

# DIENOGEST

## MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006  
Revision: 01 – Revision date: October 1, 2012

### SECTION 1 IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

#### 1.1 Product identifier

Product name: Dienogest  
Synonyms: STS 557  
CAS Number: 65928-58-7  
EC Number: No data available  
INDEX Number: No data available  
Registration Number: Not applicable  
Molecular Weight: 311.4  
Molecular Formula:  $C_{20}H_{25}NO_2$

#### 1.2 Relevant identified uses of the substance

Common use: API (Active Pharmaceutical Ingredient)

#### 1.3 Details of the supplier of the safety data sheet

Company name: STERLING S.p.A.  
Address: Via della Carboneria, 30  
06073 Solomeo di Corciano (PG) – Italy  
  
E-mail address: aragona@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)

Repr. 2 - H361fd  
Lact. - H362

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

Repr. Cat 3; R62  
Repr. Cat 3; R63  
R64

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

## 2.2 Label elements



Signal Word:

**WARNING**

### Hazard Statement

H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child  
H362 : May cause harm to breast-fed children

### Precautionary Statement

#### *Prevention*

P201 : Obtain special instructions before use  
P202 : Do not handle until all safety precautions have been read and understood  
P260 : Do not breathe dust/fume/gas/mist/vapours/spray  
P263 : Avoid contact during pregnancy/while nursing  
P281 : Use personal protective equipment as required

#### *Response*

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

#### *Storage*

P405 : Store locked up

#### *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

Product name :	Dienogest
Chemical name :	17-alpha-Cyanomethyl-17-beta-hydroxy-estra-4,9(10)-dien-3-one
Molecular Weight:	311.46
Molecular formula:	C <sub>20</sub> H <sub>25</sub> NO <sub>2</sub>
CAS No.:	65928-58-7
EC No:	No data available
Concentration:	> 99%

#### 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 copious amount of water. If the casualty is unconscious, place in the recovery position. Never give anything by mouth to an unconscious person and if not authorized by the physician.
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. Remove contaminated clothing and shoes.
Eye contact:	Check for and remove any contact lenses. 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. However, the most frequent adverse effects of Dienogest are related to metrorrhagia, headache, hot flushes, acne, nausea, increased weight, breast discomfort, abdominal pain and depressed mood.  
Reported effects on reproduction. (see sec. 11)

#### 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, and water spray, 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 (COx), nitric oxides (NOx) and CN<sup>-</sup>.

### 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.

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 at controlled room temperature. Store in the original package. 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. 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).
- 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 to white ivory crystalline powder
b) Odor	Odorless
c) Odor threshold	No data available
d) pH	No data available
e) Melting point/freezing point	209-214 °C
f) Initial boiling point and boiling range	549 °C at 760 mmHg
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	1.2 g/cm <sup>3</sup>
n) Solubility(ies)	Poor water solubility (57.88 mg/L at 25 °C). Soluble in pyridine.
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 at controlled 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<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>) and CN<sup>-</sup>.

## 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, the most frequent adverse effects of Dienogest are related to metrorrhagia, headache, hot flushes, acne, nausea, increased weight, breast discomfort, abdominal pain and depressed mood.

#### CLASS OF RELEVANT RISK FOR SUBSTANCE:

a) *Acute toxicity:*

Route	Specie	Results	Note	Reference
Oral	Rodent - mouse	LD50 4 gm/kg	Behavioral - somnolence (general depressed activity)	PHARAT 34, 319, 1979

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	Not reported evidence concerning this effect
g) Reproductive toxicity:	

Route	Specie	Results	Note	Reference
Oral	Rodent – rat male 60 day(s) pre mating	TDLo - Lowest published toxic dose 300 mg/kg	Reproductive - Paternal Effects - testes, epididymis, sperm duct Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland	<b>CCPTAY</b> 36, 253, 1987
Subcutaneous	Rodent – rat female 1-4 day(s) after conception	TDLo – Lowest published toxic dose 25 mg/kg	Reproductive - Fertility – female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated). Reproductive - Fertility – preimplantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea).	<b>CCPTAY</b> 36, 253, 1987
Subcutaneous	Rodent – rat male 21 day(s) pre mating	TDLo - Lowest published toxic dose 42 mg/kg	Reproductive - Paternal Effects – spermatogenesis (incl. genetic material, sperm morphology, motility, and count).	<b>ARANDR</b> 11, 157, 1983
Oral	Rodent mouse female 1-4 day(s) after conception	TDLo - Lowest published toxic dose 500 mg/kg	Reproductive - Fertility - abortion	<b>EXCEDS</b> 81, 197, 1983
Oral	Rodent rabbit male 56 day(s) pre mating	TDLo - Lowest published toxic dose 80 mg/kg	Reproductive - Paternal Effects - Spermatogenesis (incl. genetic material, sperm morphology, motility, and count).	<b>CCPTAY</b> 21, 641, 1980
Oral	Rodent rabbit female 1 day after conception	TDLo - Lowest published toxic dose 100 µg/kg	Reproductive - Fertility - preimplantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea).	<b>CCPTAY</b> 21, 61, 1980



<i>h) Specific target organ toxicity (STOT)-Single exposure-</i>	Not reported evidence concerning this effect
<i>h) Specific target organ toxicity (STOT)-Repeated exposure-</i>	Not reported evidence concerning this effect
<i>j) Aspiration hazard</i>	<i>Not applicable</i>
<i>Other information</i>	RTECS N. <b>RC8899500</b>

## 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.)

Not-UE: EPA GENETOX PROGRAM 1988, Positive: Sperm morphology-rabbit

### 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>	<p>Classification according to Regulation (EC) No 1272/2008 (CLP/GHS) as amended</p> <p>H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child</p> <p>H362: May cause harm to breast-fed children</p> <p>Classification according to European Directive 67/548/CEE as amended</p> <p>R62: Possible risk of impaired fertility</p> <p>R63: Possible risk of harm to the unborn child</p> <p>R64: May cause harm to breast-fed babies</p>
<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>	<p>THE MERCK INDEX-XI Ed.(1989)- Merck &amp; Co. Inc.-Rahway, N.J.- USA</p> <p>RTECS- Registry of Toxic Effects of Chemical Substances</p> <p>NCBI – PUBCHEM Compound Database</p> <p>BANCA DATI SOSTANZE CHIMICHE - ICARO S.R.L. - CORTONA (AR)</p>
<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.p.A. shall not be held liable for any damages caused from handling or from contact with the substance.

**STERLING S.p.A.**