

Material Safety Data Sheet

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

EN

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HYDROCORTISONI ACETAS

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

1.1 Product identifier

Product name:	Hydrocortisone acetate Hydrocortisoni acetas Hydrocortison acetaat Hydrocortisone (acétate d') Hydrocortisonacetat
N° CAS:	50-03-3
N° EC:	200-004-4

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. 2	H361d
Repr. 2	H361f
STOT RE 2	H373

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

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H361d	Suspected of damaging the unborn child.
H361f	Suspected of damaging fertility.
H373	May cause damage to organs through prolonged or repeated exposure.
Precautionary statements:	
P201	Obtain special instructions before use.
P281	Use personal protective equipment as required.
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:	Hydrocortisone acetate
IUPAC name:	[2-[(8S,9S,10R,11S,13S,14S,17R)-11,17-dihydroxy-10,13-dimethyl-3-oxo-2,6,7,8,9,11,12,14,15,16-decahydro-1H-cyclopenta[a]phenanthren-17-yl]-2-oxoethyl] acetate
Synonyms:	Cortisol 21-acetate Cortell
N° CAS:	50-03-3
N° EC:	200-004-4
Molecular Formula:	C ₂₃ H ₃₂ O ₆
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:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	

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After eye contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists. Remove contact lenses and rinse immediately with plenty of water, including under eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

It is suspected of damaging the foetus, impairing fertility and causing organ damage.

4.3 Indication of any immediate medical attention and special treatment needed

In case of known or suspected exposure: Get medical advice/attention. Do not administer anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water mist. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health may be produced.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water that must not enter the sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Equip the cleaning personnel with appropriate means of protection. Ventilate the area. Evacuate unnecessary personnel.

For emergency responders

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Ventilate the area. Evacuate unnecessary personnel.

6.2 Environmental precautions

Do not allow to enter sewers and water pipes. If product enters drains or public waterways, notify authorities.

6.3 Methods and material for containment and cleaning up

Store away from other materials. If on the ground, sweep or scoop (shovel or similar) into suitable containers. Limit dust production.

6.4 Reference to other sections

See sections 8, 11, 12 and 13 for more information.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Ask for special instructions before use. Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking and leaving work. Avoid breathing dust, fumes, gas, mist, fumes, vapours or spray.
Personal protection:	Not available.
Technical protective measures:	Ensure good ventilation of the processing area to avoid vapour formation.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep only in the original container.
Conditions for safe storage, including any incompatibilities:	Keep in a cool, well-ventilated place. Keep container closed when not in use.
Storage – away from:	Store away from strong acids and bases, sources of ignition and direct sunlight.

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

Since the use of appropriate technical measures must always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

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Skin protection:	Choose body protection according to the quantity and concentration of the hazardous substance in the workplace. Hygiene measures: Handle with appropriate industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after work.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.
Respiratory protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).
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:	Characteristic.
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.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble in anhydrous ethanol 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.

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Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Density (20 °C): 0.248 g/ml

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable if used properly.

No special conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

None in particular.

10.4 Conditions to avoid

Direct sunlight. Extremely high or extremely low temperatures.

10.5 Incompatible materials

Strong acids and bases.

10.6 Hazardous decomposition products

Hazardous decomposition of the product under fire conditions: fumes of carbon oxides (CO and/or CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral LD50 (rat): 5 000 mg/kg

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Suspected of damaging the foetus and impairing fertility.

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 classified as hazardous by aspiration.

Other: N° RTECS: GM8925000

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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

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

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

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.

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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

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful

Risk phrases:

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

Safety phrases:

S1 Keep locked up.

S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

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

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

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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

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