

# Material Safety Data Sheet

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

EN

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Revision: XX/XX/XXXX

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## PREDNISONUM

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

#### 1.1 Product identifier

Product name:	Prednisone Prednisonum Prednison Prednisone Prednison
N° CAS:	53-03-2
N° EC:	200-160-3

#### 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

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

The substance is not PBT or vPvB.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Prednisone
IUPAC name:	17 $\alpha$ , 21-Dihydroxyprega-1,4-diene-3,11,20-trione
Synonyms:	Dehydrocortisone Deltasone Meticorten
N° CAS:	53-03-2
N° EC:	200-160-3
Molecular Formula:	C <sub>21</sub> H <sub>26</sub> O <sub>5</sub>
Content:	97.0 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

After inhalation:	Remove from exposure. If not breathing give artificial respiration. If breathing is difficult give oxygen. Get medical attention in case of adverse reactions.
After skin contact:	Remove contaminated clothing and shoes. Wash with water and soap. Get medical attention in case of adverse reactions.
After eye contact:	Flush with copious amounts of water for at least 15 minutes. Get medical attention in case of adverse reactions.
After ingestion:	Flush out mouth with water provided is conscious. Get medical attention in case of adverse reactions.

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

Not available.

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### 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: Water spray, carbon dioxide, dry chemical powder or appropriate foam.

Unsuitable extinguishing media: Not known.

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

Hazardous combustion products: Emits toxic fumes when heated to decomposition or under fire conditions. Do not breathe fumes or dust.

### 5.3 Advice for firefighters

Surrounding fires: Keep containers cool with water spray.

Protection against fire: Wear boots, overall, gloves, eye and face protection and breathing apparatus in compliance with law.

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

Consult sections 8 and 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 personal protective equipment (See section 8).

Technical protective measures: Not available.

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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:

Store in accordance with all current regulations and standards.

Conditions for safe storage, including any incompatibilities:

Store at room temperature.

Keep in well- sealed labelled containers away from light.

Keep in a ventilated place.

Avoid direct sun light.

Avoid static discharges formation.

Store in accordance with all current regulations and standards.

Storage – away from:

Store protected from light.

Keep away from heat, sparks and ignition sources.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Monitoring procedures: Monitoring of substances in work environment shall be done with standard methods or with appropriate methods and in compliance with national law.

### 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: Wear eye protection.

Skin protection: Wear protective clothing.

Hand protection: Wear protective gloves.

Respiratory protection: Wear face protection.

Thermal hazards: Not determined.

#### Environmental exposure control

If exposed or concerned: Get medical advice/attention.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

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Melting/freezing point:	About 230 °C, with decomposition
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:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble in ethanol (96 per cent) and in methylene chloride.
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

The substance is an organic compound, may create in particular conditions (ex. temperature, pressure, powder granulometry, humidity, oxygen concentration) explosive mixtures with air. In case of accidental release remove all sources of ignition and ventilate the area gradually.

### 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

The substance is an organic compound, may create in particular conditions (ex. temperature, pressure, powder granulometry, humidity, oxygen concentration) explosive mixtures with air. In case of accidental release, remove all sources of ignition and ventilate the area gradually.

### 10.4 Conditions to avoid

Keep away from heat, flames, sources of ignition and static discharges.

### 10.5 Incompatible materials

Strong oxidizing agents, acids and bases.

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### 10.6 Hazardous decomposition products

When heated to decomposition or under fire conditions, material emits toxic fumes of carbon monoxide and carbon dioxide gas.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Not available.
Skin corrosion/irritation:	Causes skin burns.
Serious eye damage/irritation:	Causes serious eye irritation.
Respiratory/skin sensitisation:	Not applicable.
Germ cell mutagenicity:	Not applicable.
Carcinogenicity:	Not applicable.
Reproductive toxicity:	Not applicable.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
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

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

No chemical safety report done.

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### 12.6 Other adverse effects

None.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Dispose of in accordance with local regulations.

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

## 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 applicable.

#### 14.2 UN proper shipping name

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

#### 14.3 Transport hazard class(es)

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

#### 14.4 Packing group

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

#### 14.5 Environmental hazards

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

#### 14.6 Special precautions for user

Not applicable.

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

Not applicable.

#### 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:



Irritant  
Harmful

Risk phrases:

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

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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 (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

FAC SECUNDUM ARTEM NV

info@magis-pharma.be