



Material Safety Data Sheet

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HYDROCORTISONE ACETATE

IDENTIFICATION

Common Name: Hydrocortisone Acetate

Chemical Name: Pregn-4-ene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-, (11beta)-

Synonym: Hydrocortisone-21-acetate; Cortisol, 21-acetate

Formula: C₂₃H₃₂O₆

CAS Number: 50-03-3

RTECS Number: KF4375000

Chemical Family: Corticosteroid

Therapeutic Category: Glucocorticoid

INGREDIENT INFORMATION

Principle Components

Hydrocortisone Acetate

Percent

Pure Material

Exposure Limits

n/f

HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual adult dose of hydrocortisone acetate (topical, as a 0.5% or 1% product) is up to four applications per day.

Adverse Effects: Toxic signs and symptoms rarely occur with administration of less than 3 weeks duration; even a massive single dose of this material is unlikely to cause adverse effects. If they do occur, adverse effects may include decreased or blurred vision, frequent urination, increased thirst, increased appetite, indigestion, nervousness or restlessness, and trouble sleeping. 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: Possible hypersensitization, acne or other skin problems, hip or shoulder pain, fullness in face, swelling of feet or lower legs, menstrual irregularities, nausea, vomiting, irregular heartbeat, muscle cramps, weakness, osteoporosis, increased susceptibility to infection, psychosis, and eye problems.

n/f = not found

HYDROCORTISONE ACETATE

HEALTH HAZARD INFORMATION CONTINUED

Inhalation: May cause irritation. Remove to fresh air.

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

Skin: May cause irritation. Flush with copious quantities of water. This material 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. This material is absorbed from the gastrointestinal tract.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material; ocular herpes simplex; active alcoholism; AIDS or HIV infection; heart disease or hypertension; diabetes mellitus; myasthenia gravis; impaired liver or kidney function; esophagitis, gastritis or peptic ulcer; chickenpox or measles (including recent exposure); tuberculosis; and systemic

Cross Sensitivity: n/f

Pregnancy Comments: Although adequate and well-controlled pregnancy 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 in humans have not been confirmed. Studies in animals have shown that corticosteroids increase the incidence of cleft palate, placental insufficiency, miscarriage, and slowed intrauterine growth.

Pregnancy Category: C

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 for acute overdose is symptomatic and supportive; including fluids for dilution. Antacids may be used to relieve gastrointestinal irritation. Psychic disturbances (which may be delayed for up to 2 weeks following large ingestions) are treatable with a phenothiazine or lithium. Tricyclic antidepressants should NOT be used. [USP DI 2002]

TOXICOLOGICAL INFORMATION

Oral Rat: LD50: n/f

Oral Mouse: LD50: n/f

Irritancy Data: n/f

Target Organ(s): Eyes.

Listed as a Carcinogen? NTP: No
Other: No

IARC: No

OSHA: No

n/f = not found

HYDROCORTISONE ACETATE

FIREFIGHTING MEASURES

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.

PHYSICAL HAZARDS

Conditions to Avoid: Avoid exposure to moisture.

Incompatibilities: Alkalis and strong acids.

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

Stable? Yes

Hazardous Polymerization? No

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 labeled container for disposal. Wash spill site.

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

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.

n/f = not found

HYDROCORTISONE ACETATE

PHYSICAL AND CHEMICAL PROPERTIES

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

Melting Point: Approximately 225° C (decomposes at 223° C)

Solubility in Water: Practically insoluble

Solubility in Water: n/f

Boiling Point: n/f

Specific Gravity: 1.289

Vapor Pressure: n/f

Vapor Density: n/f

Evaporation Rate: n/f

Evaporation Rate: n/f

Reactivity in Water: n/f

% Volatile by Volume: n/f

n/f = not found