

# Prasterone

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Date of issue: 21/02/2012 Revision date: 23/02/2017

**628158**

Version: 2.0

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product form	: Substance
Substance name	: Prasterone
IUPAC name	: 3 $\beta$ -hydroxyandrost-5-en-17-one
EC No	: 200-175-5
CAS No	: 53-43-0
Product code	: 628158
Formula	: C <sub>19</sub> H <sub>28</sub> O <sub>2</sub>
Synonyms	: DHEA (dehydroepiandrosterone)
Product group	: Raw material

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Main use category	: Pharmaceutical
Function or use category	: Raw material

#### 1.2.2. Uses advised against

No additional information available

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

#### Supplier

Duchefa Farma BV  
A. Hofmanweg 71  
2031BH Haarlem - Nederland  
T +31(0)23-5319093  
[farma@ducheffa.nl](mailto:farma@ducheffa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

### 1.4. Emergency telephone number

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

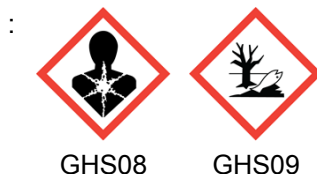
#### **Adverse physicochemical, human health and environmental effects**

No additional information available

## 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H360 - May damage fertility or the unborn child  
H362 - May cause harm to breast-fed children  
H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (CLP)

: P281 - Use personal protective equipment as required  
P260 - Do not breathe dust/fume/gas/mist/vapours/spray  
P308+P313 - IF exposed or concerned: Get medical advice/attention  
P273 - Avoid release to the environment

## 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Prasterone	(CAS No) 53-43-0 (EC No) 200-175-5	> 99	Not classified

Full text of H-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Remove victim to fresh air. Obtain medical attention if breathing difficulty persists.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
First-aid measures after ingestion	: Rinse mouth. Never give anything by mouth to an unconscious person. Seek medical advice.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries	: This material or its emissions may affect the central nervous system and/or aggravate pre-existing disorders. Fall of hair. Sleepiness.
Chronic symptoms	: May affect: . endocrine system.

**4.3. Indication of any immediate medical attention and special treatment needed**

No additional information available

**SECTION 5: Fire-fighting measures**

**5.1. Extinguishing media**

Suitable extinguishing media : Carbon dioxide. Dry powder. Foam. Water spray.  
Unsuitable extinguishing media : Do not use a heavy water stream.

**5.2. Special hazards arising from the substance or mixture**

Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide.  
Explosion hazard : Product is not explosive.

**5.3. Advice for firefighters**

Firefighting instructions : Prevent fire fighting water from entering the environment.  
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

**6.1.1. For non-emergency personnel**

Emergency procedures : Ensure adequate air ventilation. Avoid raising dust.

**6.1.2. For emergency responders**

Protective equipment : Wear proper protective equipment. Wear respiratory protection.

**6.2. Environmental precautions**

Prevent product from entering drains.

**6.3. Methods and material for containment and cleaning up**

Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Ethanol. Detergent.

**6.4. Reference to other sections**

No additional information available

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

No additional information available

**7.2. Conditions for safe storage, including any incompatibilities**

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from moisture. Protect from sunlight.  
Maximum storage period : 3 year  
Storage temperature : < 25 °C

**7.3. Specific end use(s)**

No additional information available

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

No additional information available

**8.2. Exposure controls****Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

**Eye protection:**

Safety glasses (to European standard EN 166 or equivalent)

**Skin and body protection:**

Protective clothing (with elasticated cuffs and closed neck). Chemical resistant apron

**Respiratory protection:**

Wear appropriate mask. Dustmask with filtertype P3

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 288.4 g/mol
Colour	: White.
Odour	: Not known.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 149 - 151 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Material nearly insoluble in water. Soluble in ethanol.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

Explosive limits : No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None known.

### 10.4. Conditions to avoid

High temperature. Light (daylight). Moisture.

### 10.5. Incompatible materials

Strong oxidizers.

### 10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Prasterone (53-43-0)	
LD50 oral rat	> 10000 mg/kg

Skin corrosion/irritation : Not classified  
Serious eye damage/irritation : Not classified  
Respiratory or skin sensitisation : Not classified  
Germ cell mutagenicity : Not classified  
Carcinogenicity : Not classified

Reproductive toxicity : Not classified  
STOT-single exposure : Not classified  
STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations



### 13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
	
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available	

### 14.6. Special precautions for user

#### - Overland transport

No data available

#### - Air transport

No data available

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Prasterone is not on the REACH Candidate List

Prasterone is not on the REACH Annex XIV List

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes:

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Respiratory protection	Modified	Added additional information (type of clothing related to concentration levels)

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Supplier.

SDS EU (REACH Annex II) Version 2017

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*