

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	16.07.2024 1 von 12 03
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Art.-Ref.: Prasterone, micronised (DHEA)	Art.-No.: 702326
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SECTION 1: Identification of the substance/mixture and of the company/ undertaking

1.1 Product identifier

Product name: Prasterone, micronised (DHEA)
Index-Nr.: -
EG-Nr.: 200-175-5
CAS-Nr.: 53-43-0
REACH- Registration number.: 01-2119946317-33-XXXX

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

Identified uses:

- Active pharmaceutical ingredient (API)

Uses advised against:

- Any use other than the active pharmaceutical ingredient (API)

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier

Euro OTC Pharma GmbH
Edisonstr. 6
59199 Bönen

Telephone / fax / email

- 02383 / 922020
- 02383 / 92202150
- info@euro-otc.com

1.4 Emergency telephone number

0361 / 730730 (Gemeinsames Giftnotrufzentrum, Nordhäuser Str. 74, 99089 Erfurt) (Germany)
ChemTel Contract Number MIS5311335 –
USA and Canada: +1-800-255-3924 (toll free),
Australia: +1-300-954-583,
Brazil: +0-800-591-6042,
China: +400-120-0751,
India: +000-800-100-4086,
Mexico: 800-099-0731,
International phone number: +1-813-248-0585 (collect calls accepted)

SECTION 2: Hazards identification:

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 (CLP/GHS)

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Aquatic Acute 1: Very toxic to aquatic life.
Aquatic Chronic 1: Very toxic to aquatic life with long lasting effects.
Lact.: May cause harm to breast-fed children.
Repr. 1B: May damage fertility or the unborn child

2.2 Label elements

Label elements According to Regulation (EC) No 1272/2008

Hazard pictograms:



Signal word: Danger

Hazard statements:

H302	Harmful if swallowed.
H360-H362	May damage fertility or the unborn child. May cause harm to breast-fed children.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)

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 and while nursing.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P391	Collect spillage.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

- The substance is not PBT
 - The substance is not vPvB
 - Substance does not have endocrine disrupting properties.
 - In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.
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SECTION 3: Composition/information on ingredients

3.1 Substances

Mono-constituent

Main component of the fabric
Product/ingredient name: Prasterone (DHEA)
Index-Nr.:
EG-Nr.: 200-175-5
CAS-Nr.: 53-43-0
Chemical formula: C₁₉H₂₈O₂
Molecular weight: 288,42
Purity: 100% [mass]

3.2 Mixtures

- Not Applicable.

SECTION 4: First aid measures

4.1 Description of first aid measures

Delayed effects may occur after the exposure to the product.

Inhalation:

- Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Skin contact:

- Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

Eye contact:

- Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up and seek medical assistance.

If swallowed:

- If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

- Long-term chronic exposure may result in injury to certain organs or tissues.

4.3 Indication of any immediate medical attention and special treatment needed

- In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.
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SECTION 5: Firefighting measures

The product does not present any particular risk in case of fire.

5.1 Extinguishing media

Suitable extinguishing media:

- Extinguish with carbon dioxide, fire-extinguishing powder, alcohol resistant foam or waterspray

Unsuitable extinguishing media:

- Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture

Special risks

- Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters

- Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways. Product residues and extinguishing media may contaminate the aquatic environment.

Fire protection equipment

- According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

6. SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions

- Product dangerous for the environment, in case of large spills or if the product contaminates lakes, rivers, or sewers, inform the responsible authorities according to local legislation. Prevent the contamination of drains, surface or subterranean waters, and the ground.

6.3 Methods and materials for containment and cleaning up

- Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant. Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections

- For exposure control and individual protection measures, see section 8.
- For later elimination of waste, follow the recommendations under section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

- For personal protection, see section 8.
- In the application area, smoking, eating, and drinking must be prohibited.
- Follow legislation on occupational health and safety.
- Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities

- Store according to local legislation. Observe indications on the label. Store the containers between 5 and 25 °C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidizing agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.
- The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s)

- No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values

8.2 Exposure controls

Measures of a technical nature

- Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system

Concentration	100 %
Uses:	Active pharmaceutical ingredient
Breathing protection:	
PPE:	Particle filter mask
Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.
CEN standards:	EN 149
Maintenance:	Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it should be replaced after use.
Observations:	Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding suitable use of the equipment.
Filter Type needed:	P2



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Hand protection:

PPE:	Non-disposable protective gloves against chemicals.			
Characteristics:	«CE» marking, category III. Check the list of chemicals for which the glove has been tested.			
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420			
Maintenance:	A schedule for the periodical replacement of gloves should be established in order to guarantee their replacement before pollutants permeate them. The use of contaminated gloves could be more dangerous than not using gloves, since the pollutant can gradually accumulate in the glove's material.			
Observations:	They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could reduce their strength.			
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.): > 480	Material thickness (mm): 0,35	

Eye protection:

PPE:	Protective goggles against particle impacts	
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.	
CEN standards:	EN 165, EN 166, EN 167, EN 168	
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.	
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.	

Skin protection:

PPE:	Chemical protective clothing	
Characteristics:	«CE» marking, category III. Clothing should fit properly. The level of protection must be set according to a test parameter called BT (Breakthrough Time), which indicates how long it takes for the chemical to pass through the material.	
CEN standards:	EN 464, EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034	
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.	
Observations:	The protective clothing's design should facilitate correct positioning, staying in place without moving for the period of use expected, bearing in mind environmental factors as well as any movement or position the user might adopt while carrying out the activity.	
PPE:	Anti-static safety footwear against chemicals.	
Characteristics:	«CE» marking, category III. Check the list of chemicals against which the footwear is resistant.	
CEN standards:	EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345	
Maintenance:	For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is observed.	
Observations:	The footwear should be cleaned regularly and dried when damp, although it should not be placed too close to a source of heat in order to avoid any sharp changes in temperature.	

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties Appearance

General Information

Physical state:	Solid
Color:	Yellowish
Odor:	Odourless
Odor threshold:	No information available
pH:	Not applicable.
Melting point/freezing point:	149 - 151 °C
Initial boiling point and boiling range:	426,7 °C
Flammability:	Product is not flammable.
Flash point:	182,1 °C
Lower and upper explosion limit:	No information available
Vapor pressure:	Not applicable.
Vapor density:	No information available
Density (g/ml):	No information available
Hydrosolubility	No information available
Liposolubility:	No information available
Water:	No information available
Partition coefficient: n-octanol/water:	No information available
Auto-ignition temperature:	No information available
Decomposition temperature:	No information available
Viscosity:	
Explosive properties:	No information available
Absolute density	No information available
Relative density:	1,12
Particle characteristics	No information available

9.2 Other information

- No further data available

SECTION 10: Stability and reactivity

10.1 Reactivity

- The product does not present hazards by their reactivity

10.2 Chemical stability

- Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

- At high temperatures can occur pyrolysis and dehydrogenation.

10.4 Conditions to avoid:

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- Avoid the following conditions: Heating, High temperature.

10.5 Incompatible materials:

- Avoid the following materials: Acids, Bases, Oxidizing agents.

10.6 Hazardous decomposition products

- In case of fire, dangerous decomposition products can be generated, such as carbon monoxide and dioxide and nitrogen fumes and oxides.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity-Ingestion

- Not conclusive data for classification.

Skin corrosion/irritation

- Not conclusive data for classification

Serious eye damage/irritation

- Not conclusive data for classification.

Respiratory or skin sensitisation

- Not conclusive data for classification.

Germ cell mutagenicity

- Not conclusive data for classification.

Carcinogenicity

- Not conclusive data for classification.

Reproductive toxicity

Product classified:

- Effects on or via lactation: May cause harm to breast-fed children.
- Reproductive toxicant, Category 1B: May damage fertility or the unborn child.

STOT-single exposure

- Not conclusive data for classification.

STOT-repeated exposure

- Not conclusive data for classification.

Aspiration hazard

- Not conclusive data for classification.

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11.2 Information on other hazards

Endocrine disrupting properties

- This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

- There is no information available on other adverse health effects.

SECTION 12: Ecological information

12.1 Toxicity

- No further relevant information available.

12.2 Persistence and degradability

- No further relevant information available.

12.3 Bioaccumulative potential

- No further relevant information available.

12.4 Mobility in soil

- No information is available about the mobility in soil.
- The product must not be allowed to go into sewers or waterways.
- Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties

No information is available

12.7 Other adverse effects

No information is available about other adverse effects for the environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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- Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
- Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: Transport information

Transport following ADR rules for road transport, RID rules for railway, ADN for inner waterways, IMDG for sea, and ICAO/IATA for air transport.

Land: Transport by road: ADR, Transport by rail: RID.

Transport documentation: Consignment note and written instructions

Sea: Transport by ship: IMDG.

Transport documentation: Bill of lading

Air: Transport by plane: ICAO/IATA.

Transport document: Airway bill.

14.1 UN number or ID number

- UN No: UN3077

14.2 UN proper shipping name

Description:

ADR/RID: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(CONTAINS PRASTERONE), 9, PG III, (-)

IMDG: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(CONTAINS PRASTERONE), 9, PG III, MARINE POLLUTANT

ICAO/IATA: UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (CONTAINS PRASTERONE), 9, PG III

14.3 Transport Hazard Class:

- Class(es): 9

14.4 Packing Group

- Packing group: III

14.5 Environmental hazards:

Marine pollutant:

YES



Dangerous for the environment

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-A,S-F

14.6 Special precautions for user

- Labels: 9



Hazard number: 90

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ADR LQ: 5 kg
IMDG LQ: 5 kg
ICAO LQ: 30 kg B

Provisions concerning carriage in bulk ADR:

VC1: Carriage in bulk in sheeted vehicles, sheeted containers or sheeted bulk containers is permitted.

VC2: Carriage in bulk in closed vehicles, closed containers or closed bulk containers is permitted.

Proceed in accordance with point 6.

14.7 Maritime transport in bulk according to IMO instruments

- The product is not transported in bulk.

SECTION 15: Regulatory information

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

- The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.
- Product classification according to Annex I of Directive 2012/18/EU (SEVESO III): N/A
- The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
- The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals

15.2 Chemical Safety Assessment

- No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.
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SECTION 16: Other information

Classification codes:

- Aquatic Acute 1: Acute toxicity to the aquatic environment, Category 1
- Aquatic Chronic 1: Chronic effect to the aquatic environment, Category 1
- Lact.: Effects on or via lactation
- Repr. 1B: Reproductive toxicant, Category 1B

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

- Physical hazards On basis of test data
- Health hazards Calculation method
- Environmental hazards Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly

Key literature references and sources for data:

- <http://eur-lex.europa.eu/homepage.html>
- <http://echa.europa.eu/>
- Regulation (EU) 2020/878.
- Regulation (EC) No 1907/2006.
- Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

Contact person: Mr. Dr. Abdulsalam Adam

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ARD: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LC₅₀: Lethal concentration, 50 percent
LD₅₀: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Carc. 1B: Karzinogenität Kategorie 1B
Muta. 2: Mutagenität Kategorie 2

The above information is based on the current state of our knowledge and experience. They describe the products with regard to safety requirements and do not represent a guarantee of properties. The recipient of our product is responsible for observing existing laws and regulations.