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

1.1 Product identifier

Product name: Pregnenolone

Pregnenolonum Pregnenolone Prégnénolone Pregnenolon

N° CAS: 145-13-1 N° EC: 205-647-4

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

Identified uses: Active Pharmaceutical Ingredient or Excipient.

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

Acute Tox. 4 H302
Acute Tox. 4 H312
Acute Tox. 4 H332
Carc. 2 H351
Repr. 2 H361fd

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):





Signal word(s): Attention

Hazard statements:

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H302 Harmful if swallowed.
H312 Harmful in contact with skin.

H332 Harmful if inhaled.

H351 Suspected of causing cancer.

H361fd Suspected of damaging fertility or the unborn child.

Precautionary statements:

P264 Wash face, hands and any exposed skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: wash with plenty of soap and water.

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

P405 Store locked up.
Additional applicable label Not applicable.

elements:

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Pregnenolone

IUPAC name: 1-[(3S,8S,9S,10R,13S,14S,17S)-3-hydroxy-10,13-dimethyl-

2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1*H*-cyclopenta[a]phenanthren-17-

yl]ethanone

Synonyms: Arthenolone

Pregnetan

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Remove from exposure and move to fresh air immediately. Get medical aid if cough

or other symptoms appear.

After skin contact: Get medical aid if irritation develops or persists. Flush skin with plenty of soap and

water.

After eye contact:

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Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper

and lower eyelids. Get medical aid.

If victim is conscious and alert, give 2-4 cups of milk or water. Never give anything

by mouth to an unconscious person. Get medical aid.

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms of Exposure: Electrolyte imbalance. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

After ingestion:

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

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

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.

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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 personal protective equipment (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: In an airtight container.

Conditions for safe storage, including any

incompatibilities:

Store in cool place. Keep container tightly closed in a dry and well-

ventilated place. Store locked up.

Storage – away from: Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

OEL: 1-10μg/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: White or almost white, crystalline powder.

Odour: Odourless.

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pH: Not available.

Melting/freezing point: 185 °C to 194 °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:

Solubility:

Odour threshold:

Not available.

Not available.

Vapour pressure: Not available.
Vapour density: Not available.
Relative density: Not available.

Solubility in water: Slightly soluble in water.

Partition coefficient Not available.

(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

Not available.

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

Incompatible materials, dust generation.

10.5 Incompatible materials

Strong oxidizing agents.

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10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not available.

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not listed by ACGIH, IARC, or NTP.

Reproductive toxicity: Suspected of damaging fertility. Suspected of damaging the unborn child.

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: Not available.
STOT-repeated exposure: Not available.
Aspiration Hazard: Not available.

Other: RTECS: TU5560700

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: May cause eye irritation.

Skin contact: Harmful in contact with skin. May cause skin irritation.

Inhalation: Harmful if inhaled. May cause respiratory tract irritation. The toxicological

properties of this substance have not been fully investigated.

Ingestion: Harmful if swallowed. May cause irritation of the digestive tract. The toxicological

properties of this substance have not been fully investigated.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

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Not available.

12.6 Other adverse effects

Not available.

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):

Not classified.

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea),

Not dangerous goods.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea),

Not regulated as a hazardous material.

IATA/ICAO (Air):

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

Hazard symbol:



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Irritant

Harmful

Risk phrases: R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

Safety phrases: S1 Keep locked up.

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

S28 After contact with skin, wash immediately with plenty of soap and water. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

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

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 Bioaccumalative

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

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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

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