

Material Safety Data Sheet

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

EN

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MINOCYCLINI HYDROCHLORIDUM DIHYDRICUM

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

1.1 Product identifier

Product name:	Minocycline hydrochloride dihydrate Minocyclini hydrochloridum dihydricum Minocyclinehydrochloride dihydraat Minocycline (chlorhydrate de) dihydraté Minocyclinhydrochlorid Dihydrat
N° CAS:	128420-71-3
N° EC:	686-512-0

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

Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT SE 3	H335
Repr. 2	H361
Lact.	H362

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



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Signal word(s): Attention

Hazard statements:

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H361 Suspected of damaging fertility or the unborn child.
H362 May cause harm to breast-fed children.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P501 Dispose of contents/container to an authorized destination in accordance with the applicable regulations.

Additional applicable label elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Minocycline hydrochloride dihydrate
IUPAC name: (4*S*,4*aS*,5*aR*,12*aR*)-4,7-bis(dimethylamino)-1,10,11,12*a*-tetrahydroxy-3,12-dioxo-4*a*,5,5*a*,6-tetrahydro-4*H*-tetracene-2-carboxamide; dihydrate; hydrochloride
Synonyms: 7-dimethylamino-6-demethyl-6-deoxytetracycline hydrochloride
N° CAS: 128420-71-3
N° EC: 686-512-0
Molecular Formula: C₂₃H₂₈ClN₃O₇, 2 H₂O
Content: 94.5 per cent to 102.0 per cent (anhydrous substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

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After inhalation:	Remove to fresh air.
After skin contact:	Remove contaminated clothing and shoes. Rinse thoroughly with plenty of water for at least 15 minutes. Seek medical advice.
After eye contact:	Rinse thoroughly with plenty of water, for at least 15 minutes. Assure adequate wash by keeping eyelids apart with fingers. Get medical attention if adverse reaction occurs.
After ingestion:	Flush out mouth with water, provided person is conscious. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

See section 11.

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, dry powder, carbon dioxide or foam, as appropriate for surrounding fire and materials.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Under fire conditions, emits toxic fumes.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Fire fighters should wear self-contained breathing apparatus and full protective clothing.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear respiratory mask with dust filter, rubber boots and heavy rubber gloves.

For emergency responders

Wear respiratory mask with dust filter, rubber boots and heavy rubber gloves.

6.2 Environmental precautions

Place spillage in appropriate container for waste disposal.
Avoid contamination of sewage systems, waterways and soils.

6.3 Methods and material for containment and cleaning up

Sweep up or vacuum spillage and place in appropriate container for waste disposal. Avoid raising

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dust. Ventilate and wash spillage site.

6.4 Reference to other sections

Refer to section 1 for emergency contact information.

Refer to section 8 for information on appropriate personal protective equipment.

Refer to section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Open and handle containers carefully, in a well ventilated room, avoiding dust formation.
Personal protection:	Do not breathe dust. Avoid contact with eyes, skin and clothing. Avoid long or repeated exposure to the material.
Technical protective measures:	Mechanical bulk handling equipment should be grounded in order to avoid static electricity build-up.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Keep in tightly closed and light resistant containers, in a dry place.
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

For Minocycline Hydrochloride, Hovione established 0.07 mg/m³ as an internal Occupational Exposure Limit (OEL) for 8 working hours.

Other OEL are not known.

8.2 Exposure controls

Appropriate engineering control

Provide adequate mechanical ventilation.

Assure the proximity of safety showers and eye-wash stations.

Hygiene measures: After handling the material, follow the good hygiene practices, especially before eating, drinking, smoking or going to the toilet. Wash contaminated clothing before reuse.

Individual protection measures

Eye/face protection:	Wear safety goggles and/or face protection in accordance with EN166. Eye protection equipment should be tested and approved according to regulations applicable, like NIOSH (US) or EN 166 (EU).
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Skin protection:	Wear chemical protective clothing with anti-static properties. The selection of the type of material should be in accordance with the potential concentration of the product.
Hand protection:	Wear chemical protective gloves that are in accordance with EN 374.
Respiratory protection:	In cases when the risk assessment shows the need to use respiratory protection it must be evaluated the type of respirator to use. If engineering controls are effective use a particle filter N100 (US) or P3 (EU). If the respiratory protection is the only mean of preventing exposure use a positive pressure hood tested and approved by NIOSH (US) or CEN (EU).
Thermal hazards:	Not determined.
Environmental exposure control	
Refer to section 6.	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Yellow, hygroscopic, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	3.5 to 4.5 (1% w/v sol. in water).
Melting/freezing point:	228 °C
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 ethanol (96 per cent). It dissolves in solutions of alkali hydroxides and carbonates.
Solubility in water:	Sparingly soluble 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: 0.55.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Direct sunlight and UV radiation. Carbonises at 223 °C.

10.5 Incompatible materials

Strong oxidisers.

10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide, nitrogen oxides, chloride gas.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: LD₅₀ oral: 2 380 mg/kg (rat)
LD₅₀ intraperitoneal: 331 mg/kg (rat)
LD₅₀ intravenous: 164 mg/kg (mouse)
LD₅₀ oral: 3 600 mg/kg (mouse)
LD₅₀ intraperitoneal: 299 mg/kg (mouse)
LD₅₀ intravenous: 154 mg/kg (mouse)

Skin corrosion/irritation: It may cause skin swelling in some persons.
This substance may accentuate any pre-existing dermatitis condition.
Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.
Open cuts, abraded or irritated skin should not be exposed to this material.
Entry into the blood-stream through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

Serious eye damage/irritation: It may cause ocular irritation and damages in some persons.

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Respiratory/skin sensitisation:	<p>The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.</p> <p>Inhalation of dust generated by material during the course of normal handling may be damaging to the health of the individual.</p> <p>Persons with impaired respiratory function, airway disease and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.</p> <p>Repeated or long exposure may cause allergic reactions in sensitive persons.</p>
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Possible risk of congenital malformation in the foetus. Possible risk of lactation effects: detected maximal concentrations of 0.8 mg/l in milk after administration of a dose of 200 mg.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	May cause respiratory irritation.
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 irritation.
Inhalation:	May cause respiratory irritation.
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

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Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product disposal: Dispose of contents/container to an authorized destination in accordance with the applicable regulations.

Package disposal: Dispose of as unused material.

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 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

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Risk phrases:	R36/37/38 Irritating to eyes, respiratory system and skin. R62 Possible risk of impaired fertility. R63 Possible risk of harm to the unborn child. R64 May cause harm to breastfed babies.
Safety phrases:	S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S28 After contact with skin, wash immediately with plenty of soap and water. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

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

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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