

# Material Safety Data Sheet

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

EN

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## PREDNISOLONUM

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

#### 1.1 Product identifier

Product name: Prednisolone  
Prednisolonum  
Prednisolon  
Prednisolone  
Prednisolon

N° CAS: 50-24-8

N° EC: 200-021-7

#### 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	H332
Acute Tox. 4	H312
Acute Tox. 4	H302
Eye Irrit. 2	H319
STOT SE 3	H335
Skin Irrit. 2	H315
Repr. 2	H361d

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Attention

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### Hazard statements:

H332	Harmful if inhaled.
H312	Harmful in contact with skin.
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H315	Causes skin irritation.
H361d	Suspected of damaging the unborn child.

Precautionary statements: Not applicable.

Additional applicable label elements:



### 2.3 Other hazards

Results of PBT and vPvB assessment: The results of the substance evaluation show that the substance is not a PBT or vPvB substance.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Prednisolone
IUPAC name:	11 $\beta$ ,17,21-Trihydroxypregna-1,4-diene-3,20-dione
Synonyms:	Metacortandralone Hydroretrocortine Predonine
N° CAS:	50-24-8
N° EC:	200-021-7
Molecular Formula:	C <sub>21</sub> H <sub>28</sub> O <sub>5</sub>
Content:	96.5 per cent to 102.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Do not leave the victim unattended. Move the victim out of the danger zone. Keep casualty warm, quiet and covered. Remove contaminated clothing immediately. If in doubt or if symptoms persist, consult a physician. If unconscious, place the victim in the stable side-position. Do not give anything by mouth. Avoid contact in case of pregnancy or lactation.
After inhalation:	Mouth-to-mouth resuscitation should be avoided. Use alternative methods, preferably oxygen or compressed air powered equipment. In case of respiratory irritation, consult a physician. Provide fresh air. Consult a POISON CENTER.
After skin contact:	Wipe away loose particles from the skin. Rinse/shower skin with water. Wash with plenty of soap and water. Remove contaminated clothing immediately.

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After eye contact:	Remove contact lenses, if possible. Continue rinsing. Rinse with clean, flowing water for at least 10 minutes while keeping eyelids open.
After ingestion:	Rinse mouth with water (only if the person is conscious). Do not induce vomiting. Consult a POISON CENTER.

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

May damage fertility or the unborn child.

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

None.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: Water, foam, alcohol resistant foam, dry extinguishing powder, ABC powder, carbon dioxide (CO<sub>2</sub>).

Unsuitable extinguishing media: Full water jet.

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

Dust deposits can accumulate on all surfaces in a working area.

Hazardous combustion products: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>).

### 5.3 Advice for firefighters

Surrounding fires: In case of fire and/or explosion do not breathe fumes. Adapt fire-fighting measures to the surrounding area. Do not pour extinguishing water into the sewage system or water bodies. Collect contaminated extinguishing water separately. Extinguish from a reasonable distance using normal precautions.

Protection against fire: Protective suits against chemicals. Wear self-contained breathing apparatus.

Hazardous combustion products: Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Move people to safety. Ventilate affected area.

#### For emergency responders

Wear respiratory equipment when exposed to vapours/dust particles/aerosols/gases.

### 6.2 Environmental precautions

Avoid the product getting into drains, surface water or groundwater. Retain and dispose of contaminated wash water.

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

Advice on how to contain the spillage: Cover drains, absorb mechanically.

Advice on how to clean up the spillage: Pick up mechanically.

Other information in connection with discharge or release: Transfer to suitable containers for disposal. Ventilate affected area.

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### 6.4 Reference to other sections

Hazardous combustion products: see section 5.

Personal protective equipment: see section 8.

Incompatible materials: see section 10.

Disposal considerations: see section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:

Specific remarks/data: Dust deposits may accumulate on all surfaces in an industrial area. The product in its delivered form is not capable of causing a dust explosion, however, the enrichment of fine dust leads to danger of a dust explosion.

Keep away from: strong oxidising agents.

Personal protection:

Not available.

Technical protective measures:

Measures to prevent fire and aerosol or dust generation: Use local and general ventilation. Take precautionary measures against static discharges. Use only in well-ventilated areas. Ground storage and collecting container.

Handling:

Advice on general occupational hygiene: Wash hands after use. Do not eat, drink or smoke in work areas.

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

Storage:

In an airtight container.

Store only in the original packaging.

Conditions for safe storage, including any incompatibilities:

Storage temperature: < 25 °C.

Ventilation requirements: Use of local and general ventilation.

Explosive atmospheres: Removal of dust deposits.

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

Occupational exposure limits:

Country	Substance name	Identification	TGG 8h (mm/m <sup>3</sup> )	Source
BE	Dust	VL/VCD	10	Moniteur Belge
BE	Dust	VL/VCD	3	Moniteur Belge

### 8.2 Exposure controls

**Appropriate engineering control**

General ventilation.

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### Individual protection measures

Eye/face protection:	Wear eye/face protection.
Skin protection:	Protective clothing for use against solid particles. Include rest periods for skin regeneration. Preventive skin protection (skin protecting creams) is recommended.
Hand protection:	Wear protective gloves. Type of material: NBR: acrylonitrile-butadiene rubber Material thickness: > 0.7 mm Breakthrough time of glove material: > 480 minutes (permeation level: 6) Wash hands thoroughly after use.
Respiratory protection:	Wear respiratory protection. Particle filter (EN 143). P3 (filters at least 99.95% of airborne particles, colour code: white).
Thermal hazards:	Not determined.

### Environmental exposure control

Take appropriate measures to prevent dispersal in the environment. Avoid discharge into drains, surface water or groundwater.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline, hygroscopic powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not applicable.
Melting/freezing point:	246.9 °C at 101.3 kPa
Initial boiling point:	Not determined.
Boiling range:	Not determined.
Flash point:	Not applicable.
Evaporation rate:	Not determined.
Flammability (solid/gas):	This material is flammable, but will not easily catch fire.
Upper/lower flammability or explosive limits:	Not determined.
Vapour pressure:	Not determined.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Soluble in ethanol (96 per cent) and in methanol, sparingly soluble in acetone, slightly soluble in methylene chloride.
Solubility in water:	Very slightly soluble in water. 272 mg/l at 298.2 K

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Partition coefficient (n-octanol/water):	1.6 (pH value: 7.4, 25 °C) (ECHA)
Auto-ignition temperature:	Not determined.
Decomposition temperature:	Not available.
Viscosity:	Not relevant (solid).
Explosive properties:	None.
Oxidising properties:	None.

### 9.2 Other information

Density: 1.105 g/cm<sup>3</sup> at 25 °C  
Surface tension: 60.7 mN/m (ECHA)

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

For incompatible products, see "Conditions to avoid" and "Incompatible materials".

### 10.2 Chemical stability

See under "Conditions to be avoided".

### 10.3 Possibility of hazardous reactions

No dangerous reactions known.

### 10.4 Conditions to avoid

There are no specific conditions known to be avoided.

Indications on how to avoid fire and explosions: The product in its delivered form is not capable of causing a dust explosion, however, the enrichment of fine dust leads to danger of a dust explosion.

### 10.5 Incompatible materials

Oxidising agents (oxidising).

### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Cannot be classified as acutely toxic. <u>Lethality values</u> Oral LD <sub>50</sub> (rat): 3.857 mg/kg Oral LD <sub>50</sub> (mouse): 1.680 mg/kg
Skin corrosion/irritation:	Cannot be classified as corrosive/irritating to skin. Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Cannot be classified as serious eye damage or irritation. Based on available data, the classification criteria are not met.
Respiratory/skin sensitisation:	Does not classify as inhalation or skin allergy. Based on available data, the classification criteria are not met.

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Germ cell mutagenicity:	Cannot be classified as germ cell mutagen. Based on available data, the classification criteria are not met.
Carcinogenicity:	Not classifiable as a carcinogen. Based on available data, the classification criteria are not met.
Reproductive toxicity:	May damage the unborn child. May damage fertility.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Cannot be classified as toxic to specific target organs (single exposure). Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Cannot be classified as toxic to specific target organs (repeated exposure). Based on available data, the classification criteria are not met.
Aspiration Hazard:	Not classifiable as hazardous by aspiration. Based on available data, the classification criteria are not met.
Other:	Not available.

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

Eye contact:	Causes serious eye irritation.
Skin contact:	Harmful in contact with skin. Causes skin irritation.
Inhalation:	Harmful if inhaled. May cause respiratory irritation.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Cannot be classified as hazardous to the aquatic environment.

#### Aquatic toxicity (acute)

LC<sub>50</sub> (ide (*Leuciscus idus*)): < 500 mg/l (96h)

EC<sub>50</sub> (bacteria): 2 000 mg/l (48h)

NOEC (algae): 160 mg/l (72h)

### 12.2 Persistence and degradability

N-octanol/water (log KOW): 1.6 (pH value: 7.4, 25 °C) (ECHA)

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Not available.

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### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Disposal information: Dispose of contents/container to any approved waste disposal facility.

Information on waste water disposal: Do not empty into drains. Avoid release into the environment. Ask for special instructions/safety data sheet.

Waste treatment of containers/packaging: Completely emptied packages can be recycled. Contaminated packaging should be treated like the substance itself.

Remarks: Please observe the relevant national or regional regulations. Waste is separated into the categories that can be treated separately by the local or national waste management authorities.

### 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 subject to transport regulations.

##### 14.2 UN proper shipping name

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

##### 14.3 Transport hazard class(es)

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

##### 14.4 Packing group

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

##### 14.5 Environmental hazards

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

##### 14.6 Special precautions for user

Not available.

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

The cargo is not intended to be transported in bulk.

##### 14.8 Additional transport information

Not subject to ADR, RID and ADN. Not subject to IMDG. Not subject to ICAO-IATA.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful  
Irritant



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Risk phrases: R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.  
R36/37/38 Irritating to eyes, respiratory system and skin.  
R63 Possible risk of harm to the unborn child.

Safety phrases: Not applicable.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

## 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.

### 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

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(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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