

SAFETY DATA SHEETS

According to the UN GHS revision 8

Version: 1.0

Creation Date: July 15, 2019

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1. Identification

1.1 GHS Product identifier

Product name Dexamethasone

1.2 Other means of identification

Product number D80001

Other names

1.3 Recommended use of the chemical and restrictions on use

Identified uses Veterinary Drug: GLUCOCORTICOSTEROID

Uses advised against no data available

1.4 Supplier's details

Company Tianjin Psaitong Biomedical Technology Co., Ltd

Beijing Psaitong Biotechnology Co., Ltd

Address Building 145, Yougu New Science Park, Qingguang Town, Beichen District, Tianjin City

Tel/Fax +86-10-60605840

1.5 Emergency phone number

Emergency phone number +86-10-60605840

Service hours Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

2. Hazard identification

2.1 Classification of the substance or mixture

Reproductive toxicity, Category 2

Specific target organ toxicity – repeated exposure, Category 2

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word Warning

Hazard statement(s) H373 May cause damage to organs through prolonged or repeated exposure

Precautionary statement(s)

Prevention

P201 Obtain special instructions before use.

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

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

Response

P308+P313 IF exposed or concerned: Get medical advice/ attention.

P314 Get medical advice/attention if you feel unwell.

Storage

P405 Store locked up.

Disposal

P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

2.3 Other hazards which do not result in classification

no data available

3. Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Dexamethasone	Dexamethasone	50-02-2	200-003-9	100%

4. First-aid measures

4.1 Description of necessary first-aid measures

General advice

Medical attention is required. Consult a doctor. Show this safety data sheet (SDS) to the doctor in attendance.

If inhaled

Fresh air, rest. Half-upright position. Refer immediately for medical attention.

Following skin contact

Rinse skin with plenty of water or shower. Seek medical attention if you feel unwell.

Following eye contact

First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then refer for medical attention.

Following ingestion

Rinse mouth. Do NOT induce vomiting. Give one or two glasses of water to drink. Refer immediately for medical attention.

4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this type of compound include fluid and electrolyte disturbances, pituitary-adrenal suppression, hyperglycemia, increased susceptibility to infection including tuberculosis, myopathy, growth arrest, hypokalemic alkalosis and Cushing's syndrome consisting of "moon-face", "buffalo-hump", striae, acne and hirsutism. Other symptoms of Cushing's syndrome include enlargement of supraclavicular fat pads, "central obesity" and ecchymoses. Flushing and increased bruising may also occur with this syndrome. Other symptoms of exposure include behavioral disturbances, glycosuria, nervousness, changes in mood or psyche, psychopathies of the manic-depressive or schizophrenic type and suicidal tendencies. Exposure may cause candidiasis, gluconeogenesis, cardiac failure (in extreme cases), spontaneous fractures, increased appetite, delayed wound healing, hyperhidrosis, mental and neurological disturbances, intracranial hypertension and increase in coagulability of the blood. It may also cause peptic ulceration with perforation or hemorrhage, amenorrhea, aseptic necrosis of the bone, muscular weakness, salt and water retention, hypertension, edema, increase in severity of diabetes, pancreatitis, thrombotic episodes and osteoporosis. Other symptoms of exposure to this type of compound include sleeplessness, skin eruptions, depression, euphoria, decrease in pain sensation, weakness, deafness, convulsions, intestinal perforation in ulcerative colitis, hypokalemia, muscle degeneration, rupture of the Achilles tendon, pseudotumor cerebri and cardiac conduction defect. It may cause congestive heart failure, suppression of the immune response mechanism, impairment of glucose tolerance, habituation and unmasking of latent psychiatric disorder. It may also cause potassium loss, loss of muscle mass, vertebral compression fractures, abdominal distention, ulcerative esophagitis, thin and fragile skin, petechiae, erythema, increased sweating, suppressed reactions to skin tests, allergic dermatitis, urticaria, angioneurotic edema, vertigo, headache, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness, decreased carbohydrate tolerance, exophthalmos, hypersensitivity, thromboembolism, malaise, weight gain, nausea and intracranial pressure with papilledema. Ascites may occur. Skin exposure to this type of compound may cause loss of skin collagen and subcutaneous atrophy. Other symptoms via this route include burning, secondary infections, itching, irritation, pigmentation, dryness, folliculitis and hypertrichosis. Eye exposure to this type of compound may lead to corneal ulceration, raised intraocular pressure, reduced visual function and cataracts. Glaucoma may also occur. **ACUTE/CHRONIC HAZARDS:** This compound may be harmful by inhalation, ingestion or skin

absorption. It may cause irritation. It may cause lacrimation. When heated to decomposition it emits toxic fumes of carbon monoxide, carbon dioxide and hydrogen fluoride. (NTP, 1992)

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Immediate first aid: Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand valve resuscitator, bag-valve-mask device, or pocket mask, as trained. Perform CPR if necessary. Immediately flush contaminated eyes with gently flowing water. Do not induce vomiting. If vomiting occurs, lean patient forward or place on the left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature. Obtain medical attention. Poisons A and B

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. A water spray may also be used. (NTP, 1992)

5.2 Specific hazards arising from the chemical

Flash point data for this chemical are not available; however, it is probably combustible. (NTP, 1992)

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

6.2 Environmental precautions

Personal protection: particulate filter respirator adapted to the airborne concentration of the substance. Do NOT let this chemical enter the environment. Sweep spilled substance into covered plastic containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder. Then store and dispose of according to local regulations.

6.3 Methods and materials for containment and cleaning up

Collect and arrange disposal. Keep the chemical in suitable and closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

7. Handling and storage

7.1 Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

7.2 Conditions for safe storage, including any incompatibilities

Separated from food and feedstuffs, acids and metals. See Chemical Dangers. Provision to contain effluent from fire extinguishing. Store in an area without drain or sewer access.

8. Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and

the risk-elimination area.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

Thermal hazards

no data available

9. Physical and chemical properties

Physical state	PHYSICAL DESCRIPTION: Odorless white to off-white crystalline powder with a slightly bitter taste. (NTP, 1992)
Colour	Crystals from ether
Odour	no data available
Melting point/ freezing point	255-264°C
Boiling point or initial boiling point and boiling range	568.2°C at 760 mmHg
Flammability	Combustible. Gives off irritating or toxic fumes (or gases) in a fire.
Lower and upper explosion limit / flammability limit	no data available
Flash point	297.5°C
Auto-ignition temperature	no data available
Decomposition temperature	275°C
pH	no data available
Kinematic viscosity	no data available
Solubility	less than 1 mg/mL at 77° F (NTP, 1992)
Partition coefficient n-octanol/water	no data available
Vapour pressure	8.86X10 ⁻¹⁴ mm Hg at 25 deg C (est)
Density and/or relative density	1.32 g/cm ³
Relative vapour density	no data available
Particle characteristics	no data available

10. Stability and reactivity

10.1 Reactivity

Decomposes on heating above 275°C . This produces toxic fumes. This generates fire and explosion hazard. Reacts with copper, lead, silver, mercury and carbon disulfide. This produces particularly shock-sensitive compounds. Reacts with acids. This produces toxic and explosive hydrogen azide. See Notes.

10.2 Chemical stability

Dexamethasone sodium phosphate ophthalmic solution should be stored in tight, light-resistant containers. Dexamethasone sodium phosphate

10.3 Possibility of hazardous reactions

See Notes.DEXAMETHAZONE may be sensitive to prolonged exposure to light. This chemical is incompatible with strong oxidizers, strong acids, acid chlorides and acid anhydrides. Oxidation may occur with bases. (NTP, 1992)

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

CHEMICAL PROFILE: An azide is a compound of hydrogen or a metal and the monovalent triatomic nitrogen anion. All azide salts and the acid are unstable and some decompose explosively. Extremely dangerous, shock or heat may explode them. If exposed to carbon disulfide, they form violently explosive salts. They can be sensitized by metal salts (especially heavy metal salts such as silver chloride etc.) or by traces of strong acids. They decompose explosively if heated or on impact. [Sax, 9th ed., 1996, p. 298]. (REACTIVITY, 1999)

10.6 Hazardous decomposition products

When heated to decomposition it emits toxic fumes of /hydrogen fluoride/.

11. Toxicological information

Acute toxicity

- Oral: no data available
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

TLV-A4

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

12. Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

An estimated BCF of 14 was calculated for dexamethasone(SRC), using a log Kow of 1.83(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

12.4 Mobility in soil

The Koc of dexamethasone is estimated as 240(SRC), using a log Kow of 1.83(1) and a regression-derived equation(2). According to a classification scheme(3), this estimated Koc value suggests that dexamethasone is expected to have moderate mobility in soil.

12.5 Other adverse effects

no data available

13. Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

14. Transport information

14.1 UN Number

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: No

IMDG: No

IATA: No

14.6 Special precautions for user

no data available

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

no data available

15. Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
Dexamethasone	Dexamethasone	50-02-2	200-003-9

European Inventory of Existing Commercial Chemical Substances (EINECS)	Listed.
EC Inventory	Listed.
United States Toxic Substances Control Act (TSCA) Inventory	Listed.
China Catalog of Hazardous chemicals 2015	Not Listed.
New Zealand Inventory of Chemicals (NZIoC)	Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	Listed.
Vietnam National Chemical Inventory	Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)	Listed.
Korea Existing Chemicals List (KECL)	Listed.

16. Other information

Information on revision

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Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product.