

GESTONORONE ACETATE

MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006
Revision: 00 – Revision date: 26.08.2011

SECTION 1

IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1 Product identifier

Product name: Gestonorone acetate
Synonym : 17-hydroxy-19-norpregn-4-ene-3,20-dione 17-acetate
CAS Number: 31981-44-9
EC Number: 250-882-8
INDEX Number: No data available
Registration Number: No data available
Molecular Weight: 358.48
Molecular Formula: C₂₂H₃₀O₄

1.2 Relevant identified uses of the substance

Common use: Chemical intermediate for the preparation of pharmaceutical products

1.3 Details of the supplier of the safety data sheet

Company name: STERLING S.r.l
Address: Via della Carboneria, 30
06073 Solomeo di Corciano (PG) – Italy

E-mail address: spatriarca@sterling.it
Telephone: 075/5294001
Fax: 075/5294000

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

2.1.1 Classification according to Regulation (EC) N. 1272/2008 (CLP/GHS)

Carc. 2 : H351
Repr. 1A : H360
Lact. : H362

2.1.2 Classification of the substance according to Directive 67/548/EEC

T; Repr. Cat. 1; R60
T; Repr. Cat. 2; R61
R64
Xn; Carc. Cat. 3; R40

Full text of R and H-phrases: see section 16

2.2 *Label elements*



Signal Word:

DANGER

Hazard Statement

H351 :	Suspected of causing cancer
H360 :	May damage fertility or the unborn child
H362 :	May cause harm to breast-fed children

Precautionary Statement

Prevention

P201 :	Obtain special instructions before use
P273 :	Avoid release to the environment
P281 :	Use personal protective equipment as required

Response

P308 + P313 :	IF exposed or concerned: Get medical advice/attention
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Storage

P405 :	Store locked up
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2.3 *Other hazards*

No data available

SECTION 3**COMPOSITION/INFORMATION ON INGREDIENTS****3.1 Substance**

<i>Product name :</i>	Gestonorone acetate
<i>Synonym :</i>	17-hydroxy-19-norpregn-4-ene-3,20-dione 17-acetate
<i>Chemical name :</i>	17-Acetoxy-19-nor-4-pregnene-3,20-dione
<i>Molecular Weight :</i>	358.48
<i>Molecular formula :</i>	C ₂₂ H ₃₀ O ₄
<i>CAS No. :</i>	31981-44-9
<i>EC No. :</i>	250-882-8
<i>Concentration :</i>	>97%

3.2 Mixture

Not applicable

SECTION 4**FIRST AID MEASURES****4.1 Description of first aid measures**

General advice:	In case of contact with the substances immediately change contaminated clothing and shoes.
Ingestion:	In case of ingestion, if conscious, rinse mouth with water. If the casualty is unconscious, place in the recovery position.
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.
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. Do NOT use solvents or thinners.
Eye contact:	Irrigate eyes with copious amounts of water for at least 10-15 min, holding eyelids apart to ensure thorough rinsing.

4.2 Most important symptoms and effects, both acute and delayed

Most of the toxicological data are from a Read across strategy and no information are available on sign and symptoms of exposure. Exercise due care.

4.3 Indication of any immediate medical attention and special treatment needed

Immediately call a POISON CENTER or doctor/physician for all cases of contact. Induce vomiting only if indicated by your doctor.

SECTION 5 FIRE-FIGHTING MEASURES

5.1 *Extinguishing media*

Suitable extinguishing media: Carbon Dioxide (CO₂), foam, dry chemical powder, and water spray, unless otherwise stated.

Unsuitable extinguishing media: High volume water jet.

5.2 *Special hazards arising from the substance*

Specific hazard(s): The product is combustible and, like the dust in general, can make an explosive mixture with air. When heated or in the event of a fire, vapors may be harmful to health: carbon oxides (CO_x).

5.3 *Advice for firefighters*

Special fire fighting procedures: 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*

Procedure(s) of personal precaution(s): 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.
Avoid contact with eyes and skin.
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*

Collect free product with suitable mechanical means. Avoid creating dust by spraying the product with water, if there is no contraindication. Pack separately and send back to manufacturer. 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*

Use of personal protective equipment must be consistent with good occupational hygiene practices.

Measures must be taken to prevent dust explosion when processing in fine crystalline form.

Avoid contact with skin, eyes and clothing.

Avoid prolonged or repeated exposure.

Do not breathe dust, mist, and/or vapors associated with the material.

Do not reuse contaminated clothing.

Do not eat, drink or smoke when using this product.

Wash hands and face with alkaline soap before breaks and after handling the product.

7.2 *Conditions for safe storage*

Keep container tightly closed in a dry and well-ventilated place. Protect from light. Keep away from heat.

SECTION 8

EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 *Control Parameter*

Exposure limit values (ACGIH 2010):

- TLV TWA: No data available
- TLV STEL: No data available

Monitoring procedures: Refer to Dir. 96/82/EC.

8.2 *Exposure Controls*

8.2.1 *Appropriate engineering controls*

When feasible, use closed loop systems or with local exhaust. When inside buildings or confined spaces, ensure adequate ventilation.

The lyophilized powder should be used in biological safety cabinets or in systems with equivalent content.

Provide eyewash fountains at the workplace.

8.2.2 *Personal protection measures, such as personal protective equipment*

Personal Protective Equipment: The personal protective equipment should be chosen in the configuration according to the concentration and quantity of hazardous substances specifically for the workplace.

a) *Eye / Face Protection:* Wear safety glasses with side-shields (EN 166).

b) *Skin and body Protection:* During the handling of the substance according to the intended use protection gloves from nitrile rubber have been proved (EN 374). During the handling of pure solid substances or powder mixtures a permeation of the rubber material is not to be expected. In case of doubt, especially during handling of the substance together with organic solvents, the stability of the protection gloves has to be clarified with the manufacturer. Choose body protection according to the amount and concentration of the dangerous substance at the work place.

- c) *Respiratory Protection:* Avoid inhalation of dust, respiratory protection: dust mask with filter type P3 (EN 143).
Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- d) *Heat Dangers:* The product is not handled hot.

8.2.3 Environmental Exposure Controls

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

a) Appearance	White powder
b) Odor	-
c) Odor threshold	No data available
d) pH	No data available
e) Melting point/freezing point	228 °C
f) Initial boiling point and boiling range	490.2 °C
g) Flash point	212.8 °C
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapor pressure	$p_{25} < 10^{-3} \text{ Pa}$
l) Vapor density	No data available
m) Relative density	1.16 g/cm ³
n) Solubility(ies)	Water solubility: 3.62 mg/L.
o) Partition coefficient: n-octanol/water	log Pow = 2.64
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available
r) Viscosity	Not applicable
s) Explosive properties	No data available
t) Oxidising properties	No data available

9.2 Other information

No data available

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

The substance does not present additional dangers of reactivity than those reported in the next subtitles.

10.2 Chemical stability

Store at room temperature. Store away from all heat sources, including direct sunlight, open flame, sources of ignition and sparks.

10.3 Possibility of hazardous reactions

Product does not polymerise.

10.4 Conditions to avoid

Heat. Static Electricity.

10.5 Incompatible materials

Store separately from oxidizing agents.

10.6 Hazardous decomposition products

Carbon oxides (CO_x).

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Signs and Symptoms of Exposure: Most of the toxicological data are from a Read across strategy and no information are available on sign and symptoms of exposure. Exercise due care.

CLASS OF RELEVANT RISK FOR SUBSTANCE:

a) Acute toxicity:

Route	Specie	Results	Note	Reference
Oral	Rodent - mouse	LD ₅₀ > 4 gm/kg bw	Read across transient clinical signs	Registration dossier
Intraperitoneal	Rodent - mouse	LD ₅₀ > 4 gm/kg bw	Read across Transient clinical signs	Registration dossier
Intramuscular	Dog	> 150 mg/kg bw	Read across Transient local intolerance reactions	Registration dossier

- b) *Skin corrosion / irritation:* Not reported evidence concerning this effect
- c) *Serious eye damage / serious eye irritation:* Not reported evidence concerning this effect
- d) *Respiratory / skin sensitization:* Not reported evidence concerning this effect
- e) *Germ cell mutagenicity* Not reported evidence concerning this effect
- f) *Carcinogenicity* Suspected of causing cancer
- g) *Reproductive toxicity:*

Route	Specie	Results	Note	Reference
Subcutaneous	Rodent – mouse female	NOEL > 12 mg/kg bw/day	Read across no substance related effect on reproduction	Registration dossier
Subcutaneous	Rodent – rat male	NOEL ≤ 2 mg/kg bw/day	Read across Male fertility was decreased dose dependently from 20 mg/kg onwards	Registration dossier
Subcutaneous	Rodent – rat female	NOEL ≤ 2 mg/kg bw/day	Read across Dose-dependently increased disturbance of fertility was seen at 20 mg/kg and higher	Registration dossier
Subcutaneous	Rodent – rat female	NOEL ≥ 20 mg/kg bw/day	Read across Gestonorone caproate did prevent spontaneous delivery	Registration dossier

- h) *Specific target organ toxicity (STOT)-Single exposure-* Not reported evidence concerning this effect
- h) *Specific target organ toxicity (STOT)-Repeated exposure-* Not reported evidence concerning this effect
- j) *Aspiration hazard* Not applicable
- Other information*

SECTION 12**ECOLOGICAL INFORMATION**

Ecological Information: Use according to good manufacturing practices, avoid dispersion into the environment. Notify relevant authorities according to all applicable regulations if the product can reach waterways or sewers or contaminate soil or vegetation.

12.1 Toxicity

Not reported evidence concerning this outcome

Specie	Results	Note	Reference
Daphnia magna	EC50 > 8.4 mg/L (48h)	No immobilized Daphnia were observed in test solution with 8.4 mg/l and in the control group	Registration dossier
Desmodesmus subspicatus	EC50 > 4.6 mg/L (72h)	EC50 was higher than a saturated solution	Registration dossier

12.2 Persistence and degradability

Not reported evidence concerning this outcome

12.3 Bioaccumulative potential

Not reported evidence concerning this outcome

12.4 Mobility in soil

Not reported evidence concerning this outcome

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13**DISPOSAL CONSIDERATIONS****13.1 Waste treatment methods**

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).

SECTION 15 REGULATORY INFORMATION

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

Authorizations according to REACH Regulation:	the substance is not subjected
Restrictions according to REACH Regulation:	the substance is not subjected
Other UE:	The substance is not dangerous under the Seveso Regulation (Dir. 96/82/CE and f.a.)

15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out for this product.

SECTION 16 OTHER INFORMATION

<i>List of relevant phrases</i>	Classification according to Regulation (EC) No 1272/2008 (CLP/GHS) as amended H351 : Suspected of causing cancer H360 : May damage fertility or the unborn child H362 : May cause harm to breast-fed children Classification according to European Directive 67/548/CEE as amended R60 : May impair fertility R61 : May cause harm to the unborn child R64 : May cause harm to breast-fed babies R40 : Limited evidence of a carcinogenic effect
<i>Guidelines for the formation</i>	Workers potentially exposed to this substance must be trained adequately on the basis of the contents of this MSDS.
<i>More information</i>	No data available
<i>Bibliography</i>	NCBI – PUBCHEM Compound Database BANCA DATI SOSTANZE CHIMICHE - ICARO S.R.L. - CORTONA (AR) Internal MSDS.
<i>Update Reason</i>	Update according to Annex I of Regulation UE453/2010 which amended Annex II of EC Regulation 1907/2006 (REACH).

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The contained information is based upon our current understanding. It is applicable only to the indicated product and does not constitute any guarantee of the properties of the product. The user is responsible to ensure his or her own fitness and completeness of such information in relation to the specific use. The contained information is intended for the use of the product exclusively by appropriately qualified personnel. STERLING S.r.l. shall not be held liable for any damages caused from handling or from contact with the substance.

STERLING S.r.l.