



Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

ATTENTION !

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.

PREDNISONE TABLETS

Catalog Number: 1559505

Revision Date:

March 7, 2006

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Prednisone Tablets

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.

Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW : Prednisone tablets contain excipients that may cause irritation.

Adverse Effects: Therapeutic use of corticosteroids may cause adverse effects due to the mineralocorticoid or glucocorticoid actions or from inhibition of the hypothalamic-pituitary-adrenal axis. The incidence of adverse effects increases with dose and duration of exposure; effects are rare with administration of less than three weeks. Symptoms from chronic exposure may include acne; pain in hips, shoulders, back, ribs, arms, or legs; filling or rounding out of face; increased hair growth; menstrual irregularities; muscle weakness, cramps, or pain; reddish-purple lines on skin; bruising; weight gain or loss; change in appetite; swelling of feet or lower legs; changes in vision; eye pain; irregular heartbeat; unusual tiredness or weakness; headache; insomnia; abdominal or stomach pain; nausea; vomiting; bloody or black, tarry stools; mood or mental changes; and increased susceptibility to infection. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overexposure may lead to effects listed above.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization, adrenal suppression, immune system depression, and hypercorticism or Cushing's syndrome.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material and active infection.

Cross Sensitivity: Persons sensitive to one corticosteroid may be sensitive to prednisone as well.

Target Organs: Endocrine system

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

PREDNISONE TABLETS

Catalog Number: 1559505

Revision Date:

March 7, 2006

Common Name: Prednisone Tablets

Formula: See Composition

Synonym: n/f

Chemical Name: Pregna-1,4-diene-3,11,20-trione, 17,21-dihydroxy- (Prednisone)

CAS: See Composition

RTECS Number: See Composition

Chemical Family: Corticosteroid (Prednisone)

Therapeutic Category: Glucocorticoid (Prednisone)

Composition: Prednisone [C₂₁H₂₆O₅, CAS # 53-03-2, RTECS # TU4154100] : 4.5%
Dibasic Calcium Phosphate [Ca . H₃O₄P, CAS # 7757-93-9, RTECS # TB8527000] : 38.5%
Microcrystalline Cellulose [(C₆H₁₀O₅)_n, CAS # 9004-34-6, RTECS # FJ5691460] : 52.9%
Sodium Starch Glycolate [(C₂H₄O₃)_x . (Na)_x, CAS # 9063-38-1] : 1.8%
Stearic Acid [C₁₈H₃₆O₂, CAS # 57-11-4, RTECS # WI2800000] : 1.4%
Magnesium Stearate [C₃₆H₇₀O₄.Mg, CAS # 557-04-0, RTECS # WI4390000] : 0.9%

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

Skin: May cause irritation. Avoid contact. Flush with copious quantities of soap and water.

Ingestion: May cause irritation. Avoid ingestion. Flush out mouth with water.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Treatment of overdose should be symptomatic and supportive. For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

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. Wash thoroughly after handling.

Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Store in a dry place at room temperature.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: Prednisone:

Industry: TWA 5 micrograms/m³; STEL 40 micrograms/m³

Microcrystalline Cellulose:

OSHA: TWA 5 mg/m³ (Inhalation respirable); 15 mg/m³ (Inhalation total)

ACGIH: TWA 10 mg/m³ (Inhalation total)

NIOSH: TWA 5 mg/m³ (Respirable fraction); 10 mg/m³ (Total dust)

Magnesium Stearate:

ACGIH: TWA 10 mg/m³ (stearates)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White tablets; odorless.

Odor Threshold: n/f

pH: n/f

Melting Range: n/f

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: n/f

Fat Solubility: n/f

Other Solubility: n/f

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: See Composition

Molecular Weight: n/f

PREDNISONE TABLETS

Catalog Number: 1559505

Revision Date:

March 7, 2006

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to air and moisture.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: Dibasic Calcium Phosphate: LD50: 3986 mg/kg
Microcrystalline Cellulose: LD50: > 5 grams/kg

Oral Mouse: Dibasic Calcium Phosphate: LD50: 15250 mg/kg

Other Toxicity Data: Dibasic Calcium Phosphate: Skin Rabbit LD50: >2 grams/kg
Microcrystalline Cellulose: Inhalation Rat LC50: >5800 mg/m³/4 hours; Skin Rabbit LD50: >2 grams/kg
Stearic Acid: Skin Rabbit LD50: >5000 mg/kg

Irritancy Data: Stearic Acid: Human/skin: mild; Rabbit/skin: moderate

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: Prednisone is not classifiable as to its carcinogenicity to humans.
NCI Carcinogenesis Study (Prednisone): Mouse (ipr): No evidence; Rat (ipr): Equivocal evidence.

Mutagenicity Data: Prednisone was not mutagenic to bacteria, and did not induce chromosome aberrations in bone marrow cells of rats treated in vivo.

Reproductive and Developmental Effects: There is evidence that therapeutic doses of corticosteroids may increase the risk of placental insufficiency, decreased birth weight, or stillbirth. However, birth defects in humans have not been confirmed. Studies in animals have shown that prednisone increases the incidence of abnormal fetal development, cleft palate, and miscarriage.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: n/f

PREDNISON TABLETS

Catalog Number: 1559505

Revision Date:

March 7, 2006

SECTION 16 - OTHER INFORMATION

Revision: 07-Mar-06

Previous Revision Date: 07-Feb-03