

Material Safety Data Sheet

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

EN

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Version: 00



METHYLPREDNISOLONUM

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

1.1 Product identifier

Product name:	Methylprednisolone Methylprednisolonum Methylprednisolon Méthylprednisolone Methylprednisolon
N° CAS:	83-43-2
N° EC:	201-476-4

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

Repr. 1A	H360D
STOT RE 2	H373

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H360D May damage the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

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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.
P308+P313	If exposed: Call a POISON CENTER or doctor/physician.
P314	Get medical advice/attention if you feel unwell.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.

Additional applicable label elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Methylprednisolone
IUPAC name:	(6S,8S,9S,10R,11S,13S,14S,17R)-11,17-dihydroxy-17-(2-hydroxyacetyl)-6,10,13-trimethyl-7,8,9,11,12,14,15,16-octahydro-6H-cyclopenta[a]phenanthren-3-one
Synonyms:	Medrol Medrone
N° CAS:	83-43-2
N° EC:	201-476-4
Molecular Formula:	C ₂₂ H ₃₀ O ₅
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

General notes:	In any case seek medical advice and call the nearest poison centre.
After inhalation:	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
After skin contact:	Immediately wash skin with soap and copious amounts of water. Wash contaminated clothing before reuse.
After eye contact:	Immediately flush eyes with copious amounts of water for at least 15 minutes.
After ingestion:	Call a physician. Wash out mouth with water provided person is conscious.

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 available.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Evacuate area. Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Avoid raising dust.

For emergency responders

Evacuate area. Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Avoid raising dust.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pick up is complete.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Safety shower and eye-bath.

Personal protection: Approved respirator. Chemical safety goggles. Rubber gloves. Do not get in eyes, on skin, on clothing. Avoid inhalation. Avoid prolonged or repeated exposure. Pregnant women should avoid inhaling the product and not let it come in contact with the skin.

Technical protective measures: Use only in chemical fume hood.

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Handling: Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any incompatibilities: Keep unopened in the original container.
Store at a temperature of 2 °C to 8 °C.

Storage – away from: 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

Refer to section 7.

Individual protection measures

Eye/face protection: Chemical safety goggles.

Skin protection: Not determined.

Hand protection: Rubber gloves.

Respiratory protection: Approved respirator.

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 or almost white, crystalline powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

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.

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Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Sparingly soluble in ethanol (96 per cent) and slightly soluble in acetone 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

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 oxidising agents.

10.6 Hazardous decomposition products

CO_x.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (mouse): about 1 680 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.

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Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	May damage the unborn child.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	May cause damage to organs through prolonged or repeated exposure.
Aspiration Hazard:	Not available.
Other:	RTECS: TU4152000

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

LC50 (fish: Golden orfe): > 500 mg/l
EC50 (bacteria: activated sludge): 2 000 mg/l

12.2 Persistence and degradability

Good biodegradability > 95%.
Chemical oxygen demand (COD): 2 100 mgO₂/g
Biochemical oxygen demand (BOD): < 10 mgO₂/g

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

Do not allow to enter drains or waterways.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Incinerate in an approved facility.
Observe all federal, state and local environmental regulations.

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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 classified.
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 applicable.

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

Not applicable.

14.8 Additional transport information

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful

Risk phrases:

R48 Danger of serious damage to health by prolonged exposure.

R61 May cause harm to the unborn child.

Safety phrases:

S1 Keep locked up.

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).

S53 Avoid exposure – obtain special instructions before use.

15.2 Chemical safety assessment

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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