

# 6-METHYLENEANDROSTA-4-ENE-3,17-DIONE

## 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:* 6-methyleneandrosta-4-ene-3,17-dione  
*Synonym:* Exemestane Related Compound A  
*CAS Number:* 19457-55-7  
*EC Number:* -  
*INDEX Number:* No data available  
*Registration Number:* Not applicable  
*Molecular Weight:* 298.42  
*Molecular Formula:* C<sub>20</sub>H<sub>26</sub>O<sub>2</sub>

#### 1.2 Relevant identified uses of the substance

*Common use:* Starting material 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)

Acute Tox. 4: H302  
Skin Irr. 2: H315  
Eye Irr. 2: H319  
STOT SE 3: H335

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

Xn; R22  
Xn; R36/37/38

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

## 2.2 Label elements



Signal Word: **WARNING**

### Hazard Statement

H302 : Harmful if swallowed

H315 : Causes skin irritation

H319 : Causes serious eye irritation

H335 : May cause respiratory irritation

### Precautionary Statement

#### *Prevention*

P261 : Avoid breathing dust/fume/gas/mist/vapours/spray

P281 : Use personal protective equipment as required

#### *Response*

P304 + P340 : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P332 + P313 : If skin irritation occurs: Get medical advice/attention

#### *Disposal*

P501 : Dispose of contents/container in accordance with local/regional/national/international

## 2.3 Other hazards

No data available

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

<i>Product name :</i>	6-methyleneandrosta-4-ene-3,17-dione
<i>Chemical name :</i>	6-methyleneandrosta-4-ene-3,17-dione
<i>Molecular Weight :</i>	298.42
<i>Molecular formula :</i>	C <sub>20</sub> H <sub>26</sub> O <sub>2</sub>
<i>CAS No. :</i>	19457-55-7
<i>EC No. :</i>	-
<i>Concentration :</i>	>99.9%

**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.
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.
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**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Thus, no indication on both acute and delayed effects are available.

However, exemestane (a related compound) disrupts hormone production and may increase fertility in premenopausal women. In animal studies it has caused toxic effects and miscarriage.

**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 (CO<sub>2</sub>), foam, dry chemical powder, water spray, and water jet, unless otherwise stated.

Unsuitable extinguishing media: None

### 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<sub>x</sub>).

### 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. 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.

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 thoroughly with soap and water before meals and after work shift.

### 7.2 *Conditions for safe storage*

Store below 20°C. Store away from all heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials.

## 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, glovebox, or other effective containment. 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*

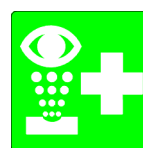
Personal Protective Equipment: The personal protective equipment should be chosen in the configuration according to the concentration and quantity of hazardous substances specifically for the workplace.

- a) *Eye / Face Protection:* Wear safety goggles (EN 166).
- b) *Skin and body Protection:* Protective clothing global. Use rubber or synthetic gloves (EN 374). For handling solutions, ensure that the glove material is protective against the solvent being used.
- 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	Off-white to yellowish crystalline powder
b) Odor	No data available
c) Odor threshold	No data available
d) pH	No data available
e) Melting point/freezing point	163 - 168 °C
f) Initial boiling point and boiling range	450.8 °C
g) Flash point	Not applicable
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	No data available
l) Vapor density	No data available
m) Relative density	1.11 g/cm <sup>3</sup>
n) Solubility(ies)	No data available
o) Partition coefficient: n-octanol/water	No data available
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 below 20 °C.

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<sub>x</sub>).

**SECTION 11****TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects**

*Signs and Symptoms of Exposure:* To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. However, exemestane (a related compound) disrupts hormone production and may increase fertility in premenopausal women. In animal studies it has caused toxic effects and miscarriage.

**CLASS OF RELEVANT RISK FOR SUBSTANCE:**

a) Acute toxicity:	Not reported evidence concerning this effect
b) Skin corrosion / irritation:	May cause skin irritation
c) Serious eye damage / serious eye irritation:	May cause eye irritation
d) Respiratory / skin sensitization:	Not reported evidence concerning this effect
e) Germ cell mutagenicity:	Not reported evidence concerning this effect
f) Carcinogenicity:	Not reported evidence concerning this effect
g) Reproductive toxicity:	Not reported evidence concerning this effect
h) Specific target organ toxicity (STOT)-Single exposure-	The product may cause mild irritation of the mucous membranes and upper respiratory tract
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 effect

**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***List of relevant phrases*

Classification according to Regulation (EC) No 1272/2008 (CLP/GHS) as amended  
H302 : Harmful if swallowed  
H315 : Causes skin irritation  
H319 : Causes serious eye irritation  
H335 : May cause respiratory irritation

Classification according to European Directive 67/548/CEE as amended  
R22: Harmful if swallowed  
R36/37/38: Irritating to eyes, respiratory system and skin

*Guidelines for the formation*

Workers potentially exposed to this substance must be trained adequately on the basis of the contents of this MSDS.

*More information*

No data available

*Bibliography*

MSDS of supplier  
US Pharmacopeia MSDS  
BANCA DATI SOSTANZE CHIMICHE - ICARO S.r.l. - CORTONA (AR)  
Internal MSDS.

*Update Reason*

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. If 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.**