

# Cholecalciferol concentrate (oily form)

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date:

Version: 1.0

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Chemical type : Mixture

Name : Cholecalciferol concentrate (oily form)

Product code : 454249

Synonyms : Vitamin D3 concentrate

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical

Function or use category : Raw material

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

Duchefa FARMA BV  
A. Hofmanweg 71  
2031BH Haarlem - Netherlands  
T +31(0)23-5319093 - F +31(0)23-5318027  
[info@duchefa.com](mailto:info@duchefa.com) - [www.duchefa.com](http://www.duchefa.com)

### 1.4. Emergency telephone number

Country	Official advisory body	Address	Emergency number
UNITED KINGDOM	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	0870 243 2241

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute Tox. 4 (Oral) H302  
Acute Tox. 4 (Dermal) H312  
Acute Tox. 3 (Inhalation:dust,mist) H331  
STOT RE 2 H373

Full text of H-phrases: see section 16.

#### Classification according to Directive 67/548/EEC or 1999/45/EC

T; R23  
Xn; R21/22  
Xn; R48/22

Full text of R-phrases: see section 16.

### Adverse physicochemical, human health and environmental effects

No additional information available

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### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS06

GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302 - Harmful if swallowed  
H312 - Harmful in contact with skin  
H331 - Toxic if inhaled  
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (CLP)

: P260 - Do not breathe mist, vapours.  
P280 - Wear eye protection, face protection, protective clothing, protective gloves.  
P304+P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing  
P311 - Call a POISON CENTER or doctor/physician

### 2.3. Other hazards

This substance/mixture does not meet the PBT/vPvB criteria of REACH, annex XIII.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Arachis oil, refined	(CAS No.) 8002-03-7 (EC no) 232-296-4	95	Not classified
Cholecalciferol	(CAS No.) 67-97-0 (EC no) 200-673-2 (EC index no) 603-180-00-4	5	T+; R26 T; R24/25-48/25

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Arachis oil, refined	(CAS No.) 8002-03-7 (EC no) 232-296-4	95	Not classified
Cholecalciferol	(CAS No.) 67-97-0 (EC no) 200-673-2 (EC index no) 603-180-00-4	5	Acute Tox. 2 (Inhalation), H330 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 STOT RE 1, H372

Full text of R-, H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation : Remove victim to fresh air. If not breathing, give artificial respiration. Seek medical attention immediately.

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|---------------------------------------|--|
| First-aid measures after skin contact | : Wash skin with mild soap and water. Seek medical attention if ill effect or irritation develops. |
| First-aid measures after eye contact  | : Rinse immediately with plenty of water. Seek medical advice.                                     |
| First-aid measures after ingestion    | : Rinse mouth. Drink plenty of water. Seek medical attention immediately.                          |

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

- |                   |   |
|-------------------|---|
| Symptoms/injuries | : Nausea. Vomiting. Diarrhea. Headache. Nervous system disorder. Gastrointestinal complaints. |
| Chronic symptoms  | : Hypercalcemia.  |

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- |                                |                                     |
|--------------------------------|-------------------------------------|
| Suitable extinguishing media   | : Dry powder. Foam. Carbon dioxide. |
| Unsuitable extinguishing media | : Water.                            |

### 5.2. Special hazards arising from the substance or mixture

- |                  |  |
|------------------|--|
| Fire hazard      | : This product is flammable. On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide. |
| Explosion hazard | : Product is not explosive.  |

### 5.3. Advice for firefighters

- |                                |   |
|--------------------------------|---|
| Firefighting instructions      | : Avoid (reject) fire-fighting water to enter environment.                                      |
| Protection during firefighting | : Do not enter fire area without proper protective equipment, including respiratory protection. |

## SECTION 6: Accidental release measures

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

- |                  |  |
|------------------|--|
| General measures | : Ensure adequate ventilation. Evacuate unnecessary personnel. |
|------------------|--|

#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

- |                      |  |
|----------------------|--|
| Protective equipment | : Wear proper protective equipment. Wear respiratory protection. |
|----------------------|--|

### 6.2. Environmental precautions

Prevent product from entering drains.

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

- |                         |   |
|-------------------------|---|
| Methods for cleaning up | : Take up liquid spill into inert absorbent material. |
|-------------------------|---|

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- |                               |  |
|-------------------------------|--|
| Precautions for safe handling | : Handle in accordance with good industrial hygiene and safety procedures. |
|-------------------------------|--|

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

- |                        |  |
|------------------------|--|
| Storage conditions     | : Store in dry, well-ventilated area. Keep container tightly closed. Protect from moisture. Protect from sunlight. |
| Maximum storage period | : 2 year   |

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### 7.3. Specific end use(s) No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Cholecalciferol (67-97-0)		
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	0,01 mg/m <sup>3</sup> 8 h

### 8.2. Exposure controls

Hand protection	: Wear suitable gloves resistant to chemical penetration.
Eye protection	: Safety glasses.
Skin and body protection	: Wear suitable protective clothing.
Respiratory protection	: Mist formation: aerosol mask with filter type P3.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Colour	: Yellow.
Odour	: Odourless.
Odour threshold	: No data available
pH	: No data available
Melting point	: No data available
Solidification point	: ca. 2 °C
Boiling point	: > 350 °C
Flash point	: > 300 °C
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosive limits	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 0,92 g/cm <sup>3</sup>
Solubility	: Insoluble in water. Ethanol: < 1 g/100ml anhydrous ethanol
Log Pow	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available

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Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

May decompose on contact with moist air or water. May decompose under the influence of light.

### 10.3. Possibility of hazardous reactions

None under normal conditions.

### 10.4. Conditions to avoid

heat. Moisture. Light (daylight).

### 10.5. Incompatible materials

Strong oxidizers. acids.

### 10.6. Hazardous decomposition products

No additional information available

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed. Harmful in contact with skin. Toxic if inhaled.

#### Cholecalciferol (67-97-0)

LD50 oral rat	35 - 47 mg/kg
LD50 dermal rat	61 - 185 mg/kg
LC50 inhalation rat (mg/l)	0,13 - 0,38 mg/l/4h
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified

Specific target organ toxicity (repeated exposure) : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

#### Cholecalciferol (67-97-0)

LC50 fishes 1	> 100 mg/l rerio, 96 h
EC50 Daphnia 1	> 100 mg/l 48 h
NOEC (acute)	> 10000 mg/l Leuciscus idus, 96 h

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### 12.2. Persistence and degradability

#### Cholecalciferol concentrate (oily form)

Persistence and degradability : Biodegradable.

#### Arachis oil, refined (8002-03-7)

Persistence and degradability : Biodegradable.

#### Cholecalciferol (67-97-0)

Persistence and degradability : Not readily biodegradable.

### 12.3. Bioaccumulative potential

#### Cholecalciferol (67-97-0)

Log Pow : 10,24

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

#### Cholecalciferol concentrate (oily form)

This substance/mixture does not meet the PBT/vPvB criteria of REACH, annex XIII.

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

Waste disposal recommendations : Dispose of this material and its container at hazardous or special waste collection point.

## SECTION 14: Transport information

In accordance with ADR / RID / ADN / IMDG / ICAO / IATA

### 14.1. UN number

UN-No. : 2810

### 14.2. UN proper shipping name

Proper Shipping Name : TOXIC LIQUID, ORGANIC, N.O.S.

Transport document description : UN 2810 TOXIC LIQUID, ORGANIC, N.O.S. (Contains cholecalciferol), 6.1, III, (E)

### 14.3. Transport hazard class(es)

Class (UN) : 6.1

Hazard labels (UN) : 6.1



### 14.4. Packing group

Packing group (UN) : III

### 14.5. Environmental hazards

Other information : No supplementary information available.

### 14.6. Special precautions for user

#### 14.6.1. Overland transport

Hazard identification number (Kemler No.) : 60

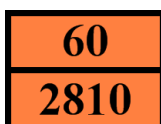
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Classification code : T1

Orange plates :



Tunnel restriction code : E

Limited quantities (ADR) : LQ07

Excepted quantities (ADR) : E1

EAC code : 2X

### 14.6.2. Transport by sea

No additional information available

### 14.6.3. Air transport

No additional information available

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

Contains no REACH candidate substance

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Full text of R-, H- and EUH-phrases:

	Acute Tox. 2 (Inhalation)	Acute toxicity (inhalation) Category 2
	Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
	Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
	Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
	Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
	Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
	STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
	STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
	H301	Toxic if swallowed
	H302	Harmful if swallowed
	H311	Toxic in contact with skin
	H312	Harmful in contact with skin
	H330	Fatal if inhaled
	H331	Toxic if inhaled
	H372	Causes damage to organs through prolonged or repeated exposure
	H373	May cause damage to organs through prolonged or repeated exposure
	R21/22	Harmful in contact with skin and if swallowed.
	R23	Toxic by inhalation.
	R24/25	Toxic in contact with skin and if swallowed.
	R26	Very toxic by inhalation.
	R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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	R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed.
	T	Toxic
	T+	Very toxic
	Xn	Harmful

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*