Fludrocortisone

sc-207690





The Power to Questi

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Fludrocortisone

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

Santa Cruz Biotechnology, Inc. 2145 Delaware Avenue Santa Cruz, California 95060 800.457.3801 or 831.457.3800

EMERGENCY

ChemWatch

Within the US & Canada: 877-715-9305 Outside the US & Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

PRODUCT NUMBERS

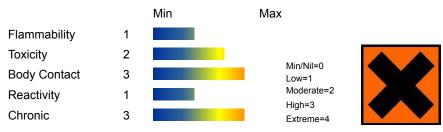
SC-218493

SYNONYMS

C21-H29-F-O5, 9alpha-fluorocortisol, fluorocortisone, 9alpha-fluorohydrocortisone, 9alpha-fluoro-17-hydroxycorticosterone, "9-fluoro-11beta, 17, 21-trihydroxypregn-4-ene-3, 20-dione", "9alpha-fluoro-11beta, 17alpha, 21-trihydroxy-4-pregnene-3, 20-dione", Alflorone, F-Col, F-Cortef, Florinef, Fluorocortone, Fluodrocortisone, Fluohydrocortisone, U-5963, "corticosteroid/ glucocorticoid/ mineralocorticoid"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS



CANADIAN WHMIS SYMBOLS





EMERGENCY OVERVIEW

RISK

Possible risk of harm to the unborn child.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- The corticosteroids cause alterations in metabolism of fats, proteins and carbohydrates, and affect a range of organs in the body including the heart, muscle and kidneys.

Blood chemistry may change and there is decreased activity and shrinkage of the thymus gland, adrenal glands, spleen and lymph nodes.

EYE

- If applied to the eyes, this material causes severe eye damage.
- When applied to the eye, corticosteroids may produce ulceration of the cornea, raised eye pressure and reduced vision; internal administration can cause cataracts.

SKIN

- The material is not thought to be a skin irritant (as classified by EC Directives using animal models). Abrasive damage however, may result from prolonged exposures.
- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

- Topically applied corticosteroids may be absorbed in sufficient quantity to produce systemic effects.
- Application to the skin may result in collagen loss and subcutaneous atrophy and local bleaching of deeply pigmented skin.
- Prolonged external application of fluoro-corticosteroids can cause red lesions in the skin; after treatment ends, there may be severe swelling and blisters with scabs.

INHALED

- The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
- Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic

bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

■ Systemic absorption of aerosols containing corticosteroids may produce adrenal insufficiency and collapse.

CHRONIC HEALTH EFFECTS

■ Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.

Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray.

Chronic exposure to glucocorticoids can lead to changes in hormone production, a characteristic "moon face" appearance and a "lemon with matchsticks" fat distribution (central obesity with wasting of limbs), susceptibility to infections, osteoporosis, cataracts, glaucoma, mental disturbance, high blood sugar and sugar in the urine. There may be muscular weakness and fatigue, acne, period disturbances in women and peptic ulcers. Growth retardation can occur in children and birth defects are possible. Corticosteroids appear in human milk and may stunt the growth of infants.

| Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS | | | | | |
|--|----------|-----|--|--|--|
| NAME | CAS RN | % | | | |
| fludrocortisone | 127-31-1 | >98 | | | |

Section 4 - FIRST AID MEASURES

SWALLOWED

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.

EYE

If this product comes in contact with the eyes

- Immediately hold eyelids apart and flush the eye continuously with running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.

SKIN

If skin contact occurs

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- · Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.

 Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.

NOTES TO PHYSICIAN

■ The adverse effects of corticosteroids are almost always due to their use in excess of physiological requirements. Symptomatic treatment is called for.

| Section 5 - FIRE FIGHTING MEASURES | | | | | | |
|------------------------------------|---------------|--|--|--|--|--|
| Vapor Pressure (mmHG) | Negligible | | | | | |
| Upper Explosive Limit (%) | Not available | | | | | |
| Specific Gravity (water=1) | Not available | | | | | |
| Lower Explosive Limit (%) | Not available | | | | | |

EXTINGUISHING MEDIA

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent area.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an
 explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust
 clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420
 micron or less) may burn rapidly and fiercely if ignited particles exceeding this limit will generally not form
 flammable dust clouds.; once initiated, however, larger particles up to 1400 microns diameter will contribute to
 the propagation of an explosion.
- In the same way as gases and vapors, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL).are applicable to dust clouds but only the LEL is of practical use; this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.

Combustion products include carbon monoxide (CO), carbon dioxide (CO2), hydrogen fluoride, other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

FIRE INCOMPATIBILITY

 Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.

• Use dry clean up procedures and avoid generating dust.

MAJOR SPILLS

Moderate hazard.

- CAUTION Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- · Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- · Glass container is suitable for laboratory quantities
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- Store in original containers.
- · Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.

NOTE Store in the dark.

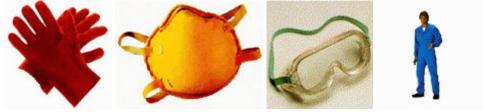
Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

• fludrocortisone CAS127-31-1

PERSONAL PROTECTION



RESPIRATOR

•Particulate. (AS/NZS 1716 & 1715, EN 1432000 & 1492001, ANSI Z88 or national equivalent)

When handling very small quantities of the material eve protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written

policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

HANDS/FEET

NOTE

- The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing
 gloves and other protective equipment, to avoid all possible skin contact.
- Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include

- · frequency and duration of contact,
- · chemical resistance of glove material,
- · glove thickness and
- dexterity
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile
 gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers. [AS/NZS 2210]

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- · butyl rubber
- fluorocaoutchouc

OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended.
 Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

ENGINEERING CONTROLS

Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid

Does not mix with water.

| State | Divided solid | Molecular Weight | 380.45 |
|-------------------------|---------------|---------------------------|-----------------|
| Melting Range (°F) | 500- 504 | Viscosity | Not Applicable |
| Boiling Range (°F) | Not available | Solubility in water (g/L) | Partly miscible |
| Flash Point (°F) | Not available | pH (1% solution) | Not Applicable |
| Decomposition Temp (°F) | Not available | pH (as supplied) | Not applicable |

| Autoignition Temp (°F) | Not available | Vapor Pressure (mmHG) | Negligible |
|---------------------------|---------------|--------------------------------|----------------|
| Upper Explosive Limit (%) | Not available | Specific Gravity (water=1) | Not available |
| Lower Explosive Limit (%) | Not available | Relative Vapor Density (air=1) | Not Available |
| Volatile Component (%vol) | Negligible | Evaporation Rate | Not Applicable |

APPEARANCE

Powder; does not mix well with water.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- · Product is considered stable.
- Hazardous polymerisation will not occur.

STORAGE INCOMPATIBILITY

· Avoid reaction with oxidising agents

Heat and light accelerate decomposition.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

fludrocortisone

TOXICITY AND IRRITATION FLUDROCORTISONE

unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered
 first
- Where in doubt contact the responsible authority.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

fludrocortisone (CAS: 127-31-1) is found on the following regulatory lists;

"US FDA Maximum Recommended Therapeutic Dose (MRTD) Database"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Inhalation, skin contact and/or ingestion may produce health damage*.
- Cumulative effects may result following exposure*.
- Eye contact may produce serious damage*.
- Possible skin sensitiser*.
- * (limited evidence).

Denmark Advisory list for selfclassification of dangerous substances

Substance CAS Suggested codes fludrocortisone 127- 31- 1 Xn: R22

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- Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. A list of reference resources used to assist the committee may be found at: www.chemwatch.net/references.
- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

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