

TCI AMERICA SAFETY DATA SHEET

Revision number: 0.9 Revision date: 09/25/2012

1. IDENTIFICATION

Product name: Prednisolone Acetate

Product code: P1283

Product use:For laboratory research purposes.Restrictions on use:Not for drug or household use.

Company: TCI America

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Chemical Emergencies:

TCI America (8:00am - 5:00pm) PST

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Transportation Emergencies: Chemtrec 24-Hour +1-800-424-9300 (U.S.A.) +1-703-527-3887 (International) **Responsible department:**

TCI America

Environmental Health Safety and Security

+1-503-286-7624

2. HAZARD(S) IDENTIFICATION

OSHA Haz Com: CFR 1910.1200: Acute Toxicity - Oral [Category 4]

Toxic to Reproduction [Category 2]

Signal word: Warning!

Hazard Statement(s): Harmful if swallowed

Suspected of damaging fertility or the unborn child Causes damage to: Bone Eye Immune System

Pictogram(s) or Symbol(s):





Precautionary Statement(s):

[Response]

[Prevention] Obtain special instructions before use. Do not handle until all safety precautions have been read and

understood. Wear protective gloves, eye protection and face protection. Wash hands thoroughly after

handling. Do not eat, drink or smoke when using this product.

If exposed or concerned: Get medical advice or attention. If swallowed: Call a poison center or doctor if

you feel unwell. Rinse mouth.

[Storage] Store locked up.

[Disposal] Dispose of contents and container in accordance with US EPA guidelines for the classification and

determination of hazardous waste listed in 40 CFR 261.3. (See Section 13)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance/Mixture: Substance

Components: Prednisolone Acetate

 $\begin{array}{lll} \textbf{Percent:} & >95.0\%(LC) \\ \textbf{CAS Number:} & 52-21-1 \\ \textbf{Molecular Weight:} & 402.49 \\ \textbf{Chemical Formula:} & C_{23}H_{30}O_6 \\ \end{array}$

Synonyms: 21-Acetoxy-1,4-pregnadiene- 11β , 17α -diol-3,20-dione

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4. FIRST-AID MEASURES

Inhalation: Move victim to fresh air. Call emergency medical service. Give artificial respiration if victim is not breathing.

Administer oxygen if breathing is difficult. Keep victim warm and quiet. Treat symptomatically and supportively Ensure that medical personnel are aware of the material(s) involved and take precautions to

protect themselves.

Skin contact: Remove and isolate contaminated clothing and shoes. If this chemical (or liquids containing this chemical)

contacts the skin, promptly wash the contaminated skin with soap and water. Call a poison center or doctor if you feel unwell. Treat symptomatically and supportively. Ensure that medical personnel are aware of the

material(s) involved and take precautions to protect themselves.

Eye contact: In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. Move

victim to fresh air. Effects of exposure to substance may be delayed. Ensure that medical personnel are

aware of the material(s) involved and take precautions to protect themselves.

Ingestion: Do not use mouth-to-mouth method if victim ingested the substance; give artificial respiration with the aid

of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Harmful if swallowed. If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth. If swallowed, seek medical advice immediately and show the container or label.

Treat symptomatically and supportively.

Symptoms/effects:

Acute: Headache.

Delayed: No data available

Immediate medical attention: Administer oxygen if breathing is difficult Ensure that medical personnel are aware of the material(s)

involved and take precautions to protect themselves.

Notes to physician: Do not use emetics. For ingestion, rinse mouth and administer 5 mL/kg up to 200 mL of water for dilution if

the patient can swallow, has a strong gag reflex, and does not drool.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray Alcohol-resistant foam Dry chemical or CO2.

Specific hazards arising from the chemical

Hazardous combustion products:
Other specific hazards:
These products include: Carbon oxides
Containers can rupture if exposed to heat.

Special precautions for fire-fighters:

Not available

Special protective equipment for fire-fighters:

Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid dust formation. Ensure adequate ventilation. Do not touch damaged containers or spilled material

unless wearing appropriate protective clothing (Section 8).

Personal protective equipment: Dust respirator. Be sure to use a MSHA/NIOSH approved respirator or equivalent. Gloves. Lab coat.

Safety glasses.

Emergency procedures: Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. In

case of a spill and/or a leak, always shut off any sources of ignition, ventilate the area, and excercise

caution. Prevent dust cloud. Stop leak if you can do so without risk.

Methods and materials for containment

and cleaning up:

In case of spill and/or leak, always shut off any sources of ignition, ventilate the area, and exercise caution. Use a shovel to put material into a convenient waste disposal container. Finish cleaning the spill by rinsing any contaminated surfaces with copious amounts of water. Consult regional, national, state and/or local authorities for assistance on disposal. Prevent dust cloud. Use a broom to put the material into a convenient waste disposal container.

Prevent entry into sewers, basements or confined areas.

7. HANDLING AND STORAGE

Environmental precautions:

Precautions for safe handling: Avoid formation of dust and aerosols. Avoid contact with skin and eyes. Good general ventilation should

be sufficient to control airborne levels. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection. Follow safe industrial hygiene practices and

always wear proper protective equipment when handling this compound.

Conditions for safe storage: Keep container tightly closed in a dry and well-ventilated place.

Storage incompatibilities: Not applicable

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits: No data available

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Appropriate engineering controls:

Good general ventilation should be sufficient to control airborne levels. Follow safe industrial engineering/laboratory practices when handling any chemical.

Personal protective equipment

Respiratory protection: Dust respirator. Be sure to use a MSHA/NIOSH approved respirator or equivalent.

Hand protection: Gloves. Eye protection: Safety glasses. Skin and body protection: Lab coat.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state (20°C): Solid

Form: crystal - powder Color: White - Almost white Odor: No data available Odor threshold: No data available No data available pH: Boiling point/range: No data available Decomposition temperature: No data available Flash point: No data available **Evaporation rate:** No data available (Butyl Acetate = 1)

Flammability (solid, gas): No data available Autoignition temperature: No data available

Flammability or explosive limits:

No data available Lower: Upper: No data available Vapor pressure: No data available Vapor density: No data available Relative density: No data available Partition coefficient: No data available

n-octanol/water (log Pow)

No data available Viscosity:

Very slightly soluble in water: one gram disolves in about 30ml of alcohol, in about 180ml of chloroform, in Solubility(ies):

about 50ml of acetone. Soluble in methanol, dioxane.

10. STABILITY AND REACTIVITY

Reactivity: No hazardous reactivity has been reported.

Chemical Stability: Stable under recommended storage conditions. (See Section 7)

Possibility of Hazardous Reactions: No hazardous reactivity has been reported.

Conditions to avoid: Avoid excessive heat and light.

Incompatible materials: Oxidizing agents **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

RTECS Number: TU4152500

Acute Toxicity:

Mouse LD50 (subcutaneous): 3500 mg/kg Rat LD50 (subcutaneous): >240 mg/kg

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:

IARC = No data available NTP = No data available OSHA = No data available

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Reproductive toxicity:

Rat TDLo (oral) 1800 mg/kg, female 2-19 days of pregnancy Toxic Effects:

Reproductive - effects on fertility, post-implantation mortality.

Reproductive - effects on fertility, abortion.

Mouse TDLo (subcutaneous): 96 mg/kg, female 11 days of pregnancy

Toxic Effects:

Reproductive - effects on fertility, post-implantation mortality.

Reproductive - effects on embryo or fetus, fetotoxicity.

Reproductive - specific developmental abnormalities, craniofacial.

Mouse TDLo (intravenous): 96 mg/kg, female 11-14 days of pregnancy Toxic Effects:

Reproductive - effects on fertility, post-implantation mortality. Reproductive - specific developmental abnormalities, craniofacial.

Routes of Exposure: Inhalation, Eye contact, Ingestion, Skin contact.

Symptoms related to exposure:

Headache. No specific information is available in our data base regarding the toxic effects of this material for humans. However, exposure to any chemical should be kept to a minimum. Always follow safe industrial hygiene practices and wear proper protective equipment when handling this compound.

Potential Health Effects:

No specific information available; skin and eye contact may result in irriatation. May be harmful if inhaled or ingested.

Target organ(s):

Causes damage to: Bone Eye Immune System

12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available Fish: Crustacea: No data available Algae: No data available

Persistence and degradability: No data available Bioaccumulative potential (BCF): 3.5 (est.) Mobillity in soil: No data available

Partition coefficient: No data available

n-octanol/water (log Pow) Soil adsorption (Koc): 180 (est.)

Henry's Law: 2.71x10-8 at 25 deg C. (est.)

constant (PaM³/mol)

Other adverse effects:

Prednisolone's production and use as a glucocorticoid may result in its release to the environment through various waste streams. If released to air, an estimated vapor pressure of 1.2X10-13 mm Hg at 25 deg C indicates prednisolone will exist solely in the particulate phase in the atmosphere. Particulate-phase prednisolone will be removed from the atmosphere by wet or dry deposition. Prednisolone contains chromophores that absorb at wavelengths >290 nm and therefore may be susceptible to direct photolysis by sunlight If released to soil, prednisolone is expected to have moderate mobility based upon an estimated Koc of 180. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 2.7X10-8 atm-cu m/mole. Biodegradation data for prednisolone in soil were not available. If released into water, prednisolone is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Biodegradation data for prednisolone in water were not available. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. An estimated BCF of 3.5 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions. Occupational exposure to prednisolone may occur through inhalation or dermal contact with this compound at workplaces where prednisolone is produced or used. Exposure to prednisolone among the general population may be limited to those administered the drug (Prednisolone Tablets and Prednisolone Syrup), a glucocorticoid.

13. DISPOSAL CONSIDERATIONS

Disposal of product: Recycle to process if possible. Send to a licensed waste management company or recycler.

Disposal of container: Dispose of as unused product.

Other considerations: Observe all federal, state and local regulations when disposing of the substance.

14. TRANSPORT INFORMATION

DOT (US) Non-hazardous for transportation.

<u>IATA</u> Non-hazardous for transportation.

IMDG Non-hazardous for transportation.

15. REGULATORY INFORMATION

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15. REGULATORY INFORMATION

Toxic Substance Control Act (TSCA 8b.):

This product is NOT on the EPA Toxic Substances Control Act (TSCA) inventory. The following notices are required by 40 CFR 720.36 (C) for those products not on the inventory list:

- (i) These products are supplied solely for use in research and development by or under the supervision of a technically qualified individual as defined in 40 CFR 720.0 et sec.
- (ii) The health risks of these products have not been fully determined. Any information that is or becomes available will be supplied on a SDS sheet.

US Federal Regulations

CERCLA Hazardous substance and Reportable Quantity:

SARA 313: Not Listed SARA 302: Not Listed

State Regulations

State Right-to-Know

MassachusettsNot ListedNew JerseyListedPennsylvaniaListedCalifornia Proposition 65:Not Listed

Other Information

NFPA Rating: HMIS Classification:

Health:2Health:2Flammability:0Flammability:0Instability:0Physical:0

International Inventories

WHMIS hazard class:

Canada: DSL

CC-No:

On DSL

200-134-1

Notice Through Official Gazettes Reference Number: (Japan)

ENCS: Not Listed

16. OTHER INFORMATION

Revision date: 09/25/2012 Revision number: 0.9

TCI chemicals are for research purposes only and are NOT intended for use as drugs, food additives, households, or pesticides. The information herein is believed to be correct, but does not claim to be all inclusive and should be used only as a guide. Neither the above named supplier nor any of its affiliates or subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All chemical reagents must be handled with the recognition that their chemical, physiological, toxicological, and hazardous properties have not been fully investigated or determined. All chemical reagents should be handled only by individuals who are familiar with their potential hazards and who have been fully trained in proper safety, laboratory, and chemical handling procedures. Although certain hazards are described herein, we can not guarantee that these are the only hazards which exist. Our SDS are based only on data available at the time of shipping and are subject to change without notice as new information is obtained. Avoid long storage periods since the product is subject to degradation with age and may become more dangerous or hazardous. It is the responsibility of the user to request updated SDS for products that are stored for extended periods. Disposal of unused product must be undertaken by qualified personnel who are knowledgeable in all applicable regulations and follow all pertinent safety precautions including the use of appropriate protective equipment (e.g. protective goggles, protective clothing, breathing equipment, face mask, fume hood). For proper handling and disposal, always comply with federal, state and local regulations.