

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

PRASTERONUM

EN

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Prasterone Prasteronum Prasterone Prastérone Prasteron
N° CAS:	53-43-0
N° EC:	200-175-5

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT SE 3	H335
Repr. 1B	H360
Lact.	H362
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

2.2 Label elements

Labelling according to (EC) n° 1272/2008

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Hazard pictogram(s):



Signal word(s):

Attention; Danger

Hazard statements:

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360	May damage fertility or the unborn child.
H362	May cause harm to breast-fed children.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long-lasting effect.

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fumes/gas/mist/vapours/spray.
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P263	Avoid contact during pregnancy/while nursing.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P281	Use personal protective equipment as required.
P302+P352	IF ON SKIN: Wash with soap and plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P308+P313	If exposed or concerned: Get medical advice/attention.
P312	Call a POISON CENTER/ doctor if you feel unwell.
P321	Specific treatment (see on this label).
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists get medical advice/attention.
P362	Take off contaminated clothing.
P391	Collect spillage.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.

Additional applicable label elements:



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2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Prasterone
IUPAC name:	(3S,8R,9S,10R,13S,14S)-3-hydroxy-10,13-dimethyl-1,2,3,4,7,8,9,11,12,14,15,16-dodecahydrocyclopenta[a]phenanthren-17-one
Synonyms:	DHEA 3 β -Hydroxy-5-androsten-17-one 5-Androsten-3 β -ol-17-one Dehydroepiandrosterone Dehydroisoandrosterone
N° CAS:	53-43-0
N° EC:	200-175-5
Molecular Formula:	C ₁₉ H ₂₈ O ₂
Content:	97.5 per cent to 102.0 per cent (anhydrous and solvent-free)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	If breathed in, move person into fresh air. If not breathing give artificial respiration. Consult a physician.
After skin contact:	Remove contaminated clothing and shoes. Wash off with soap and plenty of water. Consult a physician.
After eye contact:	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
After ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

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Suitable extinguishing media: Water spray, carbon dioxide, dry chemical powder or appropriate foam.

Unsuitable extinguishing media: None.

5.2 Special hazards arising from the substance/mixture

Fire may cause evolution of: Carbon monoxide, carbon dioxide (CO₂), nitrogen oxides (NO_x).

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self contained breathing apparatus for fire fighting if necessary.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear approved safety goggles, approved clothing and approved full face respirator P3.

For emergency responders

Wear approved safety goggles, approved clothing and approved full face respirator P3.

6.2 Environmental precautions

In case of accidental release or spill, keep away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up

Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see section 13). If emergency, enforce internal emergency plan.

6.4 Reference to other sections

For disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Keep away from heat and flames. Avoid powder dispersion. Avoid contact with incompatible substances. Avoid: direct contact with skin and eyes; inhalation of vapours and fumes.

Personal protection: Wear appropriate PPE (See section 8).

Technical protective measures: Not available.

Handling: Occupational hygiene: Do not eat, drink or smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

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Conditions for safe storage, including any incompatibilities:

Store at a temperature not exceeding 25 °C. Store in cool place.
Keep container tightly closed in a dry and well-ventilated place.
Store locked up.

Storage – away from:

Store protected from light and moisture.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

OEL: 10 – 100 µg/m³

8.2 Exposure controls

Appropriate engineering control

Provide adequate engineering control measures in confined plants or with local exhaust ventilation systems, to avoid powder dispersion.

Individual protection measures

Eye/face protection: Approved safety goggles.

Skin protection: Long sleeved clothing.

Hand protection: Rubber/latex/neoprene or other suitable chemical resistant gloves.

Respiratory protection: Approved full face respirator P3 or airline respirator.

Thermal hazards: Not determined.

Environmental exposure control

If necessary, adopt air emission treatment systems.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Fine, crystalline, white or approximately white powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: 146 °C – 151 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: 0.01Pa (25 °C)

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Vapour density:	Not available.
Relative density:	1.159 g/cm ³
Solubility:	Freely soluble in ethanol (96 per cent) and in methylene chloride.
Solubility in water:	Practically insoluble in water. 63.5 mg/L (25 °C)
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular Weight: 228,42 g/mol

Prasterone should not be considered as highly flammable.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

The substance is stable in normal conditions of temperature and pressure and if stocked in closed containers in cold and ventilated area.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong oxidizing agents, acid.

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions: carbon oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (rats): > 3 300mg/kg Oral LD ₅₀ (dogs): > 400 mg/kg Oral LD ₅₀ (male mice): > 4130 mg/kg Oral LD ₅₀ (female mice): > 4 130 mg/kg
Skin corrosion/irritation:	Conclusive but not sufficient for classification.

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Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Conclusive but not sufficient for classification.
Carcinogenicity:	Conclusive but not sufficient for classification.
Reproductive toxicity:	Repr. 1B, H360: May damage fertility or the unborn child Effects via lactation: Effect on or via lactation H362: May cause harm to breast-fed children.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Signs and Symptoms of Exposure: Electrolyte imbalance. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. RTECS: BV8396000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes eye irritation.
Skin contact:	May be harmful if absorbed through skin. Causes skin irritation.
Inhalation:	May be harmful if inhaled. Causes respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Hazardous to the aquatic environment (acute/short-term): Aquatic Acute 1 H400: Very toxic to aquatic life.
Hazardous to the aquatic environment (long-term): Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

Prasterone is described as not readily biodegradable.

12.3 Bioaccumulative potential

The bioaccumulation factor of Prasterone was estimated to be 62.83 l/kg.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

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12.6 Other adverse effects

No toxicity effect to microbes of activated sludge was observed.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : 3077

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : ADR/RID/ADN: PRASTERON
IMDG: PRASTERON
IATA/ICAO: PRASTERON

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : 9

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : III

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : ADR/RID/ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID
IATA/ICAO: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

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Hazard symbol:



Irritant
Harmful

Risk phrases:

R36/37/38 Irritating to eyes, respiratory system and skin.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R60 May impair fertility.

R61 May cause harm to the unborn child.

R64 May cause harm to breast-fed babies.

Safety phrases:

S1 Keep locked up.

S7/9 Keep container tightly closed and in a well-ventilated place.

S20/21 When using do not eat, drink or smoke.

S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S27 Take off immediately all contaminated clothing.

S28 After contact with skin, wash immediately with soap and plenty of water.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S51 Use only in well-ventilated areas.

S53 Avoid exposure- obtain special precautions before use.

S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance

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RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

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info@magis-pharma.be