.