



Material Safety Data Sheet

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

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PREDNISONE TABLETS

Catalog Number: 1559505

Revision Date:

September 8, 2010

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Prednisone Tablets

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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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: The incidence of adverse effects from the therapeutic use of corticosteroids increases with dose and duration of exposure; effects are rare with administration of less than three weeks. Flunisolide has potent glucocorticoid effects which may include bone fractures, back pain, joint pain or stiffness, weakness, high blood pressure, 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, and mental or behavioral changes. The weak mineralocorticoid actions of this material may cause disruption of fluid and electrolyte imbalance, causing swelling, increased blood pressure, confusion, lightheadedness, nausea, vomiting, numbness, and tremors. 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. Withdrawal effects after chronic exposure is discontinued include fever, muscle pain, joint pain, and malaise.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, heart disease, high blood pressure, diabetes, epilepsy, glaucoma, hypothyroidism, osteoporosis, systemic fungal infections, peptic ulcer, mental disorders, or impaired liver or kidney function.

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

Target Organs: Endocrine system, immune system.

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS**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. Flush with copious quantities of water for at least 15 minutes.**Skin:** May cause irritation. Flush with copious quantities of soap and water. Prednisone can be absorbed through the skin in sufficient amounts to cause systemic effects, especially if skin is broken or exposure is extensive.**Ingestion:** May cause irritation. Flush out mouth with water. Prednisone is readily absorbed from the gastrointestinal tract.**General First Aid Procedures:** 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.**Note to Physicians****Overdose Treatment:** Acute toxicity following overdose is uncommon. Gastrointestinal decontamination is generally not necessary. Treatment should be symptomatic and supportive. [Poisindex 2010]**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 labeled container for disposal. Wash spill site.**SECTION 7 - HANDLING AND STORAGE**

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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.

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.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

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.

Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

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).

Gloves: Chemically compatible. 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.

Eye 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.

Protective Clothing: 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.

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

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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

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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
Prednisone: Subcutaneous Mouse LD50: 101 mg/kg

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

Corrosivity: n/f

Sensitization Data: n/f

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

Other Carcinogenicity Data: Prednisone studies in mice at oral doses up to 5 mg/kg/day for 18 months were negative for carcinogenicity.

Mutagenicity Data: Prednisone was negative for mutagenicity in the Ames assay in 5 strains of Salmonella typhimurium, with and without metabolic activation. It was negative for mutagenicity in mouse lymphoma studies without metabolic activation; however, one study showed inconclusive results in the mouse lymphoma cell with metabolic activation. It did not cause chromosomal damage in peripheral lymphocytes of humans given 3 mg/kg/prednisone for 28 days, then 0.5 to 1 mg/kg/day for 18 to 120 months.

Reproductive and Developmental Effects: Studies in rats, mice and rabbits have shown that prednisone increases the incidence of abnormal fetal development, cleft palate, and miscarriage. Prednisone has caused developmental and behavioral alterations in offspring of female mice given doses 1 to 4 times those used in humans. Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in cleft palate was seen in some human studies. One study of women receiving 10 mg/day of prednisone throughout pregnancy had a statistically significant decrease in the birth weight of term infants. Infants born to mothers who received substantial doses of corticosteroids during pregnancy should be observed for signs of hypoadrenalism.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: Prednisone - Algae IC50: 31 mg/L/72 hours. Harmful to aquatic organisms.

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

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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

SECTION 16 - OTHER INFORMATION

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