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

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. 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.

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 None.

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

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.

Environmental precautions
Prevent further leakage or spillage if safe to do so. No special environmental precautions required.

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/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m3
Microcrystalline Cellulose (CAS 9004-34-6)	TWA	10 mg/m3
Stearic Acid (CAS 57-11-4)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Microcrystalline Cellulose (CAS 9004-34-6)	REL	5 mg/m3	Respirable.
		10 mg/m3	Total

Exposure limit values

Industrial Use

Components	Type	Value
Prednisone (CAS 53-03-2)	STEL	40 micrograms/m3
	TWA	5 micrograms/m3

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

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

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	Not available.
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

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.
Ingestion	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.

Information on toxicological effects

Acute toxicity Due to lack of data the classification is not possible.

Components	Species	Test Results
Dibasic Calcium Phosphate (CAS 7757-93-9)		
Acute		
Dermal		
LD50	Rabbit	> 7940 mg/kg
		> 2000 mg/kg, 24 Hours
		> 2000 mg/kg, 72 Hours

Components	Species	Test Results
Inhalation		
Dust		
LC50	Rat	> 2.6 mg/l, 4 Hours
Oral		
LD50	Rat	> 10000 mg/kg
		> 2000 mg/kg
		7940 ml/kg
Magnesium Stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2 mg/l
Oral		
LC50	Rat	> 10000 mg/kg
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
Prednisone (CAS 53-03-2)		
Acute		
Other		
LD50	Mouse	101 mg/kg (subcutaneous)
Stearic Acid (CAS 57-11-4)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Oral		
LD50	Rat	4.6 g/kg
Other		
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 Result: Non-irritant. Species: Rabbit
Stearic Acid	Draize Result: Transient mild erythema; not irritating Species: Rabbit Organ: Eye
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
Magnesium Stearate	Irritant study Result: Non-irritant. 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 or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

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 In vitro unscheduled DNA synthesis in rat liver cells Result: Negative
Prednisone	In vivo chromosome aberration studies in rat bone marrow Result: Negative In vivo human studies Result: Negative; no chromosome damage to peripheral lymphocytes.
Microcrystalline Cellulose	In vivo micronucleus assay in mouse bone-marrow erythrocytes Result: Negative
Stearic Acid	Induction of mitotic crossovers and aneuploidy in Saccharomyces cerevisiae Result: Negative
Prednisone	Mouse lymphoma studies, without activation Result: Negative
Microcrystalline Cellulose	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 Species: Rat Test Duration: 209 days

Carcinogenicity

Prednisone	5 mg/kg/day Long-term carcinogenicity study Result: Negative Species: Mouse
Stearic Acid	50 g/kg Feeding study Result: Non-carcinogenic Species: Mouse
Magnesium Stearate	Implanted 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

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 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)			
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	> 1000 mg/l
Prednisone (CAS 53-03-2)			
Aquatic			
Acute			
Algae	IC50	Algae	31 mg/l, 72 hours
Stearic Acid (CAS 57-11-4)			
Acute			
Other	EC50	Pseudomonas putida	> 100 mg/l, 16 hours
Aquatic			
Acute			
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.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

Prednisone	1.46
Stearic Acid	8.23

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.

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 dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

US federal regulations One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

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 No

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.

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Microcrystalline Cellulose (CAS 9004-34-6)

US. New Jersey Worker and Community Right-to-Know Act

Microcrystalline Cellulose (CAS 9004-34-6)

US. Pennsylvania RTK - Hazardous Substances

Microcrystalline Cellulose (CAS 9004-34-6)
Prednisone (CAS 53-03-2)

US. Pennsylvania Worker and Community Right-to-Know Law

Microcrystalline Cellulose (CAS 9004-34-6)
Prednisone (CAS 53-03-2)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

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 11-03-2016

Version # 03

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