

Material Safety Data Sheet

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

CHOLECALCIFEROLUM

EN

FORM-06-14-01 (V00)

Page 1/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



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

1.1 Product identifier

Product name: Cholecalciferol
Cholecalciferolum
Cholecalciferol
Cholécalciférol
Cholecalciferol

N° CAS: 67-97-0

N° EC: 200-673-2

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
Neerlandweg 24
2610 Wilrijk
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. 1	H300
Acute Tox. 3	H311
Acute Tox. 2	H330
STOT RE 1	H372
Aquatic chronic 4	H413

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



CHOLECALCIFEROLUM

Hazard pictogram(s):



Signal word(s):

DANGER

GEVAAR

Hazard statements:

H300

Fatal if swallowed.

H311

Toxic in contact with skin.

H330

Fatal if inhaled.

H373

Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H413

May cause long lasting harmful effects to aquatic life.

Precautionary statements:

P260

Do not breathe dust/fume/gas/mist/vapours/spray.

P264

Wash hands thoroughly after handling.

P280

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

P301+P310

IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

P304+P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P310

Immediately call a POISON CENTER/doctor/...

Additional applicable label elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:

Cholecalciferol

IUPAC name:

(1S,3Z)-3-{2-[(1R,3aS,4E,7aR)-7a-methyl-1-[(2R)-6-methylheptan-2-yl]-octahydro-1H-inden-4-ylidene]ethylidene}-4-methylidenecyclohexan-1-ol

Synonyms:

CALCIOL

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 3/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



CHOLECALCIFEROLUM

VITAMIN D3

N° CAS: 67-97-0

N° EC: 200-673-2

Molecular Formula: $C_{27}H_{44}O$

Content: 97.0 per cent to 102.0 per cent.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Notify doctor. Show the doctor the security file of this service.

After inhalation: Go outside (open air) If breathing is irregular, call a doctor immediately. Only apply artificial respiration if respiration is stopped or under medical supervision.

After skin contact: Wash immediately with soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.

After eye contact: Remove contact lenses and rinse immediately with plenty of water, clean under the eyelids, for at least minus 15 minutes. Get medical attention if needed.

After ingestion: If the person is conscious, give the person enough 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

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

First aiders need to protect themselves. Show this safety data sheet to the doctor in attendance.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist.

Unsuitable extinguishing media: Waterjet stream.

5.2 Special hazards arising from the substance/mixture

In case of fire, avoid breathing combustion products.

5.3 Advice for firefighters

Surrounding fires: Cool the containers with water to avoid decomposition of the product and the development of many dangerous potentials. Always

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 4/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



CHOLECALCIFEROLUM

Protection against fire:

wear full fire protection. Collect the water(should not enter the sewer).

Hazardous combustion products:

Wear personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas.

Hazardous combustion gases or vapours possible in the event of fire. Carbon oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear personal protective equipment. Ensure adequate ventilation. Consult an expert and observe emergency procedures.

For emergency responders

Evacuate personnel to safe zones.

6.2 Environmental precautions

Prevent further leaks or spills if it can be done without risk. Do not let the product enter the sewerage.

6.3 Methods and material for containment and cleaning up

Clean and shovel. Store in appropriate containers and closed for disposal. Cover drains. Avoid generation of dusts.

6.4 Reference to other sections

For more information about self-protection read section 8.

For dust elimination read section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precaution for safe handling:

Normal provisions of preventive fire protection. Avoid the accumulation of electrostatic charges.

Personal protection:

Avoid exposition.

Technical protective measures:

Keep the container tightly closed in a cool (2 – 8 °C) and dry place.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Store under an inert atmosphere and protect from light and moisture.

Conditions for safe storage, including any incompatibilities:

Not available.

Storage – away from:

Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

Material Safety Data Sheet

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

CHOLECALCIFEROLUM

EN

FORM-06-14-01 (V00)

Page 5/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace through effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE mark attesting to compliance with the applicable regulations. Arrange an emergency shower with a visco-elastic tray.

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Safety glasses and mask according to the regulation EN166.

Skin protection: Choose body protection according to the quantity and concentration of the hazardous substance in the workplace. Hygiene measures: Handling.

Hand protection: Gloves should be according the regulation EU 89/686/CEE and EN374.

Respiratory protection: Where risk assessment shows air purifying respirators to be appropriate, use type N95 (USA) or type P1(EN 143) dust mask. Use respirators and components tested and approved under appropriate government standards such as NIOSH (USA) or CEN (EU).

Thermal hazards: Use the correct precautions of industrial hygiene, respect the security laws. Wash your hands before breaks and after finishing working.

Environmental exposure control

Limit values (TLV)

	TWA (8h)	STEL(15m)
TLV-ACHIG	0.005mg/m ³	Intern limit of the fabricant

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Crystal dust.

Odour: Odourless.

Odour threshold: Not available.

pH: 16.5

Melting/freezing point: 83 – 86 °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.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 6/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



CHOLECALCIFEROLUM

Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	0.274 g/mL
Solubility:	Freely soluble in ethanol (96%)
Solubility in water:	Practically insoluble.
Partition coefficient (n-octanol/water):	Log P(o/w) = 10,24 (bio-accumulation potential)
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

VOC(2010/75/CE Directive): 0

VOC(volatile coal): 0

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Without special conditions. Read section 7.

10.2 Chemical stability

Stable under recommended handling and storage conditions. Read section 7.

10.3 Possibility of hazardous reactions

Acid anhydrides, acids, acid halides

10.4 Conditions to avoid

Avoid any type of incorrect manipulation, pressures or high temperatures.

10.5 Incompatible materials

Strong acids and bases, strong oxidizing agents and oxygen.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	0.23 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Can cause light irritation.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 7/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



CHOLECALCIFEROLUM

Carcinogenicity:	This product is or contains a component probably carcinogenic in humans. IARC, Group 2A: Probably carcinogenic to humans
Reproductive toxicity:	May induce fetal malformations when toxic are given to the mother.
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

EC50 (fishes): > 100 mg/L/96 hours (zebra fish)
Crustacean toxicity (EC50): > 100 mg/L/48 hours (Daphnia magna)

12.2 Persistence and degradability

No easily biodegradable.
OECD TG 301 C: $\leq 7.0\%$ (28 days)

12.3 Bioaccumulative potential

Partition coefficient (n-octanol/water): (20°C): LogPow > 6.2 \Rightarrow bio-accumulative potential.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

May cause long-term negative effects in the aquatic environment.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Consider the federal state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a fuel solvent and burn it in a chemical incinerator equipped with an afterburner and a scrubber. Contaminated packaging Dispose of as unused product.

Material Safety Data Sheet

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

CHOLECALCIFEROLUM

EN

FORM-06-14-01 (V00)

Page 8/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 2811
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), ADR / RID: TOXIC SOLID, ORGANIC, N.O.S. (COLECALCIFEROL)
IATA/ICAO (Air) : IMDG: TOXIC SOLID, ORGANIC, N.O.S. (CHOLECALCIFEROL)
IATA: TOXIC SOLID, ORGANIC, N.O.S. (CHOLECALCIFEROL)

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 6.1
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), II
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), It is not dangerous for the environment.
IATA/ICAO (Air) :

14.6 Special precautions for user

ADR / RID: HIN – Kemler: 90
Limit quantity: 0.5 Kg Restriction condition: (E)
Special conditions: -----
MDG: EMS: F-A, S-F Limit quantity 0.5 Kg
IATA: Cargo: Maximum quantity: 100 Kg Packing instructions: 676
Pass: Maximum quantity: 25 Kg Packing instructions: 669
Particular instructions: A3, A5

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:

DANGER

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 9/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



CHOLECALCIFEROLUM

GEVAAR

Safety phrases: R01 Explosive when dry.

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

Material Safety Data Sheet

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

CHOLECALCIFEROLUM

EN

FORM-06-14-01 (V00)

Page 10/10

Publication: 12/03/2022

Revision: 24/07/2024

Version: 01



(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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department
FAC SECUNDUM ARTEM NV
info@magis-pharma.be