

# Cholecalciferol concentrate (oily form)

## Safety Data Sheet

900900 / 454249

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 2.0

Date of issue: 17/04/2019 Revision date 21/11/2019

Supersedes 17/04/2019

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

### 1.1. Product identifier

Product form : Mixture  
 Product name : Cholecalciferol concentrate (oily form)  
 Product code : 900900 / 454249  
 Synonyms : Solution of cholecalciferol in vegetable fatty oil  
 Product group : Raw material

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

#### 1.2.1. Relevant identified uses

Main use category : Professional use  
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

#### 1.2.2. Uses advised against

No additional information available

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

#### Supplier

Duchefa Farma BV  
 A. Hofmanweg 71  
 2031BH Haarlem - Nederland  
 T +31(0)23-5319093  
[farma@duchefa.nl](mailto:farma@duchefa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
 +31(0)23-5319093 (M-F 09:00-17:00)  
 +31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] Mixtures/Substances: SDS EU 2015:  
 According to Regulation (EU) 2015/830 (REACH Annex I)

Acute toxicity (inhalation:dust,mist) Category 4 H332  
 Specific target organ toxicity — Repeated exposure, Category 2 H373

Full text of H statements : see section 16

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Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display/Extra classification(s) to display

Hazard pictograms (CLP)	:		
		GHS07	GHS08
Signal word (CLP)	:	Warning	
Hazardous ingredients	:	Cholecalciferol	
Hazard statements (CLP)	:	H332 - Harmful if inhaled. H373 - May cause damage to organs through prolonged or repeated exposure.	
Precautionary statements (CLP)	:	P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312 - Call a POISON CENTER/doctor if you feel unwell.	

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : 1 - 2 million International Units cholecalciferol

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Vegetable fatty oils		96 - 98	Not classified
Cholecalciferol	(CAS-No.) 67-97-0 (EC-No.) 200-673-2 (EC Index-No.) 603-180-00-4	2 - 4	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 2 (Inhalation), H330 Acute Tox. 2 (Inhalation:dust,mist) , H330 STOT RE 1, H372

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Full text of H-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: If medical advice is needed, have product container or label at hand.
First-aid measures after inhalation	: Allow affected person to breathe fresh air.
First-aid measures after skin contact	: Gently wash with plenty of soap and water. If irritation persists, consult a doctor.
First-aid measures after eye contact	: Ensure adequate flushing of eyes by separating eyelids with the fingers.
First-aid measures after ingestion	: Rinse mouth out with water If you feel unwell, seek medical advice.

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

No additional information available

#### 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 chemical powder, alcohol-resistant foam, carbon dioxide (CO <sub>2</sub> ).
Unsuitable extinguishing media	: Water.

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

Hazardous decomposition products in case of fire	: On burning: release of harmful/irritant gases/vapours e.g.: carbon monoxide - carbon dioxide.
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#### 5.3. Advice for firefighters

No additional information available

### SECTION 6: Accidental release measures

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

General measures	: Evacuate unnecessary personnel.
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##### 6.1.1. For non-emergency personnel

Protective equipment	: Use the personal protective equipment as indicated in chapter 8.
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##### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

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

For containment : Dam up the liquid spill.  
Methods for cleaning up : Clean contaminated surfaces with an excess of water.

### 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 practice.

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

Storage conditions : Protect from light  
airtight and well-filled container  
unused part is to be protected by an atmosphere of nitrogen.  
Storage temperature : 2 - 8 °C  
Storage area : Store in a well-ventilated place.  
Packaging materials : Aluminium. glass.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

#### Personal protective equipment:

Gloves. Protective goggles. Dust production: dust mask with filter type P2.

#### Hand protection:

Chemical resistant PVC gloves (to European standard EN 374 or equivalent)

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

#### Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

#### Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

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### Respiratory protection:

Dustmask with filtertype P2



## SECTION 9: Physical and chemical properties

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

Physical state	: Liquid
Appearance	: Viscous.
Colour	: Colourless to slightly yellow.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: 260 °C
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Insoluble in water Miscible with ether and chloroform.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 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

Stable at normal conditions. zie rubriek 7.

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### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

High temperature

Water, humidity.

### 10.5. Incompatible materials

Oxygen

Strong oxidizers

Acid chlorides.

### 10.6. Hazardous decomposition products

Carbon monoxide.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Harmful if inhaled.

ATE CLP (dust,mist)	1.25 mg/l/4h
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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

STOT-single exposure : Not classified

STOT-repeated exposure : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

Cholecalciferol concentrate (oily form)	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

Cholecalciferol concentrate (oily form)	
Bioaccumulative potential	No bioaccumulation data available.

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### 12.4. Mobility in soil

Cholecalciferol concentrate (oily form)	
Ecology - soil	There are no available data for a classification.

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

No additional information available



## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

## SECTION 14: Transport information

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

ADR	IATA
<b>14.1. UN number</b>	
2810	2810
<b>14.2. UN proper shipping name</b>	
TOXIC LIQUID, ORGANIC, N.O.S.	Toxic liquid, organic, n.o.s.
<b>14.3. Transport hazard class(es)</b>	
6.1	6.1
	
<b>14.4. Packing group</b>	
III	III
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

### 14.6. Special precautions for user

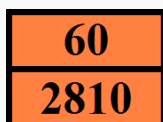
#### . Overland transport

Classification code (ADR) : T1  
 Special provisions (ADR) : 274, 614  
 Limited quantities (ADR) : 5I  
 Excepted quantities (ADR) : E1  
 Packing instructions (ADR) : P001, IBC03, LP01, R001  
 Mixed packing provisions (ADR) : MP19  
 Portable tank and bulk container instructions (ADR) : T7  
 Portable tank and bulk container special provisions (ADR) : TP1, TP28

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Tank code (ADR) : L4BH  
 Tank special provisions (ADR) : TU15, TE19  
 Vehicle for tank carriage : AT  
 Transport category (ADR) : 2  
 Special provisions for carriage - Packages (ADR) : V12  
 Special provisions for carriage - Loading, unloading and handling (ADR) : CV13, CV28  
 Special provisions for carriage - Operation (ADR) : S9  
 Hazard identification number (Kemler No.) : 60  
 Orange plates :



Tunnel restriction code (ADR) : E  
 EAC code : 2X  
 APP code : B

### - Air transport

PCA Excepted quantities (IATA) : E1  
 PCA Limited quantities (IATA) : Y642  
 PCA limited quantity max net quantity (IATA) : 2L  
 PCA packing instructions (IATA) : 655  
 PCA max net quantity (IATA) : 60L  
 CAO packing instructions (IATA) : 663  
 CAO max net quantity (IATA) : 220L  
 Special provisions (IATA) : A3, A4, A137  
 ERG code (IATA) : 6L

### 14.7. Transport in bulk according to Annex II of Marpol 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 substances with Annex XVII restrictions  
 Contains no substance on the REACH candidate list  
 Contains no REACH Annex XIV substances

#### 15.1.2. National regulations

No additional information available



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**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: Other information**

Indication of changes:

1		Modified	Change of logo
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Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
vPvB	Very Persistent and Very Bioaccumulative
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
LC50	Median lethal concentration
LD50	Median lethal dose

Data sources : Supplier. EDQM.

Full text of H- and EUH-statements:

Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) 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.
H311	Toxic in contact with skin.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.

SDS EU (REACH Annex II) duchefa nieuwe logo

*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.*