

17 α -Hydroxyprogesterone Caproate

sc-287311



The Power to Question

Material Safety Data Sheet

Hazard Alert Code
Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

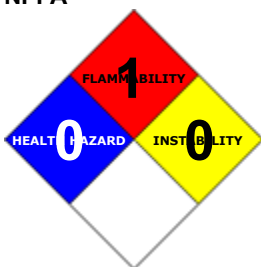
PRODUCT NAME

17 α -Hydroxyprogesterone Caproate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

Santa Cruz Biotechnology, Inc.
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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

C27-H40-O4, "pregn-4-ene-3, 20-dione, 17 α -hydroxy-, hexanoate", "17-hydroxypregn-4-ene-3, 20-dione hexanoate", "17-hydroxyprogesterone hexanoate", "17 α -hexanoyloxy-pregn-4-en-3, 20-dione caproate", "17 α -hydroxy progesterone n-caproate", "17-[(11-oxohexyl)oxy]pregn-4-ene-3, 20-dione", "progesterone, 11 β -hydroxy-caproate", "progesterone caproate", Capron, "Corlutin L.A.", Delalutin, Depo-Proluton, Duralutin, Estralutin, "Gesterol L.A.", Hormofort, HPC, Hylutin, Hyproval-PA, Hyroxon, Idrogestone, Lutate, Luteocrin, "Luteocrin Depot", Lutopron, Neolutin, NSC-17592, "Primolut Depot", "Progesterone Retard Pharon", "Proluton Depot", Relutin, Squibb, Syngynon, Teralutil, "progestogen/ steroid"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	2		Min/Nil=0 Low=1 Moderate=2
Reactivity:	1		High=3
Chronic:	3		Extreme=4

CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

May produce discomfort of the eyes*.

May be harmful to the foetus/embryo*.

May possibly affect fertility*.

Skin contact and/or ingestion may produce health damage*.

* (limited evidence).

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be damaging to the health of the individual.

■ Oral contraceptives ("The Pill") may produce side-effects as a result of changing the normal balance of female sex hormones. This may result in nausea, vomiting, brown patches on the skin, headache, swelling, weight gain, and breast tenderness.

EYE

■ There is some evidence to suggest that this material can cause eye irritation and damage in some persons.

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.

INHALED

■ The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models).

Nevertheless, adverse systemic 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.

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.

CHRONIC HEALTH EFFECTS

■ There is some evidence from animal testing that exposure to this material may result in toxic effects to the unborn baby.

Based on experience with similar materials, there is a possibility that exposure to the material may reduce fertility in humans at levels which do not cause 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. Prime symptom is breathlessness; lung shadows show on X-ray.

The use of oral contraceptives has been associated with an increased risk of clot formation and disease of the heart and blood vessels. There is also an increased risk of liver tumours.

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, mental depression, breast changes with discomfort and occasionally enlargement in males, changes in sex drive and 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, diarrhoea, 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. Other symptoms may include menstrual disorders, breast changes, effects on the cervix, Candida infections of the vagina, decreased sex drive, and inhibition of sperm production. Exposure during the first trimester may produce mild masculinization of the external genitalia of the female foetus or defects in the male. Exposure to female sex hormones during the first trimester has also been associated with various birth defects of the cardiovascular system and bones.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
17alpha-hydroxyprogesterone caproate	630-56-8	>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:

- 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.
- Seek medical attention without delay; 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 fumes, aerosols or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

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.
- 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.

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; 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 vapours, 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 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), other pyrolysis products typical of burning organic material.

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

Environmental hazard - contain spillage.

- 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

Environmental hazard - contain spillage.

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 area protected from environmental extremes.
- 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

- 17alpha-hydroxyprogesterone caproate: CAS:630-56-8

PERSONAL PROTECTION



RESPIRATOR

- Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

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], [AS/NZS 1336 or national equivalent]

HANDS/FEET

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
- fluorocautchouc

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 vapour generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.

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. 6-12 air changes per hour) is preferred.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	428.60
Melting Range (°F)	246- 250	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 Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

APPEARANCE

Powder; does not mix well with water. Soluble in chloroform. With slow heating the substance undergoes molecular rearrangement accompanied by partial resolidification and becomes completely molten only at 276 deg. C..

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

17alpha-hydroxyprogesterone caproate

TOXICITY AND IRRITATION

■ No significant acute toxicological data identified in literature search.

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

CARCINOGEN

Progestins	International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs	Group	2B
PROGESTINS	US Environmental Defense Scorecard Suspected Carcinogens	Reference(s)	IARC
17alpha-hydroxyprogesterone caproate	US - Maine Chemicals of High Concern List	Carcinogen	

Section 12 - ECOLOGICAL INFORMATION

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

This material and its container must be disposed of as hazardous waste.

Avoid release to the environment.

Refer to special instructions/ safety data sheets.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
17alpha-hydroxyprogesterone caproate	HIGH	No Data Available	LOW	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. 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



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: Passenger aircraft/rail:	No limit
Quantity Limitations: Cargo aircraft only:	No limit	Vessel stowage: Location:	A
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:	956	Maximum Qty/Pack:	400 kg
Passenger and Cargo		Passenger and Cargo	
Packing Instructions:	956	Maximum Qty/Pack:	400 kg
Passenger and Cargo Limited Quantity		Passenger and Cargo Limited Quantity	
Packing Instructions:	Y956	Maximum Qty/Pack:	30 kg G

Shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains 17alpha-hydroxyprogesterone caproate)

Maritime Transport IMDG:

IMDG Class:	9	IMDG Subrisk:	None
UN Number:	3077	Packing Group:	III
EMS Number:	F-A,S-F	Special provisions:	274 335
Limited Quantities:	5 kg	Marine Pollutant:	Yes

Shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains 17alpha-hydroxyprogesterone caproate)

Section 15 - REGULATORY INFORMATION



17alpha-hydroxyprogesterone caproate (CAS: 630-56-8) is found on the following regulatory lists;

"Canada - Alberta Ambient Air Quality Guidelines", "Canada - Alberta Ambient Air Quality Objectives", "Canada - British Columbia Occupational Exposure Limits", "Canada - Ontario Occupational Exposure Limits", "Canada - Quebec Permissible Exposure Values for Airborne Contaminants (English)", "Canada List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient ""Hotlist"")", "Canada National Pollutant Release Inventory (NPRI)", "International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs", "OSPAR List of Substances of Possible Concern", "US - California Air Toxics ""Hot Spots"" List (Assembly Bill 2588) Substances Which Need Not Be Reported Unless Manufactured By the Facility", "US - California Occupational Safety and Health Regulations (CAL/OSHA) - Hazardous Substances List", "US - California Permissible Exposure Limits for Chemical Contaminants", "US - Maine Chemicals of High Concern List", "US - Michigan Exposure Limits for Air Contaminants", "US - Minnesota Hazardous Substance List", "US - Oregon Permissible Exposure Limits (Z-1)", "US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants", "US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants", "US Clean Air Act (CAA) National Ambient Air Quality Standards (NAAQS)", "US NIOSH Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings - Appendix A: Sample list of drugs that should be handled as hazardous"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Skin contact and/or ingestion may produce health damage*.
 - May produce discomfort of the eyes*.
 - May be harmful to the foetus/embryo*.
 - May possibly affect fertility*.
- * (limited evidence).

Denmark Advisory list for selfclassification of dangerous substances

Substance	CAS	Suggested codes
17alpha- hydroxyprogesterone caproate	630- 56- 8	Rep3; R63 N; R51/53

- 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.

- For detailed advice on Personal Protective Equipment, refer to the following U.S. Regulations and Standards:

OSHA Standards - 29 CFR:

1910.132 - Personal Protective Equipment - General requirements

1910.133 - Eye and face protection

1910.134 - Respiratory Protection

1910.136 - Occupational foot protection

1910.138 - Hand Protection

Eye and face protection - ANSI Z87.1

Foot protection - ANSI Z41

Respirators must be NIOSH approved.

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