# Material Safety Data Sheet

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

## ACIDUM CHENODEOXYCHOLICUM



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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: | Chenodeoxycholic acid<br>Acidum chenodeoxycholicum<br>Chenodeoxycholzuur<br>Chénodésoxycholique (acide)<br>Chenodesoxycholsäure |
| N° CAS: | 474-25-9 |
| N° EC: | 207-481-8 |

### 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: | Magis-Pharma NV<br>Neerlandweg 24<br>2610 Wilrijk<br>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**

Reproductive toxicity (category 2) H361d

### 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.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P308 + P313 IF exposed or concerned: Get medical advice/attention.

| | |
|---|---|
| Additional applicable label elements: | Not applicable. |

### 2.3 Other hazards

The substance is solid: consider - and if needed control - the formation of dusts during the use. A chemical safety report is not required for this substance, therefore PBT and vPvB assessments were not performed. No other hazards are identified.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

| | |
|---|---|
| Product name: | Chenodeoxycholic acid |
| IUPAC name: | (4*R*)-4-[(3*R*,5*S*,7*R*,8*R*,9*S*,10*S*,13*R*,14*S*,17*R*)-3,7-dihydroxy-10,13-dimethyl-2,3,4,5,6,7,8,9,11,12,14,15,16,17-tetradecahydro-1*H*-cyclopenta[a]phenanthren-17-yl]pentanoic acid |
| Synonyms: | Not applicable. |
| N° CAS: | 474-25-9 |
| N° EC: | 207-481-8 |
| Molecular Formula: | $C_{24}H_{40}O_4$ |
| Content: | 99.0 % to 101.0 % (dried substance) |

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

| | |
|---|---|
| General notes: | In case of doubt or in the presence of symptoms contact a physician, and show him/her the material safety data sheet. In case of severe symptoms, call your local health care emergency number. Call a poison control centre in order to receive toxicological advice for the clinical management of poisoning. Do not administer anything by mouth to an unconscious person. |
| After inhalation: | Move the person to fresh air. In the case of respiratory symptoms (cough, dyspnea) place the person in a semi-seated position and administer oxygen. Provide artificial respiration if the person is not breathing. |
| After skin contact: | Flush the skin with copious amounts of water (and soap, if possible) for at least 15 minutes. Consult a physician if there are symptoms of skin irritation and/or pain. |
| After eye contact: | Remove contact lenses, if present and easy to do. Flush the eyes, kept open, with copious amounts of running water for at least 15 minutes. Consult a physician, especially if there are symptoms of eye irritation and/or pain. |
| After ingestion: | Do not induce emesis. Do not administer anything by mouth unless advised to do so by a poison control centre. Rinse the mouth and consult a physician. |

| | |
|---|---|
| Self-protection of the first aider: | Wear appropriate protective equipment to prevent the contamination of the first aid responder from the victim. |

### 4.2 Most important symptoms and effects, both acute and delayed

Most important symptoms and effects, both acute and delayed, are described in section 11.

### 4.3 Indication of any immediate medical attention and special treatment needed

Need for immediate medical attention: If the victim has severe symptoms, immediately call your local health care emergency number to request the intervention of a physician. Refer to each case a poison control centre for advice and medical toxicology specialist from the early stages of the rescue. Consult a physician if in any case any symptoms, even mild, persists.

Special treatment needed and antidotes to be available on the workplace: Freshwater for washing skin and eye. Oxygen. Activated charcoal, to be administered after toxicological advice.

Removal and handling of contaminated clothing and shoes: In case of gross contamination, remove clothing and shoes. Place them into a suitable, closed, temporary storage away from the working area.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

| | |
|---|---|
| Suitable extinguishing media: | As the substance is a solid material, the most suitable extinguishing media are water and dry chemicals (powders); foam and carbon dioxide are less effective. In the choice of extinguishing media, consider the other materials involved in the fire. |
| Unsuitable extinguishing media: | Not available. |

### 5.2 Special hazards arising from the substance/mixture

Exposure hazards arising from the substance itself, combustion products, resulting gases: In the case of fire, irritant or toxic fumes may develop from the substance and from the other materials involved in the fire.

Hazardous combustion products: Carbon oxides (COx).

### 5.3 Advice for firefighters

| | |
|---|---|
| Surrounding fires: | Not available. |
| Protection against fire: | Hardhat with visor, fireproof clothing (fireproof jacket and trousers with straps around arms, legs and waist), work gloves (fireproof, cut proof and dielectric), a depressurized mask with facemask covering the whole of the operator`s face or a self-respirator (self-protector) in the event of large quantities of fume. |
| Hazardous combustion products: | Not available. |

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel**

(a) Eliminate sources of ignition (cigarettes, flames, sparks, etc.) from the area in which the leak occurred;

(b) send away individuals who are not suitably equipped.

**For emergency responders**

(a) Do not handle damaged containers or leaked product before donning appropriate protective gear (Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing;
(b) if there are no contraindications, spray powder with water to prevent the formation of dust and provide sufficient ventilation.

### 6.2 Environmental precautions

The product must not penetrate the sewer system, surface water, ground water and neighbouring areas.

### 6.3 Methods and material for containment and cleaning up

**Appropriate advice shall be provided on how to contain a spill**

(a) make sure the leakage site is well aired.

**Appropriate advice shall be provided on how to clean-up a spill**

(a) use mechanical tools to collect the leaked product and place in a plastic container;
(b) if there are no contraindications, use jets of water to eliminate product residues.

**Any other information shall be provided relating to spills and releases, including advice on inappropriate containment or clean-up techniques**

Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

### 6.4 Reference to other sections

For any other information on risks for the environment (Section 12) and health (Section 11), on personal protection (Section 8) and disposal (Section 13), see the other sections of this sheet.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

| | |
|---|---|
| Precautions for safe handling: | Not available. |
| Personal protection: | Not available. |
| Technical protective measures: | Not available. |
| Handling: | Not available. |

### 7.2 Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| Storage: | Double antistatic polythene bag (inner packaging); plastic (outer packaging). |
| Conditions for safe storage, including any incompatibilities: | The warehouse should be closed, clean and within a suitable range of temperature (approximately, 15÷30°C). The presence of thermal, electrical or mechanical sources of ignition should be avoided (for instance, flames, hot surfaces, sparks, etc.). Packaging materials different from those indicated in §7.2.2 should be deemed incompatible. |
| Storage – away from: | Store away from incompatible materials (Section 10). The substance should be stored at room temperature avoiding direct exposure to sunlight or other source of heating and in a manner to prevent cross-contamination, keeping material in clean, properly labelled, tight containers. Packaging should be stored off the floor and suitably spaced to permit cleaning and inspection. |

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Occupational Exposure limit values

| CHENODIOL | Limit value – Eight hours | | Limit value – Short term* | | |
|---|---|---|---|---|---|
| Country | ppm | mg/m$^3$ | ppm | mg/m$^3$ | Legal basis |
| - | - | - | - | - | - |
| European Union | - | - | - | - | - |

| | | | | | |
|---|---|---|---|---|---|
| ACGIH | - | - | - | - | - |
| - | - | - | - | - | - |

*Short term is 15 minutes unless otherwise specified.

The substance has not a national occupational exposure limit value that corresponds to a Community OEL or a relevant national limit and an Indicative Occupational Exposure Limit Value (IOELV) has not been proposed by the European Commission not yet been transposed into individual Member States national law. The reported limit value is obtained applying a calculation model that includes the following three levels approaches:

| | Value: | |
|---|---|---|
| • Level I - calculation based on Therapeutic Dose approach | 75 µg/m3 | |
| • Level II - calculation based on "banding approach" | 10 µg/m3 ÷ 100 µg/m3 | (*), (**) |
| • Level III - calculation based on NOAEL or LOAEL approach | No data | |

(*) Recommended control strategies:

1. Employ good industrial hygiene practice OK
2. Use local exhaust ventilation OK
3. Enclose the process /
4. Seek the advice of a specialist /

(**) Context and limitations of the specific control banding recommendation.

The above recommended control strategies help to prevent the exposure of workers by inhalation and/or indirect ingestion (e.g. by food) to an active pharmaceutical ingredient which is biologically active if enter the human body. Local exhaust ventilation with enclosures is needed to safely contain any powder accidentally released in the working places when handling this substance.

Biological limit value

| CHENODIOL | When to take the sample | BEI | Notation |
|---|---|---|---|
| Country | - | - | |
| - | - | - | - |

| | | | |
|---|---|---|---|
| European Union | - | - | - |

**DNEL**

| CHENODIOL | **Workers** | | | |
|---|---|---|---|---|
| Route of exposure | Acute effect local | Acute effects systemic | Chronic effects local | Chronic effects systemic |
| Oral | Not required | | | |
| Inhalation | - | - | - | - |
| Dermal | - | - | - | - |

**PNEC**

| CHENODIOL | |
|---|---|
| Environmental protection target | PNEC |
| Fresh water | - |
| Freshwater sediments | - |
| Marine water | - |
| Marine sediments | - |
| Food chain | - |
| Microorganisms in sewage treatment | - |
| Soil (agricultural) | - |
| Air | - |

Information on monitoring procedures

The main recommended monitoring methods (personal air monitoring, room air monitoring) are:

• EN 481 Workplace atmospheres. Size fraction definitions for measurement of airborne particles.

• EN 482 Workplace exposure. General requirements for the performance of procedures for the measurement of chemical agents.

• EN 689 Workplace atmospheres. Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy.

• EN 1232 Workplace atmospheres. Pumps for personal sampling of chemical agents. Requirements and test methods.

• EN 1540 Workplace exposure. Terminology.

## 8.2 Exposure controls

**Appropriate engineering control**

Substance related measures to prevent exposure during identified uses: Refer to subsection 7.1.1.

Structural measures to prevent exposure: Areas where CHENODIOL is manufactured and used must be provided with equipment and tools for the safe handling, storage and transport of this substance and waste containing such chemical.

Organisational measures to prevent exposure:

Reducing to a minimum the number of workers exposed or likely to be exposed to CHENODIOL.

Reducing to a minimum the duration and intensity of exposure to CHENODIOL.

Reducing the quantity of CHENODIOL present at the workplace to the minimum required for the type of work concerned.

Written instruction for the safe handling, storage and transport of CHENODIOL.

Appropriate hygiene measures (refer to subsection 7.1.2).

Technical measures to prevent exposure: Use local exhaust ventilation with enclosures.

**Individual protection measures**

| | |
|---|---|
| Eye/face protection: | Full face mask (EN136). |
| Skin protection: | Professional disposable overall with hood for use with chemicals (EN ISO 13982; EN 1149-1). |
| Hand protection: | Natural rubber gloves (EN420; EN388; EN374). |
| Respiratory protection: | Full face mask + P3 filter (EN136 + EN14387). |
| Thermal hazards: | Not determined. |

**Environmental exposure control**

Substance/mixture related measures to prevent exposure: Refer to subsection 7.1.1.

Instruction measures to prevent exposure: The content of this safety data sheet should be clarified to personnel handling this substance at all stages of its life cycle. Written operative instructions should be available for the proper use of the substance taking into account physical and chemical properties, toxicological and ecological information, features of the working area and the actual use of this substance.

Organisational measures to prevent exposure: Written instruction for the safe handling, storage and transport of waste containing CHENODIOL.

Technical measures to prevent exposure:

Refer to subsection 7.1.1.

Refer to subsection 13.1.3.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

| | |
|---|---|
| Appearance: | White or almost white powder. |
| Odour: | Not available. |
| Odour threshold: | Not available. |
| pH: | 4.5 (100 mg of chenodiol in 10 ml of water) |
| Melting/freezing point: | 165 - 167°C |
| Initial boiling point: | 508.23°C |
| Boiling range: | 508.23°C |
| Flash point: | Not available. |

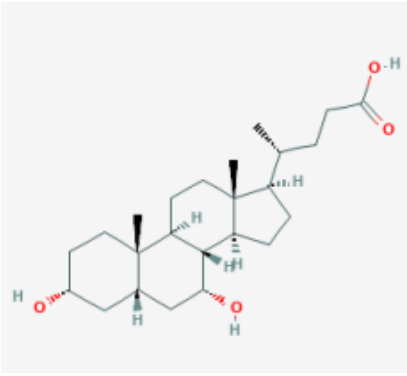
| | |
|---|---|
| Evaporation rate: | Not available. |
| Flammability (solid/gas): | Not available. |
| Upper/lower flammability or explosive limits: | Not available. |
| Vapour pressure: | $3.00x10^{-13}$ mmHg at 25°C / $3.85x10^{-12}$ mmHg at 25°C |
| Vapour density: | Not available. |
| Relative density: | 1.1±0.1 g/cm$^3$ |
| Solubility: | Very slightly soluble in water, freely soluble in ethanol (96%), soluble in acetone, slightly soluble in methylene chloride. It shows polymorphism. |
| Solubility in water: | Very slightly soluble in water. |
| Partition coefficient (n-octanol/water): | 4.15 |
| Auto-ignition temperature: | Not available. |
| Decomposition temperature: | Not available. |
| Viscosity: | Not available. |
| Explosive properties: | Not available. |
| Oxidising properties: | Not available. |

**9.2 Other information**

Molecular weight: 392.58

Molecular formula: $C_{24}H_{40}O_4$

Structural formula:



pK: pKa = 3.91

Optical Rotatory Power: +11 - +13°

| Value | Solvent | Concentration | Temperature | Wavelength |
|---|---|---|---|---|
| + 13.23° | ethanol | | 21°C | 589.3 nm |
| + 12.5° | chloroform | | 17°C | 589.3 nm |
| + 11.5° | 1,4-dioxane | | 20°C | 589.3 nm |
| + 11.22° | | | 20°C | 589.3 nm |

| | | | | |
|---|---|---|---|---|
| + 11.1° | | | 23°C | 589.3 nm |
| + 10.94° | | | 20°C | 589.3 nm |
| + 10° | 1,4-dioxane | 0.14 g/100mL | 21°C | 589.3 nm |

Polymorphism: Different crystalline polymorphic forms have been observed.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

### 10.2 Chemical stability

The substance is stable in normal condition of use.

There is evidence that the substance does not show significant degradation under alkaline, acidic or oxidising conditions but and is adversely impacted by the exposure to heating at 130°C.

### 10.3 Possibility of hazardous reactions

There are no particular hazardous reaction in normal conditions of use.

### 10.4 Conditions to avoid

As a precautionary measure, avoid dust generation and keep away from source of ignition like heat sources or electrostatic discharges.

Avoid heating the substance at high temperatures (130°C).

### 10.5 Incompatible materials

CHENODIOL is incompatible with inorganic oxidizing and reducing agents.

### 10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

In the event of fire, vapours potentially dangerous to health may be released.

Possible combustion products: carbon oxides (COx).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

| | |
|---|---|
| Acute toxicity: | Not available. |
| 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: | 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: | Not available. |
| Skin contact: | Not available. |
| Inhalation: | Not available. |
| Ingestion: | Not available. |
| Aspiration: | Not available. |

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

CDCA is an endogenous substance and is found extensively in nature and is degraded and/or metabolised in environmental compartments without any Persistence, Bioaccumulation and Toxicity (PBT) risks.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Partition coefficient n-octanol /water (log Kow) : Since log Know is greater than 4 (4.15), CHENODIOL has a potential for bioconcentration in aquatic organisms.

### 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 / Packaging disposal**

Disposal by incineration (CHENODIOL).

Reuse, when possible, the packaging for other purposes.

Product residues should be considered special hazardous waste. Disposal must be performed through an authorized waste management firm, in compliance with national and local regulations. Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

<u>Waste codes / waste designations according to LoW</u>

These codes should be used when CHENODIOL is the only substance present in the waste.

070513* Solid wastes containing hazardous substances.

160508* Discarded organic chemicals consisting of or containing hazardous substances.

**Waste treatment-relevant information**

The hazard level of waste containing this product should be evaluated according to applicable regulations.

**Sewage disposal-relevant information**

Waste should not be disposed of by release to sewers.

**Other disposal recommendations**

To ensure that risks are adequately controlled at the waste stage, disposal must be in accordance with current applicable laws and regulations and material characteristics at the time of disposal. Final decisions on the appropriate waste management method, in line with regional, national and European legislation, and possible adaptation to local conditions, remains the responsibility of the waste treatment operator.

## 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: | 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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