

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

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PREDNISOLONI NATRII PHOSPHAS

Publication: 07/04/2022

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Version: 00



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

1.1 Product identifier

Product name:	Prednisolone sodium phosphate Prednisoloni natrii phosphas Prednisolondinatriumfosfaat Prednisolone (phosphate sodique de) Prednisolondihydrogenphosphat-Dinatrium
N° CAS:	125-02-0
N° EC:	204-722-9

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	H302
Acute Tox. 4	H332
Repr. 1A	H360
Repr. 2	H361
STOT RE 2	H373

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s):

Danger
Warning

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Hazard statements:

H302	Harmful if swallowed.
H332	Harmful if inhaled.
H360	May damage fertility or the unborn child
H361	Suspected of damaging fertility or the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fumes/gas/mist/vapours/spray.
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P281	Use personal protective equipment as required.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P304+P312	IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	If exposed: Call a POISON CENTER or doctor/physician.
P312	Call a POISON CENTER/ doctor if you feel unwell.
P314	Get medical advice/attention if you feel unwell.
P330	Rinse mouth.
P405	Store locked up.
P501	Dispose of contents/container to accordance with local/regional/national/international regulation.

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:	Prednisolone sodium phosphate
IUPAC name:	Disodium;[2-[(8S,9S,10R,11S,13S,14S,17R)-11,17-dihydroxy-10,13-dimethyl-3-oxo-7,8,9,11,12,14,15,16-octahydro-6H-cyclopenta[a]phenanthren-17-yl]-2-oxoethyl] phosphate
Synonyms:	Prednisolone 21-(disodium phosphate) Phortisolone Predsol
N° CAS:	125-02-0
N° EC:	204-722-9

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Molecular Formula: $C_{21}H_{27}Na_2O_8P$

Content: 96.0 per cent to 103.0 per cent (anhydrous 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.

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 available.

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.

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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, contact with incompatible substances, direct contact with skin and eyes and 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:

Keep in well-sealed labelled containers.

Store in accordance with all current regulations and standards.

Conditions for safe storage, including any incompatibilities:

Store at room temperature.

Keep in a ventilated place.

Avoid static discharges formation.

Storage – away from:

Store protected from light.

Keep away from heat, sparks and ignition sources.

Avoid direct sunlight.

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.

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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, hygroscopic, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	About 8.0
Melting/freezing point:	Not available.
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:	Very slightly soluble in ethanol (96 per cent).
Solubility in water:	Freely soluble 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.

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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 gradually the area.

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 gradually the area.

10.4 Conditions to avoid

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

10.5 Incompatible materials

Strong oxidising agents, acids and bases.

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:	Causes skin burns.
Inhalation:	May cause respiratory irritation. Harmful if inhaled.

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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.

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 classified.

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.

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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:

R20/22 Harmful by inhalation and if swallowed.
R48 Danger of serious damage to health by prolonged exposure.
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.

Safety phrases:

S1 Keep locked up
S20/21 When using do not eat, drink or smoke.
S23 Do not breathe dust/fumes/gas/mist/vapours/spray.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S51 Use only in well-ventilated areas.
S53 Avoid exposure – obtain special instructions before use.
S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

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

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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

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