



Material Safety Data Sheet

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Responsible Party: Reference Standards Technical Services

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DEXAMETHASONE

Catalog Number: 1176007

Package Size: 125 mg

Revision Date:

July 21, 2004

SECTION 1 - IDENTIFICATION

Common Name: Dexamethasone

Formula: C₂₂H₂₉FO₅

Synonym: Superprednol

Chemical Name: Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11beta,16alpha)-

CAS Number: 50-02-2

RTECS Number: TU3980000

Chemical Family: Corticosteroid

Therapeutic Category: Glucocorticoid

SECTION 2 - INGREDIENT INFORMATION

<u>Principle Components</u>	<u>Percent</u>	<u>Exposure Limits</u>
Dexamethasone	Pure Material	n/f

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual oral adult dose of dexamethasone is 0.75 to 9 mg per day, as a single or in divided doses. It is also administered topically to the skin or eye as an 0.05% to 0.1% ointment.

Adverse Effects: Toxic signs and symptoms rarely occur with corticosteroid administration of less than three weeks duration. If they do occur, adverse effects following skin exposure may include stinging, burning, itching, dryness, acne, and discoloration of skin. Adverse effects following ingestion or systemic absorption may include decreased or blurred vision, frequent urination, increased thirst, nausea, vomiting, increased appetite, indigestion, nervousness or other mental status changes, trouble sleeping, weight gain, dizziness, flushing of face or cheeks, headache, hiccups, and increased sweating. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

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

Chronic: Long-term corticosteroid use may cause hypersensitization; acne or other skin problems; hip or shoulder pain; gradual blurring or loss of vision; eye pain or redness; sensitivity of eye to light or tearing; rounding

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out of face; unusual increase in hair growth; hypertension; menstrual irregularities; muscle weakness; reddish purple lines on arms, face, legs, trunk, or groin; unusual bruising; rapid weight gain; swelling of feet or lower legs; irregular heartbeat; muscle cramps or pain; unusual tiredness or weakness; impaired wound healing; headache; insomnia; pain in back, ribs, arms or legs; continuing abdominal or stomach pain or burning; nausea; vomiting; bloody or black, tarry stools; tendon rupture; changes in skin color; and thin, fragile skin.

Inhalation: May cause irritation. Remove to fresh air. This material may be absorbed from the lungs.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water. This material may be absorbed through broken skin or if applied to a large area of skin.

Ingestion: May cause irritation. Flush out mouth with water. This material is rapidly and almost completely absorbed from the gastrointestinal tract.

Medical Conditions

Aggravated by Exposure:

Hypersensitivity to material; ocular herpes simplex; AIDS or HIV infection; heart disease or recent heart attack; intestinal anastomoses; strongyloides infestation; diabetes mellitus; myasthenia gravis; impaired kidney function; esophagitis; gastritis, colitis, or peptic ulcer; chickenpox or measles (including recent exposure); tuberculosis; systemic fungal infections; high blood pressure; chronic infections; psychosis; hypothyroidism; glaucoma; cataracts; and osteoporosis.

Cross Sensitivity: Persons sensitive to other corticosteroids may also be sensitive to this material.

Pregnancy Comments:

Animal studies have shown dexamethasone to be associated with fetal malformations and reduced fetal and neonatal growth in animals. Studies in animals have shown that corticosteroids increase the incidence of cleft palate, placental insufficiency, miscarriage, and fetal growth retardation. Although adequate studies have not been done in humans, there is some evidence that pharmacologic doses of corticosteroids may increase the risk of placental insufficiency, decreased birth weight, or stillbirth. However, birth defects have not been confirmed.

Pregnancy Category:

n/f

SECTION 4 - FIRST AID MEASURES

General:

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.

Overdose Treatment:

Treatment of corticosteroid overdose should be symptomatic and supportive and may include the following:
1. Administer activated charcoal as an aqueous slurry, unless contraindicated. This is most effective within one hour of ingestion.
2. Dilute with fluids. [Poisindex 2004; USP DI 2004]

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: >3 grams/kg

Oral Mouse: LD50: 6.5 grams/kg

Irritancy Data: n/f

Target Organ(s): n/f

Listed as a Carcinogen? NTP: No IARC: No OSHA: No

Other: No

SECTION 6 - FIREFIGHTING MEASURES

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Flash Point: n/f

Upper Flammable Limit: n/f

Auto-Ignition Temperature: n/f

Lower Flammable Limit: n/f

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. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

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

SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: Avoid exposure to moisture.

Incompatibilities: Strong oxidizing agents, strong acids, acid chlorides and acid anhydrides.

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

Stable? Yes **Hazardous Polymerization?** No

SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

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.

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.

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

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

Ventilation: No special ventilation requirements.

Gloves: Rubber

Eye Protection: Safety Glasses

Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!

Appearance and Odor: White to practically white crystalline powder; odorless.

Melting Point: about 250° C (with some decomposition); also reported as 262 - 264 and 268 - 271° C

Solubility in Water: Practically insoluble

Vapor Density: n/f

Boiling Point: n/f

Evaporation Rate: n/f

Specific Gravity: n/f

Reactivity in Water: n/f

Vapor Pressure: n/f

% Volatile by Volume: n/f