

1. Identification

Product identifier	Prednisone Tablets	
Other means of identification		
Catalog number	1559505	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

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)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement	Causes eye irritation. Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure.	
Precautionary statement		
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Wash thoroughly after handling. 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. Get medical advice/attention if you feel unwell.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	None known.	
Supplemental information	Potent pharmacologically active material.	

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Microcrystalline Cellulose		9004-34-6	<55
Dibasic Calcium Phosphate		7757-93-9	<45
Prednisone	1-Dehydrocortisone	53-03-2	<5
Magnesium Stearate		557-04-0	<2
Sodium Starch Glycolate		9063-38-1	<2
Stearic Acid		57-11-4	<2
Other components below reportable levels			0.32

4. First-aid measures

Inhalation	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.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. 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.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of corticosteroid overdose may include the following: Toxicity is low after acute ingestion. Gastrointestinal decontamination is generally not necessary.
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. 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

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
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	Use standard firefighting procedures and consider the hazards of other involved materials.
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. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

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. 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 incompatibilities

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

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Microcrystalline Cellulose (CAS 9004-34-6)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m ³
Microcrystalline Cellulose (CAS 9004-34-6)	TWA	10 mg/m ³
Stearic Acid (CAS 57-11-4)	TWA	10 mg/m ³

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Microcrystalline Cellulose (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total

Exposure limit values

Industrial Use

Components	Type	Value
Prednisone (CAS 53-03-2)	TWA	50 micrograms/m ³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

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

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Tablet.
Color	White.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong acids. Strong oxidizing agents. Amines. Isocyanates. Fluorine. Strong bases.
Hazardous decomposition products	MgOx, POx, NaOx, CaOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Causes eye irritation. Endocrine effects.
Ingestion	Based on information from therapeutic use, this material may cause:
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.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Dibasic Calcium Phosphate (CAS 7757-93-9)		
Acute		
Dermal		
LD50	Rabbit	> 7940 mg/kg > 2000 mg/kg, 24 Hours
Inhalation		
<i>Dust</i>		
LC50	Rat	> 2.6 mg/l, 4 Hours
Oral		
LD50	Rat	> 10000 mg/kg > 2000 mg/kg
Magnesium Stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2 mg/l
Microcrystalline Cellulose (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2 g/kg
Inhalation		
LC50	Rat	> 5.05 mg/l, 4 hours
Oral		
LD50	Rat	> 5 g/kg
Stearic Acid (CAS 57-11-4)		
Oral		
LD50	Rat	4.6 g/kg
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Causes eye irritation.	
Local effects		
Magnesium Stearate		Eye irritation Result: Negative. Species: Rabbit
Microcrystalline Cellulose		Eye irritation Result: Negative. Species: Rabbit
Stearic Acid		Eye irritation Result: Negative. Species: Rabbit
Dibasic Calcium Phosphate		Irritancy test Result: Mild Species: Rabbit Organ: Eye Irritancy test Result: Non-irritant Species: Rabbit Organ: Skin

Local effects

Stearic Acid

Skin irritation
Result: Mild.
Species: Human
Test Duration: 3 day

Magnesium Stearate

Skin irritation
Result: Negative.
Species: Rabbit

Microcrystalline Cellulose

Skin irritation
Result: Negative.
Species: Rabbit

Stearic Acid

Skin irritation
Result: Negative.
Species: Rabbit
Test Duration: 24 hours
Observation Period: 72 hours**Respiratory or skin sensitization****Respiratory sensitization**

Knowledge about health hazard is incomplete.

Skin sensitization

Knowledge about health hazard is incomplete.

Stearic Acid

7 % Skin sensitization
Result: Negative.
Species: Human

Microcrystalline Cellulose

Skin sensitization
Result: Negative.
Species: Guinea pig**Germ cell mutagenicity**

Knowledge about mutagenicity is incomplete.

Mutagenicity

Microcrystalline Cellulose

Ames test
Result: Negative.

Stearic Acid

Ames test
Result: Negative.

Prednisone

Ames test (Salmonella typhimurium)
Result: Negative

Microcrystalline Cellulose

Micronucleus test
Result: Negative.

Prednisone

Mouse lymphoma assay
Result: Negative

Microcrystalline Cellulose

Mouse lymphoma assay
Result: Negative.

Prednisone

Mutagenicity, In vivo chromosome aberration studies in rat
bone marrow

Stearic Acid

Result: Negative
Mutagenicity: Induction of crossovers and aneuploidy in *S. cerevisiae*.

Microcrystalline Cellulose

Result: Negative
Unscheduled DNA synthesis
Result: Negative.**Carcinogenicity**

Knowledge about carcinogenicity is incomplete.

Stearic Acid

0.3 % Carcinogenicity
Result: Negative.
Species: Rat
Test Duration: 209 days

Microcrystalline Cellulose

30 % Oral feed study
Result: Negative.
Species: Rat

Prednisone

Test Duration: 72 weeks
5 mg/kg/day Carcinogenicity
Result: Negative

Stearic Acid

Species: Mouse
50 g/kg Oral feed study
Result: Negative.

Magnesium Stearate

Species: Mouse
Carcinogenicity: Implanted mouse bladders
Result: Negative.

Carcinogenicity

Microcrystalline Cellulose

Carcinogenicity; subcutaneous implant
Result: Negative.
Species: Rat
Test Duration: 2 years**IARC Monographs. Overall Evaluation of Carcinogenicity**

Prednisone (CAS 53-03-2)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicitySuspected 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**

Prednisone

10 mg/day Epidemiological study, Statistically significant decrease in birth weights of term infants.

Result: Positive

Species: Human

Microcrystalline Cellulose

4.6 mg/kg/day Reproductivity / developmental
Result: No adverse effects on the offspring observed.

Species: Rat

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.

Aspiration hazard

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

Further information

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information**Ecotoxicity**

Components	Species	Test Results
Dibasic Calcium Phosphate (CAS 7757-93-9)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Daphnia magna
		> 1000 mg/l
Prednisone (CAS 53-03-2)		
Aquatic		
<i>Acute</i>		
Algae	IC50	Algae
		31 mg/l, 72 hours
Stearic Acid (CAS 57-11-4)		
<i>Acute</i>		
Other	EC50	Pseudomonas putida
		> 100 mg/l, 16 hours
Aquatic		
<i>Acute</i>		
Fish	LC50	Carp (Cyprinus carpio)
		> 1000 mg/l, 48 hours

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential**Octanol/water partition coefficient log Kow**

Prednisone

1.46

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 in accordance with all applicable 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	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 dangerous goods.
IATA	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations	One or more components are not listed on TSCA. CERCLA/SARA Hazardous Substances - Not applicable. This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
SARA 304 Emergency release notification	Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not regulated.
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	Not listed.
SARA 311/312 Hazardous chemical	Yes
SARA 313 (TRI reporting)	Not regulated.
Other federal regulations	
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List	Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)	Not regulated.
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.

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)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
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)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date 09-08-2010

Revision date 11-13-2018

Version # 04

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.