

**Vitamin D2**

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Date of publication: 01/06/2007

Date of revision: 03/05/2024

Revision: 4

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name: Vitamin D2  
Chemical name: Ergocalciferol  
Index number: 603-179-00-9  
REACH registration number: The substance is not subject to registration according to REACH.

Other names or synonyms: Calciferol

**1.2 Relevant identified uses of the substance or mixture and uses advised against****1.2.1 Relevant identified uses**

Pharmaceutical production.

**1.2.2 Uses advised against**

They are not known.

**1.3 Details of the supplier of the safety data sheet**

Synthesia, a.s.  
Semtín 103  
530 02 Pardubice  
Czech Republic

Telephone: + 420 466 821 111  
Fax: + 420 466 821 020  
E-mail: [synthesia@synthesia.eu](mailto:synthesia@synthesia.eu)

E-mail address of competent person: [sds@synthesia.cz](mailto:sds@synthesia.cz)

**1.4 Emergency telephone number****Manufacturer:**

Telephone: +420 466 824 402  
Fax: +420 466 824 448

**Poison Center:**

Toxikologické informační středisko, Na Bojišti 1, 120 00 Praha 2, Czech Republic  
Telephone: +420 224 919 293, +420 224 915 402

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**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008:**

Acute Tox.2, H330  
Acute Tox.3, H311  
Acute Tox.3, H301  
STOT RE 1, H372

Full text of H-statements: see section 16.

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**The most important adverse physical, human health and environmental effects:**

Toxic if inhaled, in contact with skin and if swallowed. May cause damage to organs through prolonged or repeated exposure.

### 2.2 Label elements



**Signal word:**

Danger

**Hazard statements:**

Fatal if inhaled. (H330)

Toxic in contact with skin. (H311)

Toxic if swallowed. (H301)

Causes damage to organs through prolonged or repeated exposure. (H372)

**Precautionary statements:**

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

IF ON SKIN: Wash with plenty of water and soap. (P302+P352)

IF exposed or concerned: Call a POISON CENTER/doctor. (P308+P311)

### 2.3 Other hazards

Information is not available.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical name			
Index number CAS number EC number REACH registration number	Content [wt. %]	Classification according to Regulation (EC) No 1272/2008	Specific concentration limit, multiplying factor, acute toxicity estimate
Ergocalciferol			
603-179-00-9 50-14-6 200-014-9 *	100	Acute Tox.2, H330 Acute Tox.3, H311 Acute Tox.3, H301 STOT RE 1, H372	

\*The product is not subject to registration.

The full text of H-phrases, hazard class and hazard category code is given in section 16.

### 3.2 Mixtures

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## SECTION 4: First aid measures

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**4.1 Description of first aid measures**

In all cases keep the victim at physical and mental rest and warm. Always get medical advice.  
First aider needs to protect himself.

**4.1.1 Following inhalation**

Breake the exposure, transfer the victim to the fresh air, apply artificial respiration, if the victim is not breathing.

**4.1.2 Following skin contact**

Take off immediately contaminated clothing. Flush affected area with plenty of water (preferably lukewarm). Seek medical advice.

**4.1.3 Following eye contact**

Rinse with plenty of water for at least 15 minutes. Move to the physician, while continue rinsing.

**4.1.4 Following ingestion**

Rinse mouth with clean water, administer activated charcoal (ca 5 crushed tablets in 0,1 - 0,2 L of water), induce vomiting. Administer activated charcoal (10 - 20 tablets) repeatedly. Immediately call in physician. Induce vomiting only, if victim is still conscious.

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

Induces at first the increase of appetite and later headache, stomach-ache, diarrhoea, vomiting and other complications.

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

Information is not available.

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**SECTION 5: Firefighting measures****5.1 Extinguishing media****5.1.1 Suitable extinguishing media**

Water spray, dry chemicals, CO<sub>2</sub>, foam.

**5.1.2 Unsuitable extinguishing media**

They are not known.

**5.2 Special hazards arising from the substance or mixture**

Hazardous combustion products: carbon oxides.

**5.3 Advice for firefighters**

In the event of fire, wear self-contained breathing apparatus (EN 137) and clothing protective against chemicals.

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures****6.1.1 For non-emergency personnel**

Do not breathe dust.  
Ensure adequate ventilation.

**6.1.2 For emergency responders**

Use personal protective equipment (see section 8).  
Avoid generation of dust.

**6.2 Environmental precautions**

Avoid entering of product into a water stream or sewers.

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

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Sweep up and place in a labeled closed container.  
Dissolved product is possible to regenerate.

**6.4 Reference to other sections**

Using of personal protective equipment - see section 8. Disposal - see section 13.

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

Avoid breathing of dust.  
Avoid contact with eyes and skin.  
Use personal protective equipment (see section 8).

Advice on general occupational hygiene:  
Do not eat, drink or smoke during the work and observe the personal hygiene principles.  
Wash thoroughly with water and soap after work.

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

Store in tightly closed containers under nitrogen, at temperature 2 to 8 °C, protected from light.  
Store locked up.

**7.3 Specific end use(s)**

Accessible only for authorised persons.

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**SECTION 8: Exposure controls/personal protection****8.1 Control parameters**

**Occupational exposure limit values:**  
not determined

**8.2 Exposure controls****8.2.1 Appropriate engineering controls**

Ensure adequate ventilation/exhaustion of the workplace.  
Avoid generation of dust.

**8.2.2 Individual protection measures, such as personal protective equipment**

Protective clothing should be selected specifically for the workplace, depending on concentration and quantity of the hazardous substances handled.

All used personal protective equipment must be in accordance with Regulation (EU) 2016/425.

Respiratory protection:	dust filter mask
Hand protection:	rubber gloves
Eye/face protection:	protective chemical goggles or face shield

Body protection:	protective clothing, apron, boots, cap
Thermal hazards:	not applicable

**8.2.3 Environmental exposure controls**

Avoid uncontrolled release of the substance/mixture to the environment.

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**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Physical state: solid

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Colour:	white
Odour:	odourless
Melting point/freezing point:	115 - 119 °C
Boiling point:	not available
Flammability:	combustible material
Lower explosion limit:	not applicable
Upper explosion limit:	not applicable
Flash point:	not available
Auto-ignition temperature:	not applicable
Decomposition temperature:	not applicable
pH:	not available
Kinematic viscosity:	not applicable
Solubility:	well soluble in ethanol, methanol, chloroform, ether, acetone, toluene and benzene
Solubility in water:	insoluble
Partition coefficient n-octanol/water:	not available
Vapour pressure:	not applicable
Density or relative density:	not available
Relative vapour density:	not applicable
Particle characteristics:	not available

**9.2 Other information**

Information is not available.

**SECTION 10: Stability and reactivity****10.1 Reactivity**

Stable under recommended storage and handling conditions (see section 7).

**10.2 Chemical stability**

Keep under nitrogen at temperature 2 - 8 °C.

Product is stabilized.

Solutions in organic solvents are not stable.

**10.3 Possibility of hazardous reactions**

No dangerous reactions known.

**10.4 Conditions to avoid**

Air, light and heat.

**10.5 Incompatible materials**

Strong oxidizing agents, strong acids, strong bases.

**10.6 Hazardous decomposition products**

Hazardous decomposition products are not known.

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity:**

LD <sub>50</sub> , oral, rat (mg/kg):	56
LD <sub>50</sub> , dermal, rat or rabbit (mg/kg):	No data available.
LC <sub>50</sub> , inhalation, rat (aerosol or particle) (mg/m <sup>3</sup> ):	No data available.

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**Skin corrosion/irritation:**

No data available.

**Serious eye damage/irritation:**

No data available.

**Respiratory or skin sensitisation:**

No data available.

**Germ cell mutagenicity:**

No data available.

**Carcinogenicity:**

No data available.

**Reproductive toxicity:**

No data available.

**STOT-single exposure:**

No data available.

**STOT-repeated exposure:**

Inhalation - causes damage to organs through prolonged or repeated exposure.

**Aspiration hazard:**

No data available.

**Symptoms related to the physical, chemical and toxicological characteristics****Following ingestion:**

Toxic. It affects Ca-level in human body. Its deficiency causes rachitis. The excess induces at first the increase of appetite and later the lack of appetite, headache, stomach-ache, diarrhoea, vomiting and other complications. Serious health damage hazard through prolonged exposure.

**Following eye contact:**

May cause irritation.

**Following skin contact:**

Toxic if absorbed through skin.

**Following inhalation:**

Very toxic.

**11.2 Information on other hazards****11.2.1 Endocrine disrupting properties**

Information is not available.

**11.2.2 Other information**

Information is not available.

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**SECTION 12: Ecological information****12.1 Toxicity****12.1.1 Acute (short-term) aquatic toxicity**LC<sub>50</sub>, 96 h, fish (mg/l): No data available.EC<sub>50</sub>, 48 h, crustacea (mg/l): No data available.

No data available.

**Vitamin D2**EC<sub>50</sub>, 72 h, algae (mg/l):**12.1.2 Chronic (long-term) aquatic toxicity**

No data available.

**12.1.3 Toxicity for other organisms**

No data available.

**12.2 Persistence and degradability**

No data available.

**12.3 Bioaccumulative potential**

No data available.

**12.4 Mobility in soil**

No data available.

**12.5 Results of PBT and vPvB assessment**

No data available.

**12.6 Endocrine disrupting properties**

Information is not available.

**12.7 Other adverse effects**

Information is not available.

**SECTION 13: Disposal considerations****13.1 Waste treatment methods****13.1.1 Product disposal**

Dissolved product is possible to regenerate.

**13.1.2 Packaging disposal**

Incinerate in incinerating plant for danger waste in accordance with local environmental regulations.

**SECTION 14: Transport information****Land transport ADR/RID:**

Class/Classification code/Packing group:	6.1 / T2 / II
UN number:	2811
Proper shipping name:	TOXIC SOLID, ORGANIC, N.O.S.

(Ergocalciferol)

Environmental hazards:	no
Hazard label:	6.1

**Sea transport IMDG Code:**

Class/Packing group:	6.1 / II
UN number:	2811
Proper shipping name:	TOXIC SOLID, ORGANIC, N.O.S. (Ergocalciferol)
Marine pollutant:	no
Additional information:	EmS: F-A, S-A
Hazard label:	6.1

**Air transport ICAO-TI /IATA-DGR:**

Class/Packing group:	6.1 / II
UN number:	2811

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Proper shipping name:

TOXIC SOLID, ORGANIC, N.O.S. (Ergocalciferol)

Hazard label:

Toxic

**Additional information:**

Based on stability data no need to refrigerated transport.

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Regulation (EC) No. 1272/2008

Regulation (EC) No. 1907/2006

Water hazard class (Germany): WGK 2 - hazard to waters.

Directive 2012/18/EU (Seveso III Directive): yes

**15.2 Chemical safety assessment**

No chemical safety assessment has been carried out.

**SECTION 16: Other information****Indication of changes:**

Section 14 - additional information.

**List of abbreviations:**

CAS - Chemical Abstracts Service

EC number - EINECS (European Inventory of Existing Commercial Chemical Substance), ELINCS (European List of Notified Chemical Substances) or NLP (No-Longer-Polymers)

LD50 - lethal dose, 50%

LC50 - lethal concentration, 50%

EC50 - effective concentration, 50%

IC50 - inhibitory concentration, 50%

PBT - persistent, bioaccumulative and toxic

vPvB - very persistent and very bioaccumulative

BCF - bioconcentration factor

COD - chemical oxygen demand

BOD - biochemical oxygen demand

DNEL - derived no-effect level

PNEC - predicted no-effect concentration

NOAEL - no observed adverse effect level

NOAEC - no observed adverse effect concentration

NOEC - no observed effect concentration

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road

RID - Regulations concerning the International Carriage of Dangerous Goods by Rail

IMDG - International Maritime Dangerous Goods

ICAO - International Civil Aviation Organisation

IATA - International Air Transport Association

**Key literature references and sources for data:**

Legislation, chemical databases and tables, tests.

**Relevant information for classification of the product:**

List of harmonised classification and labelling of hazardous substances.

**Relevant hazard statements:**

Acute Tox.2, H330 Acute toxicity (inhalation), Category 2

Acute Tox.3, H311 Acute toxicity (dermal), Category 3



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Acute Tox.3, H301 Acute toxicity (oral), Category 3  
STOT RE 1, H372 Specific target organ toxicity - Repeated exposure, Category 1  
H330 Fatal if inhaled.  
H311 Toxic in contact with skin.  
H301 Toxic if swallowed.  
H372 Causes damage to organs through prolonged or repeated exposure.

**Training advice:**

Obtain special instructions before use.  
Training can be provided only by a competent expert!  
Instructions in writing regarding the substance handling must be available at workplace and have to be approved by the authority responsible for public healthcare protection.

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*The above information corresponds to the current level of our knowledge and experience. The data merely describe the product with respect to safety and cannot be construed as guaranteed parameters. The user is responsible for handling in compliance with the existing laws and regulations.*