Cyproterone Acetate



Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Cyproterone Acetate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

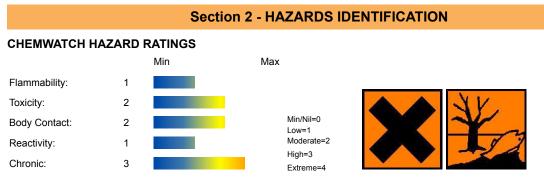


SUPPLIER

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

C23-H29-Cl-O4, "17alpha-acetoxy-6-chloro-1alpha, 2alpha-methylenepregna-4, 6-diene-3-", 20-dione, "6-chloro-delta(sup 6)-1, 2-alphamethylene-17alpha-hydroxyprogesterone", acetate, "6-chloro-17-hydroxy-1-alpha-2-alpha-methylenepregna-4, 6-diene-3, 20-", dione, "6-chloro-1, 2-alpha-methylene-6-dehydro-17alpha-hydroxyprogesterone", acetate, "1, 2-alpha-methylene-6-chloro-delta(sup 6)-17-alphahydroxyprogesterone", "1, 2-methylene-6-chloro-(sup 4, 6)-pregnadiene-17alpha-ol-3, 20-dione", 17alpha, "pregn-4, 6-diene-3, 20-dione, 6-chloro-17-hydroxy-1alpha, 2alpha-", methylene, "3' H-cyclopropa[1, 2]pregna-1, 4, 6-triene-3, 20-dione, ", "6-chloro-beta, 2beta-dihydro-17-hydroxy-, acetate", CPA, "Cyprosterone acetate", "Cyproteron acetate", "Cyproteron-R acetate", NSC-81430, "SH 714", "anti-androgen/ progestogen/ steroid", Cyprone



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Limited evidence of a carcinogenic effect. Harmful by inhalation, in contact with skin and if swallowed. Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.

■ 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.

<\p>. **EYE**

■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.

<\p>. SKIN

The material is not thought to be a skin irritant (as classified using animal models). Abrasive damage however, may result from prolonged exposures.

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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.

INHALED

• The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

 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.

CHRONIC HEALTH EFFECTS

There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment.

• 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.

Exposure to the material may cause concerns for human fertility, on the basis that similar materials provide some evidence of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which are not a secondary non-specific consequence of 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.

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

Progestogens cause gastrointestinal disturbances, acne, swelling, weight gain, skin rashes, hives, menal depression, breast changes with discomfort and occasionally enlargement in males, changes in sex drive, altered menstrual cycles or irregular menstrual bleeding. Liver abnormalities and jaundice have been reported.

Some progestogens have been associated with an increase in congenital abnormalities. Repeated intake of progesterones may produce headache, nausea, vomiting, diarrhea, inflammation of the mouth cavity with ulcers, swelling, weight change, fever, fatigue, increased or decreased sleep, mental depression, allergic rashes including hives and itching, acne, sensitivity to light, pigmented skin, hair loss, excessive hair growth, clotting and vein inflammation, obstructive jaundice, and precipitation of porphyria.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS					
NAME	CAS RN	%			
cyproterone acetate	427-51-0	>98			

Section 4 - FIRST AID MEASURES

SWALLOWED

· Immediately give a glass of water. · First aid is not generally required. If in doubt, contact a Poisons Information Center or a doctor.

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.

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 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

Treat symptomatically.

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.

 \cdot Dry chemical powder.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.

· Wear breathing apparatus plus protective gloves.

When any large container (including road and rail tankers) is involved in a fire,

consider evacuation by 100 metres in all directions.

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, other pyrolysis products typical of burning organic material.

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.
- Environmental hazard contain spillage.

MAJOR SPILLS

- Environmental hazard contain spillage.
- Moderate hazard.
- \cdot 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

· Polyethylene or polypropylene container.

· Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

Observe manufacturer's storing and handling recommendations.

NOTE: Store in the dark.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m³	STEL ppm	STEL mg/m³	Peak ppm	Peak mg/m³	TWA F/CC	Notes
US - California Permissible Exposure Limits for Chemical Contaminants	cyproterone acetate (Particulates not otherwise regulated Respirable fraction)		5						(n)
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	cyproterone acetate (Particulates not otherwise regulated Respirable fraction)		5						
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	cyproterone acetate (Particulates not otherwise regulated (PNOR)(f)- Respirable fraction)		5						
US - Michigan Exposure Limits for Air Contaminants	cyproterone acetate (Particulates not otherwise regulated, Respirable dust)		5						
Canada - Prince Edward Island Occupational Exposure Limits	cyproterone acetate (Particles (Insoluble or Poorly Soluble) [NOS] Inhalable particles)		10						See Appendix B current TLV/BEI Book

ENDOELTABLE

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

· Safety glasses with side shields

· Chemical goggles.

HANDS/FEET

Wear chemical protective gloves, eg. PVC.

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,

- \cdot 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.

OTHER

- · Overalls.
- · P.V.C. apron.
- · Barrier cream.
- · Skin cleansing cream.
- · Eye wash unit.

ENGINEERING CONTROLS

· Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.

· Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid. Does not mix with water.			
State	Divided solid	Molecular Weight	416.9
Melting Range (°F)	392- 393.8	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	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

White crystalline powder; does not mix well with water.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

 \cdot Presence of incompatible materials.

· Product is considered stable.

STORAGE INCOMPATIBILITY

Avoid reaction with oxidizing agents.
 Heat and light accelerate decomposition.

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

Section 11 - TOXICOLOGICAL INFORMATION

TOXICITY AND IRRITATION

CYPROTERONE ACETATE:

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

Image:	unless otherwise	specified data extracted	from RTECS - Regis	ter of Toxic Effects	of Chemical Substances.	
Intraperitoneal (rat) LD50: 565 mg/kg Subcutaneous (rat) LD50: >5000 mg/kg Oral (mouse) LD50: >5000 mg/kg Subcutaneous (mouse) LD50: >5000 mg/kg Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Paternal effects, maternal effects, effects on fertility, foetotoxicity, effects on embryo (torus, specific developmental effects (craniofacial, skin, cardiovascular, respiratory system, orgenital system), effects on embryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital system), effects on enbryo (torus cular, respiratory system, orgenital enbryo enbryo enbryo (torus cular, respiratory system, orgenital enbryo enbry	то	XICITY	IRRITATION			
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PROGESTINS Suspected Carcinogens Reference(s) IARC Suspected Carcinogens Reference(s) IARC	CARCINOGEN					
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Ingredient Persistence: Persistence: Air Bioaccumulation Mobility	Ecotoxicity					
cyproterone acetate HIGH LOW LOW			Persisten	ce: Air E	Bioaccumulation	Mobility
	cyproterone acetate	HIGH		L	.OW	LOW

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



DOT: Symbols: G Hazard class or Division: 9 Identification Numbers: UN3077 PG: III Label Codes: 9 Special provisions: 8, 146, 335, B54, IB8, IP3, N20, T1, TP33 Packaging: Exceptions: 155 Packaging: Non- bulk: 213 Packaging: Exceptions: 155 Quantity limitations: No limit Passenger aircraft/rail: Quantity Limitations: Cargo No limit Vessel stowage: Location: A aircraft only: Vessel stowage: Other: None Hazardous materials descriptions and proper shipping names: Environmentally hazardous substance, solid, n.o.s Air Transport IATA: ICAO/IATA Class: 9 ICAO/IATA Subrisk: None UN/ID Number: 3077 Packing Group: III Special provisions: A97 Cargo Only Packing Instructions: 911 Maximum Qty/Pack: 400 kg Passenger and Cargo Passenger and Cargo Packing Instructions: 911 Maximum Qty/Pack: 400 kg Passenger and Cargo Limited Quantity Passenger and Cargo Limited Quantity Packing Instructions: Y911 Maximum Qty/Pack: 30 kg G Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. *(CONTAINS CYPROTERONE ACETATE) Maritime Transport IMDG: IMDG Class: 9 IMDG Subrisk: None UN Number: 3077 Packing Group: III EMS Number: F-A, S-F Special provisions: 179 274 335 909 Limited Quantities: 5 kg Marine Pollutant: Yes

Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Section 15 - REGULATORY INFORMATION

cyproterone acetate (CAS: 427-51-0) is found on the following regulatory lists;

"International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs", "US - California Occupational Safety and Health Regulations (CAL/OSHA) - Hazardous Substances List", "US - Minnesota Hazardous Substance List"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- May be harmful to the foetus/ embryo*.
- May possibly affect fertility*.
- * (limited evidence).

ND

Substance CAS Suggested codes cyproterone acetate 427-51-0

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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.

www.chemwatch.net/relefences.

• 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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Issue Date: Mar-8-2009 Print Date:Nov-25-2010