

Vitamin D3 Crystalline

5009278

Version 5.1

Revision Date 10.05.2017

Date of last issue: 27.06.2014

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

1.1 Product identifier

Trade name : Vitamin D3 Crystalline

Substance name : colecalciferol
CAS-No. : 67-97-0

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

Use of the Sub-stance/Mixture : Ingredient for pharmaceutical products, For the fortification of foods

1.3 Details of the supplier of the safety data sheet

Company : DSM Nutritional Products Europe Ltd
PO Box 2676
CH-4002 Basel

Telephone : +41618157777
Telefax : +41618157770
E-mail address of person responsible for the SDS : sds.nutritionalproducts@dsm.com

1.4 Emergency telephone number

+41 848 00 11 77 (Carechem 24 International)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 2	H300: Fatal if swallowed.
Acute toxicity, Category 2	H330: Fatal if inhaled.
Acute toxicity, Category 3	H311: Toxic in contact with skin.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Chronic aquatic toxicity, Category 4	H413: May cause long lasting harmful effects to aquatic life.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :  

Signal word : Danger

Hazard statements : H300 + H330 Fatal if swallowed or if inhaled
H311 Toxic in contact with skin.
H372 Causes damage to organs through prolonged or repeated exposure.
H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements : **Prevention:**
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

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P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing.
Response:
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/doctor. Rinse mouth.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
Storage:
P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

2.3 Other hazards

Risk of dust explosion.

SECTION 3: Composition/information on ingredients

Synonyms : 9,10-Secocholesta-5,7,10(19)-trien-3-ol, (3 beta,5Z,7E)-
Brief description of the product : Substance
Molecular formula : C₂₇ H₄₄ O

3.1 Substances

Hazardous components

Chemical name	CAS-No. EC-No.	Concentration (% w/w)
cholecalciferol	67-97-0 200-673-2	>= 90 - <= 100

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Symptoms of poisoning may appear several hours later.

If inhaled : Move to fresh air.
Keep patient warm and at rest.
Keep respiratory tract clear.
If unconscious, place in recovery position and seek medical advice.
Call a physician or poison control centre immediately.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.
If symptoms persist, call a physician.
Take victim immediately to hospital.

In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.
Induce vomiting immediately and call a physician.

Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Acute overdose produces the following symptoms:
Nausea, Vomiting, Headache, Weakness, Abdominal pain,
Dry mouth, Metallic taste, Loss of appetite

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water
Foam

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : None known.

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Consider dust explosion hazard.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Evacuate personnel to safe areas.
Use personal protective equipment.
Ensure adequate ventilation.
Avoid dust formation.
Avoid breathing dust.

6.2 Environmental precautions

Do not flush into surface water or sanitary sewer system.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust.
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For personal protection see section 8.
For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : Avoid formation of respirable particles.
Avoid exceeding the given occupational exposure limits (see section 8).
Avoid contact with skin and eyes.
For personal protection see section 8.
Provide sufficient air exchange and/or exhaust in work rooms.
Dispose of rinse water in accordance with local and national regulations.
Do not breathe vapours/dust.
Smoking, eating and drinking should be prohibited in the application area.
- Advice on protection against fire and explosion : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed. Take precautionary measures against static discharges.
- Hygiene measures : When using do not eat or drink. When using do not smoke.
Avoid contact with skin, eyes and clothing.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight.
Keep under inert gas.
Keep container tightly closed and dry.
Prevent unauthorized access.

7.3 Specific end use(s)

- Specific use(s) : Not applicable

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
cholecalciferol	67-97-0	TWA	0.005 mg/m ³	DSM Internal Limit

8.2 Exposure controls

Personal protective equipment

- Eye protection : Safety glasses with side-shields
- Hand protection : Consider the hazard characteristics of this product and any special workplace conditions when selecting the appropriate type of protective gloves.
Glove material: for example nitrile rubber
- Skin and body protection : Dust impervious protective suit
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

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Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : crystalline, powder
Colour : white
Odour : odourless
Odour Threshold : No information available.
pH : No data available
Melting point/range : 82 - 87 °C
Boiling point/boiling range : not determined
Flash point : Not applicable
Flammability (solid, gas) : May form combustible dust concentrations in air.
Vapour pressure : not determined
Relative vapour density : Not applicable
Density : not determined
Water solubility : < 1.0 mg/l (ca. 20 °C)
Solubility in other solvents : Acetone: soluble
Ethanol: soluble
Chloroform: soluble
Ether: soluble
Peanut oil: soluble
Partition coefficient: n-octanol/water : log Pow > 6.2 (OECD Test Guideline 107)
Auto-ignition temperature : No data available
Thermal decomposition : Decomposes on heating.
Potential for exothermic hazard
Explosive properties : Not explosive
Oxidizing properties : No data available

9.2 Other information

Combustibility index for deposited dust : 2 (ca. 21 °C)
Dust explosion class : St(H)2 (Milled sample, Median value of the tested sample < 0.01 mm, Loss on drying 0.16 %; The value was determined in the modified Hartmann tube.)
Minimum ignition energy : < 1 mJ (Milled sample, Median value of the tested sample < 0.01 mm, Loss on drying 0.16 %)
The Minimum ignition energy (MIE) of a dust/air mix depends on the particle size the water content and the temperature of the dust. The finer and the dryer the dust the lower the MIE.
: General remark: The indicated dust explosion characteristics are only valid for this product and are sensitive to the sample's

parameters.

Powder volume resistivity	: 2E+07 Ohmm (Product sample)
Minimum ignition temperature of a dust/air mix	: ca. 280 °C Product sample, determined in the BAM oven
Molecular weight	: 384.65 g/mol

SECTION 10: Stability and reactivity

10.1 Reactivity

No hazards to be specially mentioned.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Strongly exothermic reaction with air.

Dust may form explosive mixture in air.

10.4 Conditions to avoid

Heat

10.5 Incompatible materials

Oxygen

Strong acids and strong bases
Strong oxidizing agents

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke).

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity	: LD50 (Rat): > 5 - < 50 mg/kg (OECD Test Guideline 423) : LD50 (Mouse): 41.5 mg/kg
Acute inhalation toxicity	: LC50 (Rat, 4 h): 0.13 - 0.38 mg/l
Acute dermal toxicity	: Acute toxicity estimate : 300 mg/kg (Converted acute toxicity point estimate)
Skin irritation	: slight irritation (Rabbit)
Eye irritation	: No eye irritation (Rabbit, Draize Test) : Dust contact with the eyes can lead to mechanical irritation.

Sensitisation	: Did not cause sensitisation on laboratory animals. (Guinea pig, Optimization Test (Maurer))
Genotoxicity in vitro	: not mutagenic (Ames test, OECD Test Guideline 471) : not genotoxic (Chromosome aberration test in vitro, OECD Test Guideline 473)
Genotoxicity in vivo	: not genotoxic (Rat, Bone marrow, Mutagenicity (micronucleus test))
Carcinogenicity	: No indication for carcinogenicity known.
Teratogenicity	: May lead to malformations at dose levels that cause maternal toxicity. NOAEL: 0.0095 mg/kg bw/d (Rabbit female, OECD Test Guideline 414)
STOT - single exposure (Acute exposure)	: The substance or mixture is not classified as specific target organ toxicant, single exposure.
STOT - repeated exposure	: NOAEL (Oral, Rat) : 0.06 mg/kg bw/d Sub-chronic toxicity study (90-day) (OECD Test Guideline 408)
Experience with human exposure	: RDA (Recommended Daily Allowance) 0.005 - 0.01 mg
Experience with human exposure: Ingestion	: Acute overdose produces the following symptoms: : Nausea, Vomiting, Headache, Weakness, Abdominal pain, Dry mouth, Metallic taste, Loss of appetite
Aspiration toxicity	: No aspiration toxicity classification

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish	: Danio rerio (zebra fish) LC50 (96 h) > 100 mg/l (nominal concentration) (OECD Test Guideline 203)
Toxicity to daphnia and other aquatic invertebrates	: Daphnia magna (Water flea) EC50 (48 h) > 100 mg/l (nominal concentration) (OECD Test Guideline 202)
Toxicity to algae	: Scenedesmus capricornutum (fresh water algae) EC50 (96 h) > 100 mg/l

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(nominal concentration)
(OECD Test Guideline 201)

12.2 Persistence and degradability

Biodegradability : Not readily biodegradable.
<= 7 % (28 d)
(OECD Test Guideline 301C)

12.3 Bioaccumulative potential

Partition coefficient: n-
octanol/water : log Pow > 6.2 (OECD Test Guideline 107)

12.4 Mobility in soil

Distribution among environ-
mental compartments : No data available

12.5 Results of PBT and vPvB assessment

Assessment : The substance does not fulfill the PBT criteria.
: The substance does not fulfill the vPvB criteria.

12.6 Other adverse effects

Additional ecological informa-
tion : May cause long-term adverse effects in the aquatic environ-
ment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Discharge into the environment must be avoided.
Do not contaminate ponds, waterways or ditches with chemi-
cal or used container.
Do not dispose of waste into sewer.
Offer surplus and non-recyclable solutions to a licensed dis-
posal company.

Contaminated packaging : Dispose of as unused product.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number

ADN : UN 2811
ADR : UN 2811
RID : UN 2811
IMDG : UN 2811
IATA : UN 2811

14.2 UN proper shipping name

ADN : TOXIC SOLID, ORGANIC, N.O.S.
(cholecalciferol)

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ADR : TOXIC SOLID, ORGANIC, N.O.S.
(cholecalciferol)

RID : TOXIC SOLID, ORGANIC, N.O.S.
(cholecalciferol)

IMDG : TOXIC SOLID, ORGANIC, N.O.S.
(cholecalciferol)

IATA : Toxic solid, organic, n.o.s.
(cholecalciferol)

14.3 Transport hazard class(es)

ADN : 6.1

ADR : 6.1

RID : 6.1

IMDG : 6.1

IATA : 6.1

14.4 Packing group

ADN
Packing group : II
Classification Code : T2
Hazard Identification Number : 60
Labels : 6.1

ADR
Packing group : II
Classification Code : T2
Hazard Identification Number : 60
Labels : 6.1
Tunnel restriction code : (D/E)

RID
Packing group : II
Classification Code : T2
Hazard Identification Number : 60
Labels : 6.1

IMDG
Packing group : II
Labels : 6.1
EmS Code : F-A, S-A

IATA (Cargo)
Packing instruction (cargo aircraft) : 676
Packing instruction (LQ) : Y644
Packing group : II
Labels : Toxic Substances

IATA (Passenger)
Packing instruction (passenger aircraft) : 669
Packing instruction (LQ) : Y644
Packing group : II
Labels : Toxic Substances

14.5 Environmental hazards**ADN**

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Environmentally hazardous : no

ADR

Environmentally hazardous : no

RID

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

Remarks : No additional requirements.

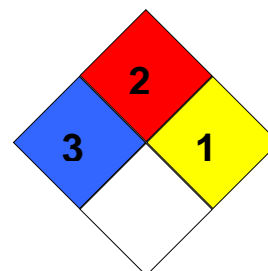
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable

SECTION 15: Regulatory information

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

NFPA Classification : Health hazard: 3
Fire Hazard: 2
Reactivity Hazard: 1



15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not

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according to Regulation (EC) No. 1907/2006



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Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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