Clobetasol Propionate

sc-204692

Material Safety Data Sheet



Hazard Alert Code Key: EXTREME HIGH MODERATE LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Clobetasol Propionate

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

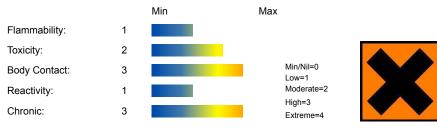
Within the US & Canada: 877-715-9305 Outside the US & Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS

C25-H32-Cl-F-O5, "clobetasol 17-propionate", "21-chloro-9alpha-fluoro-11beta, 17alpha-dihydroxy-16beta-methylpregna-", "1, 4-diene-3, 20-dione 17-propionate", "pregna-1, 4-diene-3, 20-dione, 21-chloro-9-fluoro-11beta, 17-dihydroxy-", "16-beta-methyl-, 17-propionate", Butavat, CCI-4725, GR2/925, Clobesol, Clovate, Decloban, Dermadex, Dermovate, Dermatovate, Dermoval, Dermovat, Dermoxin, Dermoxinale, Temovate, "synthetic corticosteroid", "corticoid anti-inflammatory"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW RISK

Irritating to eyes, respiratory system and skin.

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

- This material can cause eye irritation and damage in some persons.
- 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

- This material can cause inflammation of the skin oncontact in some persons.
- The material may accentuate any pre-existing dermatitis condition.
- 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 can cause respiratory irritation in some persons.

The body's response to such irritation can cause further lung damage.

- 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.
- Systemic absorption of aerosols containing corticosteroids may produceadrenal insufficiency and collapse.

CHRONIC HEALTH EFFECTS

■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

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

There is some evidence that human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects.

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.

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

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.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

| NAME | CAS RN | % |
|-----------------------|------------|-----|
| clobetasol propionate | 25122-46-7 | >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.

FVF

■ 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

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

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 | | | | |
|------------------------------------|---------------|--|--|--|
| Vapour 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.

FIRE FIGHTING

- · Alert Emergency Responders and tell them location and nature of hazard.
- · Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- · Combustible solid which burns but propagates flame with difficulty.
- 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.

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

May emit poisonous fumes.

May emit corrosive fumes.

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

- · 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.
- · Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- · Dampen with water to prevent dusting before sweeping.
- · Place in suitable containers for disposal.

MAJOR SPILLS

- Moderate hazard.
- · CAUTION: Advise personnel in area.
- · Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- · Avoid all personal contact, including inhalation.
- · Wear protective clothing when risk of exposure occurs.

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.
- · Polyethylene or polypropylene container.
- · Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- · Store in original containers.
- · Keep containers securely sealed.

NOTE: Store in the dark.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

• clobetasol propionate: CAS:25122-46-7

PERSONAL PROTECTION









RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

■ When handling very small quantities of the material eye 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].

HANDS/FEET

■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

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

- · frequency and duration of contact,
- chemical resistance of glove material,
- \cdot glove thickness and
- · dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- · 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.
- · Head covering.

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

· polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

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.
- · Eye wash unit.
- · Ensure there is ready access to an emergency shower.
- · For Emergencies: Vinyl suit.

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.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid

Does not mix with water.

| State | Divided solid | Molecular Weight | 467.0 |
|---------------------------|---------------|--------------------------------|-----------------|
| Melting Range (°F) | 383 | Viscosity | Not Applicable |
| Boiling Range (°F) | Not available | Solubility in water (g/L) | Partly miscible |
| 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 Applicable |
| Volatile Component (%vol) | Negligible | Evaporation Rate | Not Applicable |

APPEARANCE

Powder; does not mix well with water. Soluble in ethanol, acetone.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- · Presence of incompatible materials.
- · Product is considered stable.

STORAGE INCOMPATIBILITY

· Avoid strong acids, bases.

Avoid reaction with oxidizing agents.

Heat and light accelerate decomposition.

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

Section 11 - TOXICOLOGICAL INFORMATION

CLOBETASOL PROPIONATE

TOXICITY AND IRRITATION

CLOBETASOL PROPIONATE:

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

TOXICITY IRRITATION

Oral (rat) LD50: >3000 mg/kg Nil Reported

Intraperitoneal (rat) LD50: 351 mg/kg

Subcutaneous (rat) LD50: 366 mg/kg

Oral (mouse) LD50: >3000 mg/kg

Intraperitoneal (mouse) LD50: 118 mg/kg

Subcutaneous (mouse) LD50: 81.7 mg/kg

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with

abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Maternal effects, effects on newborn recorded.

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

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

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.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- · Recycle wherever possible.
- · Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

clobetasol propionate (CAS: 25122-46-7) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)", "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

ND

Substance CAS Suggested codes clobetasol propionate 25122- 46- 7

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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. 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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