Material Safety Data Sheet

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

TETRACYCLINI HYDROCHLORIDUM

Publication: 19/04/2022
Revision: XX/XX/XXXX
Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Tetracycline hydrochloride Tetracyclini hydrochloridum Tetracycline hydrochloride Tétracycline (chlorhydrate de) Tetracyclinhydrochlorid
N° CAS:	64-75-5
N° EC:	200-593-8

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

This product does not meet the classification and labelling criteria given in the Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	

2.3 Other hazards

Not available.

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TETRACYCLINI HYDROCHLORIDUM

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Tetracycline hydrochloride
IUPAC name:	(4S,4aS,5aS,6S,12aR)-4-(dimethylamino)-1,6,10,11,12a-pentahydroxy-6-methyl-3,12-dioxo-4,4a,5,5a-tetrahydrotetracene-2-carboxamide;hydrochloride
Synonyms:	Achromycin hydrochloride Supramycin Sustamycin Sumycin Telotrex
N° CAS:	64-75-5
N° EC:	200-593-8
Molecular Formula:	$C_{22}H_{25}ClN_2O_8$
Content:	95.0 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 case of persisting adverse effects, consult a physician.
After inhalation:	Remove affected person from the immediate area. Ensure supply of fresh air.
After skin contact:	In case of contact with skin wash off immediately with copious amounts of water.
After eye contact:	In case of contact with eyes rinse thoroughly with water.
After ingestion:	Rinse out mouth and give plenty of water to drink. Induce vomiting if patient is conscious, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Nausea; gastrointestinal complaints.

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:	Carbon dioxide; extinguishing powder; alcohol-resistant foam; water spray.
Unsuitable extinguishing media:	Full water jet.

5.2 Special hazards arising from the substance/mixture

Combustion products of this material have to be classed invariably as respiratory poison. In the event of fire, the following can be released: Carbon dioxide (CO_2); carbon monoxide (CO).

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Fire-fighting operations, rescue and clearing work under effect of combustion and smoulder gases just may be done with breathing apparatus.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Avoid dust formation. Keep away sources of ignition.

For emergency responders

No data available. Personal protective equipment (PPE) - see section 8.

6.2 Environmental precautions

Do not allow to enter drains or waterways.

6.3 Methods and material for containment and cleaning up

Take up mechanically. Send in suitable containers for recovery or disposal.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	No special measures necessary if stored and handled as prescribed. Avoid the formation and deposition of dust. Provide good ventilation of working area (local exhaust ventilation, if necessary).
Personal protection:	Not available.
Technical protective measures:	Advice on protection against fire and explosion: Dust can form an explosive mixture with air. Take precautionary measures against static charges. Keep away from sources of heat and ignition.
Handling:	General protective and hygiene measures: Do not eat, drink or smoke during work time. Clean skin thoroughly after work; apply skin cream. Avoid contact with eyes and skin. Provide eye wash fountain in work area. Do not inhale dust.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed in a cool, well-ventilated place, open and handle carefully. Keep only in the original container. Do not store together with foodstuffs. If the substance is sterile, store in a sterile, tamper-evident container.

Storage – away from:	Store protected from light. Protect from heat and direct sunlight. Do not store together with foodstuffs.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No parameters available for monitoring.

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection:	Safety glasses (EN 166).
Skin protection:	Normal chemical work clothing.
Hand protection:	In case of intensive contact, wear protective gloves (EN 374). Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Appropriate material:	Nitrile
Material thickness:	> 0.3 mm
Breakthrough time:	> 480 min.
Appropriate material:	Rubber
Material thickness:	> 0.5 mm
Breakthrough time:	> 240 min.

Respiratory protection:	Short term: filter apparatus, filter A/P2; In case of dust formation, use a fine dust face mask.
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:	Yellow, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.

pH:	Value:	2.1 – 2.3
	Reference temperature:	20 °C
	Concentration:	2 g/l
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:	Soluble in ethanol (96 per cent), practically insoluble in acetone. Solutions in water become turbid on standing, owing to the precipitation of tetracycline.	
Solubility in water:	Soluble in water. 50 – 100 g/l (22 °C)	
Partition coefficient (n-octanol/water):	Not available.	
Auto-ignition temperature:	Not available.	
Decomposition temperature:	Value:	214 °C
	Remarks:	No decomposition below 210 °C
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

Reactions with strong oxidising agents.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD_{50} (rat) 6 443 mg/kg (source: RTECS)
Skin corrosion/irritation:	Evaluation: Slightly irritant.
Serious eye damage/irritation:	Evaluation: Slightly irritant.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Evaluation: No experimental information on genotoxicity in vivo available.
Carcinogenicity:	Evaluation: No indications of carcinogenic effects are available from long-term trials.
Reproductive toxicity:	Remarks: Indications of toxic effects are available from reproduction studies in animals.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Allergic reactions possible (analogy-reasons). Irritates the mucous membrane.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Irritates the eyes.
Skin contact:	Irritates the the skin.
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

Do not discharge product unmonitored into the environment. Ecological data are not available..

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging: Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

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 relevant.

14.8 Additional transport information

The product is not subject to ADR/RID/ADN, IMDG and ICAO-TI/IATA regulations.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:	Not applicable.
Risk phrases:	Not applicable.
Safety phrases:	Not applicable.

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 Bioaccumalative

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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