

Fluticasone propionate

sc-218517



The Power is Question

Material Safety Data Sheet

Hazard Alert Code
Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

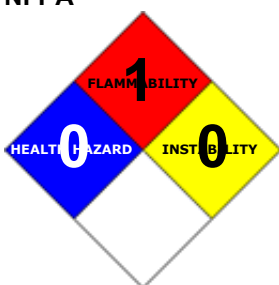
PRODUCT NAME

Fluticasone propionate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

Company: Santa Cruz Biotechnology, Inc.

Address:

2145 Delaware Ave

Santa Cruz, CA 95060

Telephone: 800.457.3801 or 831.457.3800

Emergency Tel: CHEMWATCH: From within the US and

Canada: 877-715-9305

Emergency Tel: From outside the US and Canada: +800 2436

2255 (1-800-CHEMCALL) or call +613 9573 3112

PRODUCT USE

Corticosteroid used as a topical anti-inflammatory agent. Also investigated in gthe management of asthma.

SYNONYMS

C25-H31-F3-O5-S, "androst-1, 4-diene-17-carbothioic acid, 6, 9-difluoro-11-hydroxy-16-", "methyl-3-oxo-17-(1-oxopropoxy)-S-(fluoromethyl) ester, (6alpha, 11beta, ", "16alpha, 17alpha)", "androst-1, 4-diene-17-carbothioic acid, 6, 9-difluoro-11-hydroxy-16-", "methyl-3-oxo-17-(1-oxopropoxy)-S-(fluoromethyl) ester, (6alpha, 11beta, ", "16alpha, 17alpha)", S-(fluoromethyl)-6alpgha-9-difluoro-11beta-17-dihydroxy-16alpha-methyl-, "3-oxoandrosta-1, 4-diene-17beta-carbothioate", S-(fluoromethyl)-6alpgha-9-difluoro-11beta-17-dihydroxy-16alpha-methyl-, "3-oxoandrosta-1, 4-diene-17beta-carbothioate", CCI-18781, corticosteroid, "corticoid anti-inflammatory"

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Although ingestion is not thought to produce harmful effects, the material may still be damaging to the health of the individual

following ingestion, especially where pre-existing organ (e.g. liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality (death) rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

- 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. The liver becomes enlarged, thyroid activity decreases, and mineral is drawn away from bone. Muscle wasting occurs, and the immune system is adversely affected causing the person to be more susceptible to infections, especially of the eye. Allergies can occur. Wound healing is slowed. In large doses, corticosteroids cause a severe chemical imbalance in the body's minerals, leading to salt and water being retained in the body, causing swelling and high blood pressure. This is more severe when natural rather than synthetic drugs are used. Blood glucose is raised, and in extreme cases the heart may fail. The characteristic "moon-face" appearance may be seen, with weakness of the muscles and bones, high blood pressure, cessation of periods, profuse sweating, mental disturbance, flushing, a humped back, hairiness, and obesity of the trunk with wasting of the arms and limbs ("lemon with matchsticks" shape). These generally improve when treatment is stopped. High pressure in the head, an inflamed pancreas and mental disturbance become more common, and bone tissue may die. The blood also condenses more easily leading to an increased risk of clots. Psychiatric changes include mood swings, personality changes, severe depression and psychosis (hallucinations and delusions). One should be beware of an increased susceptibility to a wide range of infections which may be masked by the ability of corticosteroids to reduce pain, inflammation and fever. Those with ulcers, gastrointestinal disease, kidney impairment, hypothyroidism, high blood pressure, liver damage and osteoporosis may be especially susceptible to the adverse effects of corticosteroids. Prolonged exposure can cause cataracts and eye nerve damage, leading to blindness.

EYE

- Although the material is not thought to be an irritant, direct contact with the eye may produce transient discomfort characterized by tearing or conjunctival redness (as with windburn).
- The dust may produce eye discomfort causing smarting, pain and redness.
- When applied to the eye, corticosteroids may produce ulceration of the cornea, raised eye pressure and reduced vision; internal administration can cause cataracts.

SKIN

- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- The material is not thought to be a skin irritant (as classified using animal models). Temporary discomfort, however, may result from prolonged dermal exposures. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
- Toxic effects may result from skin absorption.
- 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. Systemic absorption may produce adrenal suppression and collapse.
- 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

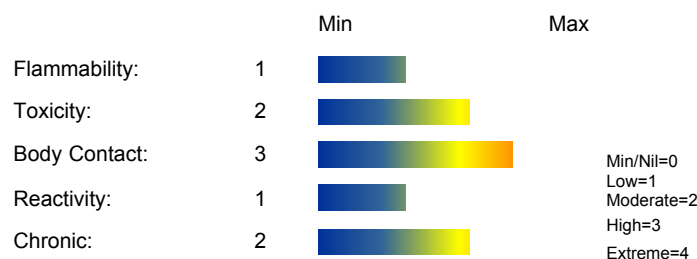
- The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless inhalation of the material, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.
- Systemic absorption of aerosols containing corticosteroids may produce adrenal insufficiency and collapse.

CHRONIC HEALTH EFFECTS

- Principal routes of exposure are by accidental skin and eye contact and inhalation of generated dusts. 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

HAZARD RATINGS



NAME	CAS RN	%
fluticasone propionate	80474-14-2	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

- If poisoning occurs, contact a doctor or Poisons Information Center. Poison Information Centers in each State capital city can provide additional assistance.

EYE

- If this product comes in contact with the eyes:
 - Wash out immediately with fresh 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.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

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 dust is inhaled, remove from contaminated area.
 - Encourage patient to blow nose to ensure clear passage of breathing.
 - If irritation or discomfort persists seek medical attention.

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. Where possible the dose should be withdrawn or reduced. Acute renal insufficiency should be treated with intravenous hydrocortisone sodium succinate with infusions of 0.9% dextrose. MARTINDALE, The Extra Pharmacopoeia, 29th Ed. Patients or individuals exposed regularly in an occupational setting, should be evaluated periodically for evidence of HPA axis suppression. The evaluation may be performed by using the ACTH stimulation, A.M. plasma cortisol and urinary free cortisol tests. If HPA axis suppression is confirmed the individual should be removed from exposure. Recovery of the HPA axis function is generally prompt upon exposure cessation. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids.

Section 5 - FIRE FIGHTING MEASURES

Upper Explosive Limit (%):	Not available
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available
Relative Vapor Density (air=1):	Not available

EXTINGUISHING MEDIA

- - Foam.
 - Dry chemical powder.
 - BCF (where regulations permit).
 - Carbon dioxide.
 - Water spray or fog - Large fires only.

FIRE FIGHTING

- - Alert Emergency Responders and tell them location and nature of hazard.
 - Wear breathing apparatus plus protective gloves for fire only.
 - Prevent, by any means available, spillage from entering drains or water course.
 - Use fire fighting procedures suitable for surrounding area.
 - Do not approach containers suspected to be hot.
 - Cool fire exposed containers with water spray from a protected location.
 - If safe to do so, remove containers from path of fire.
 - Equipment should be thoroughly decontaminated after use.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- - Solid which exhibits difficult combustion or is difficult to ignite.
 - 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 may burn rapidly and fiercely if ignited.
 - Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
 - Build-up of electrostatic charge may be prevented by bonding and grounding.
 - Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

Combustion products include: carbon monoxide (CO), sulfur oxides (SOx) and hydrogen fluoride.

FIRE INCOMPATIBILITY

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

PERSONAL PROTECTION

Glasses:
Chemical goggles.
Gloves:
Respirator:
Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- - Remove all ignition sources.

- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact by using protective equipment.
- Use dry clean up procedures and avoid generating dust.
- Place in a suitable, labelled container for waste disposal.

MAJOR SPILLS

-
- Clear area of personnel and move upwind.
- Alert Emergency Responders and tell them location and nature of hazard.
- Control personal contact by using protective equipment and dust respirator.
- Prevent spillage from entering drains, sewers or water courses.
- Avoid generating dust.
- Sweep, shovel up.
- Recover product wherever possible.
- Put residues in labeled plastic bags or other containers for disposal.
- If contamination of drains or waterways occurs, advise emergency services.

ACUTE EXPOSURE GUIDELINE LEVELS (AEGLE) (in ppm)

AEGLE 1: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.

AEGLE 2: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

AEGLE 3: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

-
- Avoid generating and breathing dust
- Avoid contact with skin and eyes.
- Wear nominated personal protective equipment when handling.
- Use in a well-ventilated area.
- Use good occupational work practices.
- Observe manufacturer's storing and handling recommendations.

RECOMMENDED STORAGE METHODS

- Packaging as recommended by manufacturer.
 - Check that containers are clearly labeled
- Plastic container.

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.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



X: Must not be stored together

O: May be stored together with specific preventions

+: May be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- fluticasone propionate: CAS:80474-14-2

MATERIAL DATA

FLUTICASONE PROPIONATE:

- CEL TWA: 0.02 mg/m³

(compare Merck, Sharp and Dohme recommendation for dexamethasone) All corticosteroids have numerous and varied pharmacological actions. In humans, single dose or short term (several days) use is virtually without harmful effects. However prolonged therapeutic use of corticosteroids may result in suppression of the pituitary function. The daily threshold dose for this effect is approximately 0.5 mg for a 50 kg individual. Therefore typical exposure limits of about 0.02 mg/m³ have been calculated from the threshold dose. This is thought to provide about a two-fold safety factor.

PERSONAL PROTECTION



Consult your EHS staff for recommendations

■ EYE

No special equipment needed when handling small quantities of substance.

For bulk handling wear:

Chemical goggles or

Face shield.

HANDS/FEET

Rubber gloves

PVC gloves

Protective shoe covers

Head covering.

OTHER

No special equipment when handling small quantities of substance otherwise:

Coveralls

For Emergencies:

Vinyl suit

Safety shower

RESPIRATOR

High Efficiency Dust Respirator (P2, P3)

For non-routine emergencies wear full face mask self-contained breathing apparatus.

RESPIRATOR

Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
10 x PEL	P1	-	PAPR-P1
	Air-line*	-	-
50 x PEL	Air-line**	P2	PAPR-P2
100 x PEL	-	P3	-
	-	Air-line*	-
100+ x PEL	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

Explanation of Respirator Codes:

Class 1 low to medium absorption capacity filters.

Class 2 medium absorption capacity filters.

Class 3 high absorption capacity filters.

PAPR Powered Air Purifying Respirator (positive pressure) cartridge.

Type A for use against certain organic gases and vapors.

Type AX for use against low boiling point organic compounds (less than 65°C).

Type B for use against certain inorganic gases and other acid gases and vapors.

Type E for use against sulfur dioxide and other acid gases and vapors.

Type K for use against ammonia and organic ammonia derivatives

Class P1 intended for use against mechanically generated particulates of sizes most commonly encountered in industry, e.g. asbestos, silica.

Class P2 intended for use against both mechanically and thermally generated particulates, e.g. metal fume.

Class P3 intended for use against all particulates containing highly toxic materials, e.g. beryllium.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.

Use appropriate NIOSH-certified respirator based on informed professional judgement. In conditions where no reasonable estimate of exposure can be made, assume the exposure is in a concentration IDLH and use NIOSH-certified full face pressure demand SCBA with a minimum service life of 30 minutes, or a combination full facepiece pressure demand SAR with auxiliary self-contained air supply. Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

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.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapors, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	500.62
Melting Range (°F)	Not available	Boiling Range (°F)	Not applicable
Solubility in water (g/L)	Immiscible	Flash Point (°F)	Not available
pH (1% solution)	Not available	Decomposition Temp (°F)	Not available
pH (as supplied)	Not applicable	Autoignition Temp (°F)	Not available
Vapour 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 available		

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 polymerization will not occur.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents.
- Be sure container is tightly closed when not in use.

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

Section 11 - TOXICOLOGICAL INFORMATION

fluticasone propionate

TOXICITY AND IRRITATION

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (rat) LD50: >2000 mg/kg	Nil Reported
Inhalation (rat) LC(50?): >40.77 mg/m ³ /1h	

Subcutaneous (rat) LD50: >1000 mg/kg

Cardiac weight changes, changes in blood concentration (TP, bilirubin, cholesterol) recorded.

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:
FLUTICASONE PROPIONATE:

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
fluticasone propionate	HIGH		LOW	MED

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

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

1

- Recycle wherever possible. Special hazard may exist - specialist advice may be required.
- Consult manufacturer for recycling options.
- Consult Waste Management Authority for disposal.
- Bury or incinerate residue at an approved site.
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
- Puncture containers to prevent re-use and bury at an authorized landfill.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

fluticasone propionate (CAS: 80474-14-2) is found on the following regulatory lists;

"US - California Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity", "US - California Proposition 65 - Reproductive Toxicity", "US - Maine Chemicals of High Concern List"

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 sensitizer*.

* (limited evidence).

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- Classification of the mixture 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. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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