

Material Safety Data Sheet

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

EN

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HYDROCORTISONUM

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

1.1 Product identifier

Product name: Hydrocortisone
Hydrocortisonum
Hydrocortisone
Hydrocortisone
Hydrocortison
N° CAS: 50-23-7
N° EC: 200-020-1

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

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

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Hydrocortisone
IUPAC name:	(8S,9S,10R,11S,13S,14S,17R)-11,17-dihydroxy-17-(2-hydroxyacetyl)-10,13-dimethyl-2,6,7,8,9,11,12,14,15,16-decahydro-1H-cyclopenta[a]phenanthren-3-one
Synonyms:	Cortisol Hytone
N° CAS:	50-23-7
N° EC:	200-020-1
Molecular Formula:	C ₂₁ H ₃₀ O ₅
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

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 that the patient is conscious. Get medical attention in case of adverse reactions.

4.2 Most important symptoms and effects, both acute and delayed

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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

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

Protective equipment: Wear approved safety goggles (eye protection), approved clothing (skin protection) and approved full face respirator P3 (respiratory protection).

For emergency responders

Protective equipment: Wear approved safety goggles (eye protection), approved clothing (skin protection) and approved full face respirator P3 (respiratory protection).

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.

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Personal protection:	Wear appropriate PPE (See section 8).
Technical protective measures:	Avoid powder dispersion.
Handling:	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 at room temperature. Store in accordance with all current regulations and standards.
Conditions for safe storage, including any incompatibilities:	Keep in a ventilated place. Avoid static discharges formation. Keep in well-sealed labelled container.
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/face 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:	About 7.0
Melting/freezing point:	220 °C

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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:	1.35×10^{-13} mm Hg at 25 °C (est)
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Sparingly soluble in acetone and in ethanol (96%), slightly soluble in methylene chloride.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	LogP 1.61
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 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 oxidizing agents, acids and bases.

10.6 Hazardous decomposition products

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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 available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
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 burns.
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

Not available.

12.6 Other adverse effects

Not available.

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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.

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:

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
R36/37/38 Irritating to eyes, respiratory system and skin.
R63 Possible risk of harm to the unborn child.

Safety phrases:

S9 Keep container in a well-ventilated place.
S15 Keep away from heat.

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15.2 Chemical safety assessment

Not available.

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