



SAFETY DATA SHEET

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			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US		
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)	
OSHA hazard(s)	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. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. 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	Store locked up.		
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.		
Hazard(s) not otherwise classified (HNOC)	Not classified.		

3. Composition/information on ingredients

Mixture

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Dibasic Calcium Phosphate		7757-93-9	38.5

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Prednisone		53-03-2	4.5

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
Microcrystalline Cellulose		9004-34-6	52.9
Sodium Starch Glycolate		9063-38-1	1.8
Stearic Acid		57-11-4	1.4
Magnesium Stearate		557-04-0	0.9

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 or persists.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops or persists. If eye irritation persists: Get medical advice/attention.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes.
Indication of immediate medical attention and special treatment needed	Treatment of overdose should be symptomatic and supportive. Acute toxicity following overdose is uncommon. Gastrointestinal decontamination is generally not necessary. (Poisindex)
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 spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and 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	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.

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. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.
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. Wash spill site.

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.
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

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. NIOSH: Pocket Guide to Chemical Hazards

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

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

Exposure limit values

Industrial Use

Components	Type	Value
Prednisone (CAS 53-03-2)	STEL	40 micrograms/m ³
	TWA	5 micrograms/m ³

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.

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.

Individual protection measures, such as personal protective equipment

Eye/face protection

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.

Skin protection

Hand protection

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.

Other

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.

Respiratory protection

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).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White tablets.
Physical state	Solid.
Form	Tablet.

Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
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 density	Not available.
Relative density	Not available.
Solubility in water	Not available.
Partition coefficient (n-octanol/water)	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

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	Moisture.
Incompatible materials	Strong oxidizing agents. Fluorine. Strong acids. Strong bases. Amines. Isocyanates. Iron salts.
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

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	Causes eye irritation.

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.
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Delayed and immediate effects of exposure	Corticosteroids: Fluid and electrolyte imbalance. Cushing's syndrome. Adrenal suppression. Immune system depression. Withdrawal.
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Cross sensitivity	Persons sensitive to other corticosteroids may be sensitive to this material also.
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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.
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Acute toxicity	Due to lack of data the classification is not possible.
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Components	Species	Test Results
Dibasic Calcium Phosphate (CAS 7757-93-9)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 7940 mg/kg
<i>Oral</i>		
LD50	Rat	> 10000 mg/kg

Components	Species	Test Results
Magnesium Stearate (CAS 557-04-0)		
Acute		
<i>Inhalation</i>		
LC50	Rat	> 2 mg/l
<i>Oral</i>		
LD50	Rat	> 10000 mg/kg
Microcrystalline Cellulose (CAS 9004-34-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2 g/kg
<i>Inhalation</i>		
LC50	Rat	> 5.05 mg/l, 4 hours
<i>Oral</i>		
LD50	Rat	> 5 g/kg
Prednisone (CAS 53-03-2)		
Acute		
<i>Other</i>		
LD50	Mouse	101 mg/kg, (subcutaneous)
Stearic Acid (CAS 57-11-4)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 5000 mg/kg
<i>Oral</i>		
LD50	Rat	4.6 g/kg
<i>Other</i>		
LD50	Mouse	23 mg/kg, (Intravenous)
	Rat	21.5 mg/kg, (Intravenous)
Skin corrosion/irritation	Due to lack of data the classification is not possible.	
Serious eye damage/eye irritation	Causes eye irritation.	
Local effects		
Magnesium Stearate	Dermal corrosion study, abraded and intact skin Result: Primary Irritation Index = 0 Species: Rabbit Organ: Skin Test Duration: 4 hours Dermal irritation study, abraded and intact skin Result: Primary Irritation Index = 0 Species: Rabbit Organ: Skin Test Duration: 24 h	
Stearic Acid	Draize Result: Transient mild erythema; not irritating Species: Rabbit Organ: Eye	
Magnesium Stearate	Eye irritation study, not rinsed Result: Scores = 0 on day 1, 2, 3 Species: Rabbit	
Dibasic Calcium Phosphate	Irritancy test Result: Mild Species: Rabbit Organ: Eye Irritancy test Result: Non-irritant Species: Rabbit Organ: Skin	
Microcrystalline Cellulose	Irritancy test Result: Non-irritating; Primary Irritation Index = 0 Species: Rabbit Organ: Skin	

Local effects

Microcrystalline Cellulose

Irritancy tests
 Result: Minimally irritating; non-irritating
 Species: Rabbit
 Organ: Eye

Stearic Acid

Patch test - intact and abraded skin
 Result: Non-irritant
 Species: Rabbit
 Organ: Skin
 Test Duration: 24 hours
 Observation Period: 72 hours
 Standard Draize
 Result: Mild
 Species: Human
 Organ: Skin
 Test Duration: 3 day
 Standard Draize
 Result: Moderate
 Species: Rabbit
 Organ: Skin
 Test Duration: 24 hours

Respiratory sensitization

Due to lack of data the classification is not possible.

Skin sensitization

Due to lack of data the classification is not possible.

Sensitization

Stearic Acid

7 % Sensitization test
 Result: Negative
 Species: Human
 Organ: Skin

Microcrystalline Cellulose

Sensitization test
 Result: Non-sensitizing
 Species: Guinea pig
 Organ: Skin

Germ cell mutagenicity

Due to lack of data the classification is not possible.

Mutagenicity

Stearic Acid

Ames test in Salmonella typhimurium
 Result: Negative

Prednisone

Ames test in Salmonella, with and without activation
 Result: Negative

Microcrystalline Cellulose

Forward mutation in mouse lymphoma cells, with and without activation.
 Result: Negative

Prednisone

In vitro unscheduled DNA synthesis in rat liver cells
 Result: Negative

Microcrystalline Cellulose

In vivo chromosome aberration studies in rat bone marrow
 Result: Negative

Stearic Acid

In vivo human studies
 Result: Negative; no chromosome damage to peripheral lymphocytes.

Prednisone

In vivo micronucleus assay in mouse bone-marrow erythrocytes
 Result: Negative

Microcrystalline Cellulose

Induction of mitotic crossovers and aneuploidy in Saccharomyces cerevisiae
 Result: Negative

Mouse lymphoma studies, without activation
 Result: Negative

Reverse mutation in S.typhimurium and E.coli, with and 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.

Stearic Acid

0.3 % Long-term dietary study
 Result: Negative

Prednisone

Species: Rat
 Test Duration: 209 days
 5 mg/kg/day Long-term carcinogenicity study
 Result: Negative

Stearic Acid

Species: Mouse
 50 g/kg Feeding study
 Result: Non-carcinogenic
 Species: Mouse

Magnesium Stearate	Implanted in mouse bladders Result: Not carcinogenic
Microcrystalline Cellulose	Long-term carcinogenicity study, implanted in female rats. Result: Not carcinogenic Species: Rat Test Duration: 741 days Long-term feeding study, 30 % in diet Result: Not carcinogenic Species: Rat Test Duration: 72 weeks

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	
Prednisone	10 mg/day Epidemiological study Result: Statistically significant decrease in birth weights of term infants. Species: Human
Microcrystalline Cellulose	4.6 mg/kg/day Reproductivity and development study, administered in diet. Result: No adverse effects on the offspring Species: Rat Reproductivity and development study, 30% in diet, administered during gestation. Result: Not teratogenic Species: Mouse

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

Components	Species	Test Results
Dibasic Calcium Phosphate (CAS 7757-93-9)		
<i>Acute</i>		
Crustacea	EC50	Daphnia magna > 1000 mg/l
Prednisone (CAS 53-03-2)		
<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 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 One or more components are not listed on TSCA.
CERCLA/SARA Hazardous Substances - Not applicable.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
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 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)	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 09-08-2010

Revision date 05-15-2013

Version # 02

Further information Not available.

Disclaimer

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Revision Information

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