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SAFETY DATA SHEET

1. Identification

Product identifier:	**Dexamethasone**
Chemical name:	9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione
Synonym(s):	/
Recommended use of the chemical and restrictions on use:	Drug substance for further manufacturing, process or repacking. For Human Compounding/Rx Only.
Manufacturer information:	
Company name:	Zhejiang Xianju Pharmaceutical Co., Ltd
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2. Hazard(s) identification

Classification of the substance or mixture

Physical hazards:	Not classified	
Health hazards:	Serious eye damage/eye irritation	Category 2B
	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (endocrine system)
OSHA hazard(s):	Not classified	
Hazard statement:	Causes eye irritation. 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.
Response:	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention.
Storage:	Preserve in well-closed containers.
Disposal:	Dispose of contents/container in accordance with local/regional/national/ international regulations.
Other hazards which do not result in classification:	Not classified.

3. Composition/information on ingredients

Molecular formula:	$C_{22}H_{29}FO_5$
Molecular weight:	392.46
Chemical name:	Dexamethasone
CAS number:	50-02-0
Concentration:	100%

4. First-aid measures

Inhalation:	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact:	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact:	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion:	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms /effects, acute and delayed:	Endocrine system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
General information:	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.
Indication of immediate medical attention and special treatment needed:	Treat symptomatically. Treatment of corticosteroid overdose may include the following: Toxicity is low after acute ingestion. Gastrointestinal decontamination is generally not necessary.

5. Fire-fighting measures

Suitable extinguishing	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media

media:	appropriate for surrounding materials.
Unsuitable extinguishing media:	None known.
Specific hazards arising from the chemical:	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
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:	Cool containers exposed to flames with water until well after the fire is out.
General fire hazards	No unusual fire or explosion hazards noted.

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.
Environmental precautions:	Avoid discharge into drains, water courses or onto the ground.
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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

incompatibilities:

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Dexamethasone (CAS 50-02-2)	TWA	3 micrograms/m3

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

Exposure guidelines: No exposure standards allocated.

Appropriate engineering controls: Airborne exposure should be controlled primarily by engineering 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: Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other: Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

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

Thermal hazards: Wear appropriate thermal protective clothing, when necessary.

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

9. Physical and chemical properties

Appearance:	White to almost white crystalline powder.
Physical state:	Solid.
Form:	Powder.
Odor:	Odorless
Odor threshold:	Not available
pH:	Not available
Melting point/ freezing point:	503.6 - 507.2 °F (262 - 264 °C)
Initial boiling point and boiling:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid, gas):	Not available.
Upper/lower flammability or explosive limits:	
Flammability limit - lower(%):	Not available.
Flammability limit - upper(%):	Not available.
Explosive limit - lower (%):	Not available.
Explosive limit - upper (%):	Not available.
Vapor pressure:	< 0.0000001 kPa (77 °F (25 °C))
Vapor density:	Not available.
Relative density:	Not available.
Solubility in water:	Very slightly soluble.
Partition coefficient (n-octanol/water):	1.62
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Other information:	**Chemical family:** Corticosteroid.

10. Stability and reactivity

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability:	Stable at normal conditions.
Possibility of hazardous reactions:	No dangerous reaction known under conditions of normal use.
Conditions to avoid:	Avoid temperatures exceeding the decomposition temperature. Contact with incompatible materials.
Incompatible materials:	Strong oxidizing agents. Strong acids. Acid chlorides. Acid anhydrides.

Hazardous decomposition products:	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure:

Ingestion:	Based on information from therapeutic use, this material may cause: Endocrine effects.
Inhalation:	Knowledge about health hazard is incomplete.
Skin contact:	Knowledge about health hazard is incomplete.
Eye contact:	Causes eye irritation.
Symptoms related to the physical, chemical, and toxicological characteristics:	Corticosteroids: Fluid and electrolyte imbalance. Adrenal suppression. Immunosuppression. Cushing's syndrome. High blood pressure. Gastrointestinal disturbances. Headache. Lightheadedness. Weakness. Visual disturbances. Mood or mental status changes. Infection. Thinning skin. Swelling. Bruising. Bone fractures. Back pain. Joint pain. Tremors. Menstrual irregularities. Impotence.

Acute toxicity:

Product	**Species**	**Test Results**
Dexamethasone (CAS 50-02-2)		
Acute *Oral*	Mouse	6.5 g/kg
LD50	Rat	more than 3 g/kg

Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation:	Causes eye irritation.
Local effects	Eye irritation Result: Irritant. Species: Rabbit Severity: Mild. Skin irritation Result: Irritant. Species: Rabbit Severity: Mild.
Respiratory sensitization:	Knowledge about health hazard is incomplete.
Skin sensitization:	Knowledge about health hazard is incomplete.
Germ cell mutagenicity:	Knowledge about health hazard is incomplete.
Mutagenicity	Ames test (Salmonella typhimurium) Result: Negative Micronucleus test Result: Positive Mutagenicity: human lymphocytes Result: Positive
Carcinogenicity:	Knowledge about carcinogenicity is incomplete.

Reproductive toxicity:	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. Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects.
Reproductivity	1 mg/kg/day Reproductivity, Caused structural malformations in the offspring. Result: Positive Species: Rat Reproductivity, Fetotoxicity; increased incidence of malformations at maternally toxic doses. Result: Positive
Specific target organ toxicity-single exposure:	Knowledge about health hazard is incomplete.
Specific target organ toxicity-repeated exposure:	Causes damage to organs (endocrine system) through prolonged or repeated exposure.
Further information:	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity:	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability:	No data is available on the degradability of this product.
Bioaccumulative potential:	Octanol/water partition coefficient log Kow: 1.83
Mobility in soil:	No data available.
Other adverse effects:	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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 regulations:	Dispose of in accordance with local regulations.

Hazardous waste code:	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues/ unused products:	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).
Contaminated packaging:	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

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

15. Regulatory information

US federal regulations:	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
Superfund Amendments and Reauthorization Act of 1986 (SARA):	
SARA 302 Extremely hazardous substance:	Not listed
SARA 311/312 Hazardous chemical:	Yes
Classified hazard categories	Serious eye damage or eye irritation Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
SARA 313 (TRI reporting)	Not regulated.
Other federal regulations:	
Safe Drinking Water Act (SDWA):	Not regulated.
US state regulations:	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

Issue date:	18-9-2020
Version #:	01
Further information:	Not available.