

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 - 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 II)

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 (CO₂).
- Unsuitable extinguishing media : Water.

5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition : On burning: release of harmful/irritant gases/vapours e.g.: carbon monoxide - carbon dioxide.

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.

6.1.1. For non-emergency personnel

- Protective equipment : Use the personal protective equipment as indicated in chapter 8.

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 |
|---------------------|--------------|

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

14.6. Special precautions for user

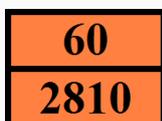
. Overland transport

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 |
|---|----------|----------------|

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.