

Material Safety Data Sheet

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

EN

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FLUDROCORTISONI ACETAS

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

1.1 Product identifier

Product name: Fludrocortisone acetate
Fludrocortisoni acetas
Fludrocortisonacetaat
Fludrocortisone (acétate de)
Fludrocortisonacetat

N° CAS: 514-36-3

N° EC: 208-180-4

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

Repr. 2	H361d
Acute Tox. 4	H302

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H361d	Suspected of damaging the unborn child.
H302	Harmful if swallowed.

Precautionary statements:

P201	Obtain special instructions before use.
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P202	Do not handle until all safety precautions have been read and understood.
P264	Wash face, hands and exposed skin thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P308+P313	If exposed: Call a POISON CENTER or doctor/physician.
P330	Rinse mouth.

Additional applicable label elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Fludrocortisone acetate
IUPAC name:	[2-[(8S,9R,10S,11S,13S,14S,17R)-9-fluoro-11,17-dihydroxy-10,13-dimethyl-3-oxo-1,2,6,7,8,11,12,14,15,16-decahydrocyclopenta[a]phenanthren-17-yl]-2-oxoethyl] acetate
Synonyms:	Fludrocortisone 21-acetate Cortineff Florinef acetate Alflorone acetate
N° CAS:	514-36-3
N° EC:	208-180-4
Molecular Formula:	C ₂₃ H ₃₁ FO ₆
Content:	97.0 per cent to 103.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Symptoms of poisoning may occur even after several hours; therefore, medical observation for at least 48 hours after the accident is recommended.
After inhalation:	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
After skin contact:	Immediately wash with water and soap and rinse thoroughly for at least 15 minutes.
After eye contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	Rinse mouth. Do not induce vomiting. Call for a doctor immediately.

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

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Hazardous combustion products: Carbon monoxide (CO). Carbon dioxide (CO₂). Hydrogen fluoride.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

For emergency responders

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

6.2 Environmental precautions

Do not allow to enter sewers/surface or ground water. Do not release into the environment.

6.3 Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

See section 7 for information on safe handling.

See section 8 for information on personal protection equipment.

See section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid contact with eyes, skin, or clothing. Avoid ingestion and inhalation. Avoid dust formation.

Personal protection: Wear personal protective equipment/face protection.

Technical protective measures: Ensure adequate ventilation.

Handling: Not available.

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7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep container tightly closed.
Conditions for safe storage, including any incompatibilities:	Store in cool, dry and well-ventilated place.
Storage – away from:	Store away from foodstuffs. Keep away from sources of ignition and heat. Keep away from strong oxidizing agents.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

8.2 Exposure controls

Appropriate engineering control

Ensure that eyewash stations and safety showers are close to the workstation location. Keep away from foodstuffs, beverages and feed. Handle in accordance with good industrial hygiene and safety practice.

Individual protection measures

Eye/face protection:	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
Skin protection:	Wear appropriate protective gloves and clothing to prevent skin exposure.
Hand protection:	Protective gloves. The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Respiratory protection:	In case of brief exposure or low pollution, use respiratory filter device. In case of intensive or longer exposure, use respiratory protective device that is independent of circulating air.
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.

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Melting/freezing point:	233 – 234 °5
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not applicable.
Evaporation rate:	Not applicable.
Flammability (solid/gas):	Not applicable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Sparingly soluble in anhydrous ethanol.
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:	Product does not present an explosion hazard.
Oxidising properties:	Not available.

9.2 Other information

Molecular weight: 422.39 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None known, based on information available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization does not occur.
No dangerous reactions known.

10.4 Conditions to avoid

Incompatible materials. Heat.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

Carbon monoxide (CO), carbon dioxide (CO₂), hydrogen fluoride.
Formation of toxic gases is possible during heating or in case of fire.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): > 1 000 mg/kg Intraperitoneal LD50 (mouse): 240 mg/kg
Skin corrosion/irritation:	No irritant effect.
Serious eye damage/irritation:	No irritant effect.
Respiratory/skin sensitisation:	No sensitising effects known.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	IARC/NTP/OSCHA-Ca: Substance is not listed.
Reproductive toxicity:	Contains ingredients that are suspected reproductive hazards. Suspected of damaging the unborn child.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	The toxicological properties have not been fully investigated.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Do not empty into drains.

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

Not applicable.

12.6 Other adverse effects

Not available.

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Contaminated packaging: Recommendation: Disposal must be made according to official regulations.

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.

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.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.
R63 Possible risk of harm to the unborn child.

Safety phrases:

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S53 Avoid exposure – obtain special precautions before use.

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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

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