



SAFETY DATA SHEET

1. Identification

Product identifier	Dissolution Performance Verification Standard - Prednisone	
Other means of identification		
Catalog number	1222818	
Recommended use	For analytical laboratory 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	Customer Service	301-881-0666
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/fume/gas/mist/vapors/spray. 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	Potent pharmacologically active material.	

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Dicalcium Phosphate Anhydrous		7757-93-9	>40
Microcrystalline Cellulose		9004-34-6	>40
Colloidal silicone dioxide		112945-52-5	<10
Magnesium Stearate		557-04-0	<10
Prednisone	1-Dehydrocortisone	53-03-2	<10
Sodium Dodecyl Sulfate Fine	Sulfuric acid monododecyl ester sodium salt	151-21-3	<10
Sodium Starch Glycolate Type A		9063-38-1	<10

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. Endocrine system effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
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 CO ₂ . 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	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. For waste disposal, see section 13 of the SDS.
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 materials, 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. 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. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
Colloidal silicone dioxide (CAS 112945-52-5)	TWA	0.8 mg/m ³
		20 mppcf

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Inhalable fraction.
Microcrystalline Cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Colloidal silicone dioxide (CAS 112945-52-5)	TWA	6 mg/m ³	
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 USP materials.

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. Off-white.
Odor	Not available.
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 oxidizing agents. Fluorine.
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

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

Components	Species	Test Results
Colloidal silicone dioxide (CAS 112945-52-5)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg, 24 Hours
Oral		
LD50	Rat	> 3300 mg/kg
Dicalcium Phosphate Anhydrous (CAS 7757-93-9)		
<u>Acute</u>		
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
Microcrystalline Cellulose (CAS 9004-34-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2 g/kg
Inhalation		
LC50	Rat	> 5.05 mg/l, 4 hours
Oral		
LD50	Rat	> 5 g/kg
Sodium Dodecyl Sulfate Fine (CAS 151-21-3)		
Inhalation		
LC50	Rat	> 3900 mg/m3, 3 hours
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	1200 mg/kg
Sodium Starch Glycolate Type A (CAS 9063-38-1)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	

Serious eye damage/eye irritation

Causes eye irritation.

Local effects

Colloidal silicone dioxide

Draize Test
Result: Negative.
Species: Rabbit
Organ: Eye

Sodium Dodecyl Sulfate Fine

Eye irritation (Draize)
Result: Irritant.
Species: Rabbit
Eye irritation (Draize)
Result: Irritant.
Species: Rabbit
Severity: Moderate.
Eye irritation (Draize)
Result: Irritant.
Species: Rabbit
Severity: Severe.

Magnesium Stearate

Eye irritation
Result: Negative.
Species: Rabbit

Microcrystalline Cellulose

Eye irritation
Result: Negative.
Species: Rabbit

Dicalcium Phosphate Anhydrous

Irritancy test
Result: Mild
Species: Rabbit
Organ: Eye
Irritancy test
Result: Non-irritant
Species: Rabbit
Organ: Skin

Colloidal silicone dioxide

Irritation test
Result: Slight
Species: Rabbit
Organ: Skin

Sodium Dodecyl Sulfate Fine

Skin irritation (Draize)
Result: Irritant.
Species: Human
Skin irritation (Draize)
Result: Irritant.
Species: Rabbit

Magnesium Stearate

Skin irritation
Result: Negative.
Species: Rabbit

Microcrystalline Cellulose

Skin irritation
Result: Negative.
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization

Knowledge about health hazard is incomplete.

Skin sensitization

Knowledge about sensitization hazard is incomplete.

Colloidal silicone dioxide

Guinea pig maximization test
Result: Negative.

Sodium Dodecyl Sulfate Fine

Maximisation Test
Result: Not sensitizing
Species: Guinea pig
Organ: Skin.

Microcrystalline Cellulose

Skin sensitization
Result: Negative.
Species: Guinea pig

Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

Mutagenicity

Prednisone

Ames test (Salmonella typhimurium)
Result: Negative

Sodium Dodecyl Sulfate Fine

Ames test (Salmonella typhimurium)
Result: Negative.

Mutagenicity

Colloidal silicone dioxide	Ames test Result: Negative.
Microcrystalline Cellulose	Ames test Result: Negative.
Colloidal silicone dioxide	Chromosome aberration test (CHO) Result: Negative.
Microcrystalline Cellulose	Micronucleus test Result: Negative.
Prednisone	Mouse lymphoma assay Result: Negative
Microcrystalline Cellulose	Mouse lymphoma assay Result: Negative.
Sodium Dodecyl Sulfate Fine	Mutagenicity, In vitro clastogenic assay (Chinese hamster fibroblasts) Result: Negative.
Prednisone	Mutagenicity, In vivo chromosome aberration studies in rat bone marrow Result: Negative
Sodium Dodecyl Sulfate Fine	Mutagenicity, Sister chromatid exchange (Chinese hamster ovary cells) Result: Weakly positive.
Colloidal silicone dioxide	Unscheduled DNA synthesis assay Result: Negative.
Microcrystalline Cellulose	Unscheduled DNA synthesis Result: Negative.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

Microcrystalline Cellulose	30 % Oral feed study Result: Negative. Species: Rat Test Duration: 72 weeks
Prednisone	5 mg/kg/day Carcinogenicity Result: Negative Species: Mouse
Sodium Dodecyl Sulfate Fine	Carcinogenicity Result: Negative. Species: Dog Test Duration: 1 years
Colloidal silicone dioxide	Carcinogenicity, Dietary study (5%) Result: Negative. Species: Mouse Carcinogenicity, Dietary study (5%) Result: Negative. Species: Rat
Magnesium Stearate	Carcinogenicity: Implanted mouse bladders Result: Negative.
Microcrystalline Cellulose	Carcinogenicity; subcutaneous implant Result: Negative. Species: Rat Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

Colloidal silicone dioxide (CAS 112945-52-5)	3 Not classifiable as to carcinogenicity to humans.
Prednisone (CAS 53-03-2)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

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, Statistically significant decrease in birth weights of term infants. Result: Positive Species: Human
Sodium Dodecyl Sulfate Fine	170 - 1700 mg/kg/day Reproductivity, Increased rates of fetal malformation and death at maternally toxic doses (topical). Species: Mouse 200 mg/kg/day Reproductivity, Increased rates of fetal malformations and death at maternally toxic doses (oral). Species: Mouse
Microcrystalline Cellulose	4.6 mg/kg/day Reproductivity / developmental Result: No adverse effects on the offspring observed. Species: Rat
Colloidal silicone dioxide	500 mg/kg Reproductivity Result: No evidence of adverse effects. 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	
Dicalcium Phosphate Anhydrous (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
Sodium Dodecyl Sulfate Fine (CAS 151-21-3)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia obtusa)	9.2 - 10.4 mg/l, 48 hours
Fish	LC50	Carp, hawk fish (Cirrhinus mrigala)	1.36 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

Prednisone	1.46
Sodium Dodecyl Sulfate Fine	1.6

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 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 This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Serious eye damage or eye irritation
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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 Proposition 65

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. For more information go to www.P65Warnings.ca.gov.

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

Country(s) or region	Inventory name	On inventory (yes/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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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 11-02-2022

Version # 01

Disclaimer USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use 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 materials 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.