



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Prednisone</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1559006	
<b>Chemical name</b>	Pregna-1,4-diene-3,11,20-trione, 17,21-dihydroxy-	
<b>Synonym(s)</b>	1-Dehydrocortisone	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<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.	

### Label elements



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.	
<b>Response</b>	If exposed or concerned: Get medical advice/attention.	
<b>Storage</b>	Store locked up.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	Not classified.	

## 3. Composition/information on ingredients

### Substance

### Hazardous components

<b>Chemical name</b>	<b>Common name and synonyms</b>	<b>CAS number</b>	<b>%</b>
Prednisone	1-Dehydrocortisone	53-03-2	100

## 4. First-aid measures

<b>Inhalation</b>	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. 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>	Not available.
<b>Indication of immediate medical attention and special treatment needed</b>	Acute toxicity following overdose is uncommon. Gastrointestinal decontamination is generally not necessary. Treatment should be symptomatic and supportive. [Poisindex 2010]
<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. In the United States, the national poison control center phone number is 1-800-222-1222. 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.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	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. Wash spill site.

## 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP Reference Standards, 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.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 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>

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
--------------------------------	------------------------------------------------------------

<b>Appropriate engineering controls</b>	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. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Skin protection</b>	
<b>Hand protection</b>	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. This material is extremely potent. 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.
<b>Other</b>	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
<b>Respiratory protection</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

<b>Appearance</b>	White or almost white crystalline powder.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	Not available.
<b>Melting point/freezing point</b>	446 - 455 °F (230 - 235 °C) (decomposes)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<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>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Corticosteroid.
<b>Molecular formula</b>	C <sub>21</sub> H <sub>26</sub> O <sub>5</sub>
<b>Molecular weight</b>	358.44

**Solubility (other)** Slightly soluble in ethanol, in chloroform, in dioxane, and in methanol.

## 10. Stability and reactivity

**Reactivity** No reactivity hazards known.  
**Chemical stability** Material is stable under normal conditions.  
**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.  
**Conditions to avoid** None known.  
**Incompatible materials** Strong oxidizing agents.  
**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** Due to lack of data the classification is not possible.  
**Inhalation** Due to lack of data the classification is not possible.  
**Skin contact** Due to lack of data the classification is not possible.  
**Eye contact** Due to lack of data the classification is not possible.

**Symptoms related to the physical, chemical, and toxicological characteristics** 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.

**Delayed and immediate effects of exposure** Corticosteroids: Fluid and electrolyte imbalance. Cushing's syndrome. Adrenal suppression. Immune system depression. Withdrawal.

**Cross sensitivity** Persons sensitive to other corticosteroids may be sensitive to this material also.

**Medical conditions aggravated by exposure** 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** Due to lack of data the classification is not possible.

Product	Species	Test Results
---------	---------	--------------

Prednisone (CAS 53-03-2)

**Acute**

*Other*

LD50

Mouse

101 mg/kg, (subcutaneous)

**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** Based on available data, the classification criteria are not met.

**Mutagenicity**

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

**Carcinogenicity** Based on available data, the classification criteria are not met.  
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.  
IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans.

5 mg/kg/day Long-term carcinogenicity study  
Result: Negative  
Species: Mouse

**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.

**Reproductivity**

10 mg/day Epidemiological study  
Result: Statistically significant decrease in birth weights of term infants.  
Species: Human

**Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure** Causes damage to organs (endocrine system) through prolonged or repeated exposure.

**Aspiration hazard** Based on available data, the classification criteria are not met.

## 12. Ecological information

### Ecotoxicity

Product	Species	Test Results
Prednisone (CAS 53-03-2)		
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** This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.

**Local disposal regulations** Not available.

**Hazardous waste code** Not regulated.

**Waste from residues / unused products** 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** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - Yes  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance** No

**SARA 311/312 Hazardous chemical** No

**Other federal regulations**

**Safe Drinking Water Act (SDWA)** Not regulated.

**Food and Drug Administration (FDA)** Not regulated.

**US state regulations**

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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

**Issue date** 08-20-2010

**Revision date** 04-22-2013

**Version #** 03

**Further information** Not available.

**Disclaimer** USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

**Revision Information** This document has undergone significant changes and should be reviewed in its entirety.