

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 26/08/2022

Revision: XX/XX/XXXX

Version: 00



## ALFATRADIOLUM

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

#### 1.1 Product identifier

Product name: Alfatradiol  
Alfatradiolum  
Alfatradiol  
Alfatradiol  
Alfatradiol

N° CAS: 57-91-0

N° EC: 200-354-8

#### 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

Carc. 2	H351
Repr. 1A	H360
Repr. 2	H361
Lact.	H362

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H351 Suspected of causing cancer.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 26/08/2022

Revision: XX/XX/XXXX

Version: 00



## ALFATRADIOLUM

H360+H361+H362

May damage fertility or the unborn child. Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

Precautionary statements:

P201

Obtain special instructions before use.

P263

Avoid contact during pregnancy/while nursing.

P281

Use personal protective equipment as required.

P308+P313

IF exposed or concerned: Get medical advice/attention.

P405

Store locked up.

P501

Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional applicable label elements:



### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:

Alfatradiol

IUPAC name:

(8R,9S,13S,14S,17R)-13-methyl-6,7,8,9,11,12,14,15,16,17-decahydrocyclopenta[a]phenanthrene-3,17-diol

Synonyms:

17-alpha-Estradiol

Epiestradiol

N° CAS:

57-91-0

N° EC:

200-354-8

Molecular Formula:

C<sub>18</sub>H<sub>24</sub>O<sub>2</sub>

Content:

Alfatradiol contains at least 97.0 and at most 102.0 per cent of Estra-1,3,5(10)-triene-3,17α-diol, calculated on the dried substance.

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:

Consult a physician. Show this safety data sheet to the doctor in attendance.

After inhalation:

Move to fresh air. If not breathing, give artificial respiration. Consult a physician.

After skin contact:

Wash off with soap and plenty of water. Consult a physician.

After eye contact:

Immediately flush eye(s) with plenty of water for at least 15 minutes. Remove contact lenses. If eye irritation persists, consult a specialist.

After ingestion:

Rinse mouth with water. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.

# Material Safety Data Sheet

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

## ALFATRADIOLUM

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 26/08/2022

Revision: XX/XX/XXXX

Version: 00



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

Not available.

### 4.3 Indication of any immediate medical attention and special treatment needed

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: Not available.

### 5.2 Special hazards arising from the substance/mixture

Specific hazards during firefighting: Carbon oxides, nitrogen oxides (NO<sub>x</sub>)

### 5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self-contained breathing apparatus for firefighting 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 respiratory protection. Avoid dust formation. Avoid breathing vapors, dust, mist or gas. Ensure adequate ventilation.

#### For emergency responders

Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, dust, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

### 6.2 Environmental precautions

Do not let product enter the canalization.

### 6.3 Methods and material for containment and cleaning up

Arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, well-closed containers for disposal.

### 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: Avoid contact with eyes and skin. Avoid formation of dust.

Personal protection: Not available.

Technical protective measures: Provide appropriate ventilation at places where dust is formed. Normal measures for preventive fire protection.

# Material Safety Data Sheet

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

## ALFATRADIOLUM

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 26/08/2022

Revision: XX/XX/XXXX

Version: 00



Handling: Not available.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage: In a well-closed container, protected from light.

Conditions for safe storage, including any incompatibilities: Keep container tightly closed in a dry, cool and well-ventilated places.

Storage – away from: Store protected from light.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Not available.

#### Individual protection measures

Eye/face protection: Face shield and safety glasses. Equipment tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection: Not determined.

Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: White to almost white powder.

Odour: Odourless.

Odour threshold: Not available.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 26/08/2022

Revision: XX/XX/XXXX

Version: 00



## ALFATRADIOLUM

pH:	Not available.
Melting/freezing point:	222 - 226 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not applicable.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Sparingly soluble in acetone and ethanol (96%). Slightly soluble in ether.
Solubility in water:	Practically insoluble in water.
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

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Not available.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Strong oxidizing agents.

### 10.6 Hazardous decomposition products

Not available.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 26/08/2022

Revision: XX/XX/XXXX

Version: 00



## ALFATRADIOLUM

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Based on available data, the classification criteria are not met.
Oral LD <sub>50</sub>	> 4000.0 mg/kg (mouse) > 4000.0 mg/kg (rat)
	<b>Specific symptoms in biological assay:</b>
LD <sub>50</sub> oral	> 4000.0 mg/kg mouse /estradiol valerate
LD <sub>50</sub> oral	> 4000.0 mg/kg rat /estradiol valerate
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Suspected of causing cancer.
Reproductive toxicity:	May damage fertility or the unborn child. 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:	<b>Signs and Symptoms of Exposure:</b> To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. <b>RTECS:</b> KG3750000

#### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
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.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 26/08/2022

Revision: XX/XX/XXXX

Version: 00



## ALFATRADIOLUM

### General notes

Water hazard class 3 (German Regulation) (Assessment by list): extremely hazardous for water.

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

**Product:** Contact a licensed professional waste disposal service. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

**Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

## SECTION 14: TRANSPORT INFORMATION

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

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 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 classified.  
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.

# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 26/08/2022

Revision: XX/XX/XXXX

Version: 00



## ALFATRADIOLUM

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R60 May impair fertility.

R61 May cause harm to the unborn child.

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

R64 May cause harm to breast-fed babies.

Safety phrases:

S1 Keep locked up.

S53 Avoid exposure – obtain special instructions before use.

#### 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 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.



# Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 26/08/2022

Revision: XX/XX/XXXX

Version: 00



## ALFATRADIOLUM

### 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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