

Chlormadinone Acetate

sc-211070



The Power to Question

Material Safety Data Sheet

Hazard Alert Code
Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

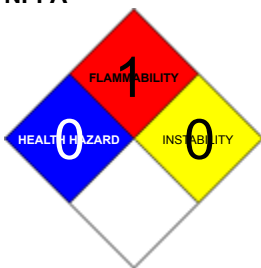
PRODUCT NAME

Chlormadinone Acetate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

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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, 17-acetoxy-6-chloro-6-dehydropregesterone, 17alpha-acetoxy-6-chloro-6-dehydropregesterone, "17alpha-acetoxy-6-chloro-6, 7-dehydropregesterone", "17alpha-acetoxy-6-chloro-4, 6-pregnadiene-3, 20-dione", "17alpha-acetoxy-6-chloropregna-4, 6-diene-3, 20-dione", "17-(acetyloxy)-6-chloropregna-4, 6-diene-3, 20-dione", "6-chloro-17alpha-acetoxy-4, 6-pregnadiene-3, 20-dione", "delta(sup 6)-6-chloro-17alpha-acetoxyprogesterone", "6-chloro-delta(sup 6)-17-acetoxyprogesterone", "6-chloro-delta(sup 6)-(17alpha)acetoxyprogesterone", "6-chloro-delta(sup 6)-dehydro-17-acetoxyprogesterone", 6-chloro-6-dehydro-17alpha-acetoxyprogesterone, "6-chloro-6-dehydro-17-alpha-hydroxyprogesterone acetate", "6-chloro-17-alpha-hydroxypregna-4, 6-diene-3, 20-dione acetate", "6-chloro-17-alpha-hydroxy-delta(sup 6)-progesterone acetate", "6-chloro-delta(sup 4, 6)-pregnadiene-17-alpha-ol-3, 20-dione-17-", acetate, "6-chloro-pregna-4, 6-dien-17-alpha-ol-3, 20-dione acetate", 6-dehydro-6-chloro-17alpha-acetoxyprogesterone, "pregna-4, 6-diene-3, 20-dione, 17-(acetoxy)-6-chloro-", CAP, "Chlormadinon Acetate", "Chlormadinone Acetate", Clordion, CMA, C-Quens, Gestafortin, Lormin, Lutinyll, Matrol, Menstridyl, NSC-92338, RS-1280, Skedule, ST-155, "progestogen/ steroid"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

| | | Min | Max |
|--------------|---|---|-----|
| Flammability | 1 |  | |
| Toxicity | 2 |  | |
| Body Contact | 2 |  | |
| Reactivity | 1 |  | |
| Chronic | 3 |  | |

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Danger of serious damage to health by prolonged exposure.

Limited evidence of a carcinogenic effect.

May impair fertility.

May cause harm to the unborn child.

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 damaging to the health of the individual.

■ Oral contraceptives may produce side-effects as a result of altering the normal balance of oestrogenic and progestogenic effects.

Such effects may include nausea, vomiting, chloasma and other skin and hair changes, headache, oedema, weight gain and breast tenderness.

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.

SKIN

■ The material is not thought to be a skin irritant (as classified 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 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.

This material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects.

Ample evidence exists from experimentation that reduced human fertility is directly caused by exposure to the material.

Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.

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.

The use of oral contraceptives has been associated with an increased risk of thrombo-embolic and cardiovascular disease, related, at least in part, to the oestrogen content of combined oral contraceptives. An increased risk of the incidence of benign liver tumours, though marked, is thought to be rare.

Large doses of chlormadinone acetate and megestrol acetate given to beagle dogs induced mammary tumours. This was not considered to be a useful indicator of carcinogenicity in women.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

| NAME | CAS RN | % |
|-----------------------|----------|-----|
| chlormadinone acetate | 302-22-7 | >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.

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 fumes 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.

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.

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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.

Environmental hazard - contain spillage.

MAJOR SPILLS

Environmental hazard - contain spillage.

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

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 |
|---|---|------------|--------------|-------------|---------------|-------------|---------------|-------------|---|
| Canada - Ontario Occupational Exposure Limits | chlormadinone acetate (Particles (Insoluble or Poorly Soluble) Not Otherwise) | | 10 (I) | | | | | | |
| Canada - British Columbia Occupational Exposure Limits | chlormadinone acetate (Particles (Insoluble or Poorly Soluble) Not Otherwise Classified (PNOC)) | | 10 (N) | | | | | | |
| Canada - Ontario Occupational Exposure Limits | chlormadinone acetate (Specified (PNOS) / Particules (insolubles ou peu solubles) non précisées par ailleurs) | | 3 (R) | | | | | | |
| US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants | chlormadinone acetate (Particulates not otherwise regulated Respirable fraction) | | 5 | | | | | | |
| US - California Permissible Exposure Limits for Chemical Contaminants | chlormadinone acetate (Particulates not otherwise regulated Respirable fraction) | | 5 | | | | | (n) | |
| US - Oregon Permissible Exposure Limits (Z-1) | chlormadinone acetate (Particulates not otherwise regulated (PNOR) (f) Total | - | 10 | | | | | | Bold print identifies substances for which the Oregon Permissible Exposure Limits |

| | | | | |
|--|---|----|--|---|
| | Dust) | | | (PELs) are different than the federal Limits. PNOR means "particles not otherwise regulated." |
| US - Michigan Exposure Limits for Air Contaminants | chlormadinone acetate (Particulates not otherwise regulated, Respirable dust) | 5 | | |
| US - Oregon Permissible Exposure Limits (Z-1) | chlormadinone acetate (Particulates not otherwise regulated (PNOR) (f) Respirable Fraction) | 5 | | Bold print identifies substances for which the Oregon Permissible Exposure Limits (PELs) are different than the federal Limits. PNOR means "particles not otherwise regulated." |
| US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants | chlormadinone acetate (Particulates not otherwise regulated (PNOR)(f)-Respirable fraction) | 5 | | |
| Canada - Prince Edward Island Occupational Exposure Limits | chlormadinone acetate (Particles (Insoluble or Poorly Soluble) [NOS] Inhalable particles) | 10 | | See Appendix B current TLV/BEI Book |

PERSONAL PROTECTION



RESPIRATOR

•Particulate. (AS/NZS 1716 & 1715, EN 1432000 & 1492001, 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

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- 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, AS/NZS 2161.10.1 or national equivalent) 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, AS/NZS 2161.10.1 or national equivalent) 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. [AS/NZS 2210]
- 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
- fluorocarbon
- 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 | 404.93 |
| Melting Range (°F) | 414- 417 | 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

Odorless crystalline powder; does not mix well with water.

Unconjugated steroidal estrogens have low solubility in water (0.8-13.3 mg L⁻¹) and are moderately hydrophobic (log Kow 2.6-4.0). Therefore the potential for bioaccumulation exists. Estrogenic compounds are generally bioaccumulative and may biomagnify through the food chain resulting in adverse physiological effects. Accumulation into milk may be particularly worrying as it is fed to infants and children and their immune systems are not fully developed, therefore the physiological effects may be more serious.

| Material | Value |
|----------|-------|
|----------|-------|

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- 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

chlormadinone acetate

TOXICITY AND IRRITATION

CHLORMADINONE ACETATE

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

| TOXICITY | IRRITATION |
|--|--------------|
| Oral (rat) LD50 >10000 mg/kg | Nil Reported |
| Intraperitoneal (rat) LD50 5000 mg/kg | |
| Subcutaneous (rat) LD50 >10000 mg/kg | |
| Oral (mouse) LD50 >15000 mg/kg | |
| Intraperitoneal (mouse) LD50 3000 mg/kg | |
| Subcutaneous (mouse) LD50 >10000 mg/kg | |
| Intravenous (mouse) LD50 >2000 mg/kg | |
| IARC Cancer Review Animal Limited Evidence | |

Eye effects, taxia, diabetes mellitus, skin tumours, paternal effects, maternal effects, effects on fertility, specific developmental effects (central nervous system, craniofacial, body wall, musculoskeletal system, endocrine system, urogenital system), foetotoxicity, foetolethality, effects on newborn recorded.

Equivocal tumourigen by RTECS criteria

Two-hundred and sixty-seven patients took chlormadinone acetate, 0.5 mg daily, for a total of 3,199 months. The overall pregnancy rate and the rate for method failure were 4.5 and 3.7 pregnancies/100 women years, respectively, as calculated by the Pearl formula. Similar results were obtained using the life-table method. The main advantage of this oral contraceptive was its lack of oestrogenic side effects. The major disadvantages were

the relatively high pregnancy rate and the high incidence of abnormal bleeding among its users.

CARCINOGEN

| | | | |
|-----------------------|---|--------------|------|
| chlormadinone acetate | 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 |

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.

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

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

‡ Puncture containers to prevent re-use and bury at an authorized landfill.

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: 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 Subrisk: | III | 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 CHLORMADINONE ACETATE) | | | |
| 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 chlormadinone acetate) | | | |

Section 15 - REGULATORY INFORMATION

chlormadinone acetate (CAS: 302-22-7) is found on the following regulatory lists;

"US - Connecticut Hazardous Air Pollutants", "US - Massachusetts Oil & Hazardous Material List"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

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

* (limited evidence).

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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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