

17-HYDROXYPROGESTERONE ACETATE

MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006, (EC) No. 1272/2008 and (UE) No. 453/2010 (Annex I)

Revision date: January 2011 – Revision No. 00

SECTION 1.

IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1. Product identifier

Product name:	17-α-HYDROXYPROGESTERONE ACETATE
Synonyms (if available):	17-APA 17 α -acetoxypregesterone 17-idroxypregn-4-ene-3,20-dione acetate
CLP Annex VI Name:	Not applicable
C&L Inventory Name:	Not data available
CAS Number:	302-23-8
REACH Registration Number	Not applicable

1.2. Relevant identified uses of the substance and uses advised against

Common uses:	API (Active Pharmaceutical Ingredient)
Uses advised:	none

1.3. Details of the supplier of the safety data sheet

Company name: **STERLING S.r.l**
Address: **Via della Carboneria, 30 Solomeo**
06073 Corciano (PG) – Italy
Telephone: 075/5294001
Fax: 075/5294000

E-mail address: aragona@sterling.it

1.4. Emergency telephone number

Italy: +39 02 66101029 (Poison Information Centre Niguarda Ca' Granda – Milano)
Foreign countries: Contact the closest Poisons Information Centre.

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance

Classification according to Regulation (EC) n. 1272/2008:

Hazard Class	Hazard Class and Category Code(s)	Hazard statement Code(s)	Hazard statements
Reproductive toxicity	Repr. Cat. 2	H361f	Suspected of damaging fertility

Classification according to Directive 67/548/CEE:

Classification	Risk Phrases	
Repr. Cat 3, R62	R62	Possible risk of impaired fertility

Main adverse effects:

Physico-chemical hazards

Human health hazard

none known

Possible risk of impaired fertility. There are no known adverse effects. Possible irritation to eyes, skin and gastrointestinal tract and / or respiratory. Possible allergic reaction to material if inhaled, ingested or in contact with skin


Environmental hazard

No adverse effects known.

See also sections 9 to 12

2.2 Label elements

Labelling according to Regulation (EC) n. 1272/2008

Pictogram/s	
Signal Word	Warnig
Hazard Statement (H)) ^[1]	H361f
Precautionary Statement (P) ^[1]	
- <i>Prevention</i>	P201, P202, P281
- <i>Response</i>	P308+313
- <i>Storage</i>	P405
- <i>Disposal</i>	P501

^[1] Full text of R and H-phrases: see section 16

2.3 Other hazards

The substance meets the criteria for

- PBT

- vPvB

Yes	No
	X
	X

- Human health hazard:

Could be harmful if swallowed, inhaled or in contact with skin. It may be irritating or sensitizing

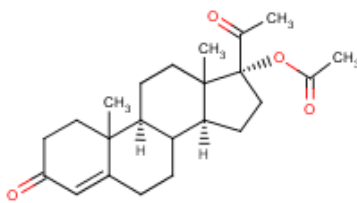
- Environmental hazards:

Not known

- Physico-chemical hazards: Not known
- Specific effects: Not known

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Description: Active Pharmaceutical - steroid hormone

<i>Product name</i>	17- α -Idrossiprogesterone acetato
<i>Concentration:</i>	> 98%
<i>Structural formula:</i>	
<i>Chemical name:</i>	C ₂₃ H ₃₂ O ₄
<i>Molecular Weight:</i>	372.51 g/mol
<i>Substance with UE exposure limit values</i>	No
<i>Name CAS:</i>	Pregn-4-ene-3,20-dione, 17-(acetyloxy)-
<i>Number CAS:</i>	302-23-8
<i>Name IUPAC:</i>	(17-acetyl-10,13-dimethyl-3-oxo-2,6,7,8,9,11,12,14,15,16-decahydro-1H-cyclopenta[a]fenantrene-17-yl) acetate
<i>Number EC:</i>	206-119-6
<i>Index Nr.:</i>	Not available
<i>Impurities (if classified)</i>	-
<i>Additives (if classified)</i>	-

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

- *Eye contact* Irrigate eyes with copious amounts of water or saline solution, holding eyelids apart to ensure thorough rinsing. Consult a physician if necessary.
- *Skin contact* In case of skin contact with powders or solutions immediately rinse affected area with copious amount of water and then wash with soap and water. Remove contaminated clothing and shoes. Consult a physician if necessary.
- *Ingestion* In case of ingestion, if conscious, rinse mouth with water. If the casualty is unconscious, place in the recovery position. Consult a physician if necessary.
- *Inhalation* Remove casualty to fresh air as quickly as possible. Keep warm and at rest. If breathing is difficult, give oxygen if possible, or assisted ventilation. Consult a physician if necessary.

4.2 Most important symptoms and effects, both acute and delayed

- *Acute effects* Possible irritation to eyes, skin and gastrointestinal tract and/or respiratory.
- *Chronic Effects* Suspected of damaging fertility. Possible allergic reaction to material if inhaled, ingested or in contact with skin

4.3 Indication of any immediate medical attention and special treatment needed

- Medical monitoring	In case of prolonged exposure
- Antidotes, if known	not known
- Counter-indication:	not known
- Immediate specific treatment:	not known

SECTION 5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

- Suitable extinguishing media	water spray, dry chemical powder, carbon dioxide (CO ₂), foam
- Unsuitable extinguishing media	none

5.2 Special hazards arising from the substance

- Specific hazard(s)	When heated or in the event of a fire, vapors may be harmful to health: carbon oxides (CO _x)
- Others	None

5.3 Advice for firefighters

- Special fire fighting procedures	Cool containers with water spray.
- Protective Equipment	Wear full fire resistant self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Keep non-involved personnel away from the area of spillage. Avoid the generation and spreading of dust. Ventilate area. Eliminate sources of ignition. Avoid contact with skin, eyes and inhalation of dust. See also sections 8 (protective equipment)

6.2 Environmental precautions

Prevent product from entering sewers, rivers or other bodies of water. If required, notify relevant authorities according to all applicable regulations.

6.3 Methods and material for containment and cleaning up

- Spill Containment:	Coverage of the discharges
- Cleaning up spills:	Collect free product with suitable mechanical means. Avoid creating dust by spraying the product with water, if there is no contraindication. Ventilate area and wash spill site after material pickup is complete. Transfer the gathered product and the washings to suitable tanks or containers and store/dispose according to relevant regulations. .

6.4 Reference to other sections

See also sections 8 (protective equipment) and 13 (disposal).

SECTION 7 HANDLING AND STORAGE

7.1. Precautions for safe handling

- *Recommendations for handling:*
 - Keep away from flames and sparks - Sources of ignition.
 - Handle in well-ventilated place
 - Avoid contact with incompatible materials.
 - Use of personal protective equipment (see section 8)
 - Prevent product from entering sewers
- *Good occupational hygiene practices:*
 - Do not eat, drink or smoke when using this product.
 - Wash hands thoroughly with soap and water before meals and after work shift.

7.2. Conditions for safe storage

The substance is not classified for any physical and chemical properties are not planned how to manage the particular risk..

Other precautions:

- *ventilation* Use in well ventilated area at room temperature
- *container* Keep container tightly closed and properly labeled
- *specific planning of local* Not required based on the classification.
- *storage limits* Not required based on the classification.
- *compatibility of packaging* See 10.5

7.3 Specific end use

- Recommendations for specific end-use: Active Pharmaceutical Ingredient

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment attached		X
- Other safety assessments available (industry, specific sector)		X

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameter

- Exposure limit values:
 - TLV TWA: No data available
 - TLV STEL: No data available
- Monitoring procedure

The measurement of substances in the workplace must be carried out using standardized methods (i.e. EN 689:1997: Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurements strategy; EN 482:2006: Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) or, failing that, with other appropriate methods.
- DNEL :

No data available

- PNEC : No data available

8.2. Exposure Controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment attached		X

8.2.1. Appropriate engineering controls

The choice of appropriate engineering controls shall be carried out based on risk assessments carried out by the employer in its employment practices (use of the substance) in the absence of a unique exhibition and standardized scenario described in the REACH registration dossier.

8.2.2. Personal protection measures, such as personal protective equipment

- a) Eye / Face Protection Wear safety goggles (EN 166).
- b) Skin and body Protection
 - Hands protection Use protective rubber gloves (EN 374 parts 1, 2 and 3).
 The glove material has to be impermeable and resistant to the product / the substance / the preparation.
 Make the choice of the glove material by considering the penetration times, rates of diffusion and degradation.
 The choice of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- Body protection Choose the Body protection according to the activity and exposure. Wear apron, boots and suited, according to EN 13982.
- c) Respiratory Protection Avoid inhalation of dust, respiratory protection: dust mask with proper filter type.
 Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
 In the case of brief exposure or low pollution use breathing filter. In case of intensive and protracted exposure wear self-contained breathing apparatus (SCBA).
- d) Heat Dangers Not specified in the standard practice of use of the substance. Assess any personal protective equipment according to particular conditions of usage.

8.2.3 Environmental Exposure Controls

	SI	NO
- Exposure scenario attached		X
- Chemical Safety Assessment attached		X

Use according to good manufacturing practices avoiding litter.

Take all the technical precautions necessary to prevent the spread of the product into the surrounding.



SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White crystalline powder
Odor:	No data available
Odor threshold:	No data available
pH	No data available
Melting point/freezing point:	>237 °C
Initial boiling point and boiling range:	490.2 °C at 760 mmHg (estimated) ⁽¹⁾
Flash point:	211.576 °C (estimated) ⁽¹⁾
Auto-ignition temperature:	No data available
Surface tension:	44.279 dyne/cm (estimated) ⁽¹⁾
Vapor pressure:	0 mmHg a 25°C (estimated) ⁽¹⁾
Relative density:	1,15 g/cm ³ (estimated) ⁽¹⁾
Water solubility:	3.323 mg/l a 25°C (estimated) ⁽¹⁾
Solubility in organic solvents:	No data available
Partition coefficient: <i>n</i> -octanol/water:	3.64 (estimated) ⁽¹⁾
Explosive properties:	No data available
Oxidising properties:	No data available

9.2. Other information

No data available.

SECTION 10 STABILITY AND REACTIVITY

10.1. Reactivity

Stable under normal storage conditions.

10.2. Chemical stability

The substance is stable under normal conditions of temperature and pressure and when stored in closed containers in a cool and ventilated place.

	NO	YES	Stabilizer used
- Need for stabilizers:	X	-	
- Dangers of change in physical state:	X	-	

10.3. Possibility of hazardous reactions

- Possibility of a hazardous exothermic reaction:
- Possibility of a decomposition reaction with increasing pressure:
- Possibility of degradation to unstable products:

NO	YES
X	-
X	-
X	-

10.4 Conditions to avoid

Protect from light, moisture and high temperatures.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Heating at high temperatures decomposes releasing toxic fumes and gases (CO_x),

SECTION 11 TOXICOLOGICAL INFORMATION

- Exposition routes:

- Inhalation:
- Ingestion:
- Skin contact:
- Eye contact:

YES	NO
X	
X	
X	
X	

- Effects (immediate, delayed, chronic) following exposure (short and / or long-term):

- Inhalation: Possible risk of impaired fertility.
Could be harmful if inhaled or sensitizing.
- Ingestion: Could be harmful if swallowed.
- Skin contact: It may be irritating or sensitizing.
- Eye contact: May be irritating.

- - Toxicokinetics (Absorption, Distribution, Metabolism, Excretion):

Not reported evidence concerning this effect

- Acute toxicity:

- Oral: Not reported evidence concerning this effect
- Dermal: Not reported evidence concerning this effect
- Inhalation: Not reported evidence concerning this effect
- Other: -

- Corrosion/Irritation: Not reported evidence concerning this effect

- Serious eye damage / irritation: Not reported evidence concerning this effect

- Sensitization: Not reported evidence concerning this effect

- Toxicity by prolonged exposure (experim.): Not reported evidence concerning this effect

- CMR effects:

- Germ cell mutagenicity: Not reported evidence concerning this effect
- Carcinogenicity: Not reported evidence concerning this effect
- Reproductive toxicity: ⁽²⁾:

Type of Test: TDLo -Lowest published toxic dose, oral rat (male 9 day (s) pre-mating

Dose data: 72 mg/kg

Toxic Effects: Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands

Type of Test: TDLo Subcutaneous mouse/rabbit (female 1 day pre-mating)

Dose data: 1 mg/kg/40 ug/kg

Toxic Effects: Reproductive – Maternal Effects - uterus, cervix, vagina
Reproductive - Fertility - other measures of fertility

Type of Test: TDLo -, oral dog (female 32 week(s) pre-mating)

Dose data: 896 mg/kg

Toxic Effects: Reproductive - Maternal Effects - menstrual cycle changes or disorders

Type of Test: TDLo -, oral dog (female 23 week(s) pre-mating)

Dose data: 80500 ug/kg

Toxic Effects: Reproductive - Maternal Effects - uterus, cervix, vagina

Type of Test: TDLo -, oral rabbit (female 1 day(s) pre-mating)

Dose data: 2.5 and 5 mg/kg

Toxic Effects: Reproductive - Fertility - mating performance, other measures of fertility

Type of Test: TDLo -, Administration onto the skin rabbit (female 1 day(s) pre-mating)

Dose data: 500 ug/kg

Toxic Effects: Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)

Type of Test: TDLo -, Subcutaneous rabbit (female 5 day(s) pre-mating)

Dose data: 100 ug/kg

Toxic Effects: Reproductive - Maternal Effects - uterus, cervix, vagina

- Specific target organ toxicity (STOT)-Single exposure:

Not reported evidence concerning this effect

- Specific target organ toxicity (STOT)-Repeated exposure:

Not reported evidence concerning this effect

- Aspiration hazard: Not reported evidence concerning this effect

- Epidemiology: Data non available

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

Not reported evidence concerning this effect

12.2. Persistence and degradability

Not reported evidence concerning this effect

12.3 Bioaccumulative potential

Log Pow = 3.64 (estimated) ⁽¹⁾

12.4 Mobility in soil

Not reported evidence concerning this effect

12.5 Results of PBT and vPvB assessment

Rating not available - in relation to the logPow do not expect a potential for bioaccumulation.

12.6. Other adverse effects

No data available.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

- Waste of substance:
- Contaminated Packaging/containers:

Incineration	Recycling	Landfill disposal
X		
	X	

Prevent environmental discharge.

Dispose of waste or used sacks/containers according to local regulations.

SECTION 14 TRANSPORT INFORMATION

The substance is not considered dangerous within the meaning of the regulations governing the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and by air (IATA/ICAO).

SEZIONE 15 INFORMAZIONI SULLA REGOLAMENTAZIONE

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and f.a.
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment
- Council Directive 98/24/CE of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work and f.a.

- Regulation (ec) no 689/2008 of the EU Parliament and of the council of 17 June 2008 concerning the export and import of dangerous chemicals

15.2 Chemical Safety Assessment

- Exposure scenario attached
- Chemical Safety Assessment attached

YES	NO
	X
	X

SECTION 16 OTHER INFORMATION

Revision:

- **Created on** January 2011 (according to Annex I of Regulation UE453/2010) **Revision n. 00**

Bibliography:

⁽¹⁾ Chempider data base, search for CAS 302-23-8

⁽²⁾ RTECS TU5074000-Chemical Toxicity Database

Legend to abbreviations and acronyms:

- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Accord Dangerousness Route
- BCF: Bioconcentration factor
- BEI : Biological Exposure Indices
- CAS: Chemical Abstract Service (division of the American Chemical Society)
- CHETAH : Computer programme for chemical thermodynamics and energy release evaluation
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogenic, mutagenic and reprotoxic
- EINECS: European Inventory of Existing Commercial Chemical Substances
- EPA: US Environmental Protection Agency
- GHS: Global Harmonized System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association
- IMDG: International Maritime Dangerous Goods
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- NOAEL: No Observed Adverse Effect Level
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PBT: Persistent, Bioaccumulative and Toxic substance
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- TLV/TWA: Threshold Limit Values
- vPvB: Very Persistent and Very Bioaccumulative

Information relating to health, safety, and environmental protection in accordance with Regulation (EC) No 1272/2008

List of hazards statements

H361f: Suspected of damaging fertility

List of P statements

Prevention

P201 Obtain special instructions before use

P202	Do not handle until all safety precautions have been read and understood
P281	Use personal protective equipment as required
<u>Reaction</u>	
P308+P313:	I IF exposed or concerned: Get medical advice/attention
<u>Storage</u>	
P405	Store locked up
<u>Disposal</u>	
P501:	Dispose of contents/container according to local regulations.

Information related to Directive 67 / 548 / EEC, Directive 1999/45/EC and Regulation (EC) No 1907/2006

R Phrases

R62	Possible risk of impaired fertility
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Guidelines for the formation

Workers potentially exposed to this substance must be trained adequately on the basis of the contents of this MSDS (Dir. 98/24/CE).

Authorizations according to REACH Regulation: No

Restrictions according to REACH Regulation: No

WARNING TO USERS

This document is intended to provide guidance and appropriate precautionary handling of this substance by qualified personnel or operating under the supervision of experienced personnel in the handling of chemicals. The substance should not be used for purposes other than those mentioned in section 1, except when they have received adequate written information on safe handling of the material.

The head of this document cannot provide warnings of the dangers arising from the use or interaction with other chemicals or materials. The user is responsible for the safe use of the substance, the adequacy of the substance which is applied to the use and proper disposal. The following information is not intended to be a representation or warranty, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with the provisions of Annex I to Council Regulation No 453/2010/EU.

MSDS developed by: Chemsafe Srl, Colleretto Giacosa (TO) Italia.

Tel. 0039 0125 538888, fax 0039 0125 538475, email :chemsafe@chemsafe-consulting.com