

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Vitamin D3 1.0 MIU/g

5011574

Version 4.0

Revision Date 24.06.2014

Print Date 26.06.2014

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Vitamin D3 1.0 MIU/g

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

Use of the Substance/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 (UK) Ltd.
Heanor Gate
αGB061EI0017
Delves Road
GB-DE75 7SG Heanor

Telephone : +441773536500
Telefax : +441773536600
E-mail address : sds.nutritionalproducts@dsm.com
Responsible/issuing person

1.4 Emergency telephone number

+441773536623 / +41628662314

2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 3	H301: Toxic if swallowed.
Acute toxicity, Category 4	H332: Harmful if inhaled.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.

Classification (67/548/EEC, 1999/45/EC)

Toxic	R23: Toxic by inhalation.
Harmful	R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H301 Toxic if swallowed.
H332 Harmful if inhaled.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**

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P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.

Response:
 P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. Get medical advice/ attention if you feel unwell.
 P314

Disposal:
 P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:
 67-97-0 cholecalciferol (Vitamin D3)

Additional Labelling:EUH208 Contains: dl- α -tocopherol: May produce an allergic reaction.**2.3 Other hazards**

None known.

3. Composition/information on ingredients

Brief description of the product : Mixture (preparation) containing active ingredient and auxiliary substances

3.2 Mixtures**Hazardous components**

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
cholecalciferol (Vitamin D3)	67-97-0 200-673-2	T; R24/25-R48/25 T+; R26 R53	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 3; H311 STOT RE 1; H372 Aquatic Chronic 4; H413	>= 1 - < 3
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol (dl- α -tocopherol)	10191-41-0 233-466-0	R43 R53	Skin Sens. 1B; H317 Aquatic Chronic 4; H413	>= 0,1 - < 1

For the full text of the R-phrases mentioned in this Section, see Section 16.

For the full text of the H-Statements mentioned in this Section, see Section 16.

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.

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- 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.
- 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.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
Obtain medical attention.

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.

5. Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Alcohol-resistant foam
Dry chemical
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

- Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : 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.

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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.

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 materials for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
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.

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid exceeding of the given occupational exposure limits (see section 8).
Avoid contact with skin and eyes.
For personal protection see section 8.
Avoid formation of aerosol.
Provide sufficient air exchange and/or exhaust in work rooms.
Dispose of rinse water in accordance with local and national regulations.
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Take necessary action to avoid static electricity discharge.
Product will burn under fire conditions.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep under inert gas.
Protect against light.
: Keep container tightly closed and dry.
Prevent unauthorized access.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Storage temperature : < 15 °C

7.3 Specific end use(s)

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Specific use(s) : not applicable

8. Exposure controls/personal protection**8.1 Control parameters**

Components	CAS-No.	Value (Form of exposure)	Control parameters	Update	Basis
cholecalciferol	67-97-0	TWA	0,005 mg/m ³		DSM Internal Limit

8.2 Exposure controls**Personal protective equipment**

- Respiratory protection : In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit.
- Hand protection : Glove material: Chloroprene
: Glove material: Nitrile rubber
: Consider the hazard characteristics of this product and any special workplace conditions when selecting the appropriate type of protective gloves.
- Eye protection : Safety glasses with side-shields
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : When using do not eat or drink.
When using do not smoke.
Avoid contact with skin, eyes and clothing.
Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties**9.1 Information on basic physical and chemical properties**

- Appearance : clear liquid, oily
- Colour : colourless - pale yellow
- Odour : No information available.
- Odour Threshold : No information available.
- pH : No data available
- Melting point/range : not determined
- Boiling point/boiling range : not determined
- Flash point : 244 °C
- Evaporation rate : not determined
- Lower explosion limit : not determined
- Upper explosion limit : not determined
- Vapour pressure : not determined

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Relative vapour density	: not applicable
Density	: 0,948 g/cm ³ (at 20 °C) 0,925 g/cm ³ (at 50 °C)
Water solubility	: practically insoluble
Partition coefficient: n-octanol/water	: not applicable
Auto-ignition temperature	: No data available
Ignition temperature	: 390 °C (DIN 51794)
Thermal decomposition	: Not relevant
Viscosity, dynamic	: 31,85 mPa.s (at 20 °C) 10,51 mPa.s (at 50 °C)
Explosive properties	: Not explosive
Oxidizing properties	: No data available

9.2 Other information

No data available

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

Possible incompatibility with materials listed under section 10.5.

10.4 Conditions to avoid

Exposure to light.

Heat.

10.5 Incompatible materials

Strong acids and strong bases
Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if used as directed.

11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity	: Acute toxicity estimate : > 200 mg/kg (Expert judgement)
Acute inhalation toxicity	: Acute toxicity estimate : 4 mg/l

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(Expert judgement)

- Acute dermal toxicity : Acute toxicity estimate : > 5 000 mg/kg
(Calculation method)
- Skin corrosion/irritation : No skin irritation (rabbit)
- Serious eye damage/eye irritation : No data available
- Respiratory or skin sensitisation : Did not cause sensitisation on laboratory animals. (guinea pig)
- Genotoxicity in vivo cholecalciferol : not genotoxic (rat, Bone marrow, Mutagenicity (micronucleus test))
- Carcinogenicity : No indication for carcinogenicity known.
- Teratogenicity cholecalciferol : 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 - repeated exposure cholecalciferol : NOAEL (Oral, rat) : 0,06 mg/kg bw/d
Sub-chronic toxicity study (90-day)
(OECD Test Guideline 408)
- STOT - repeated exposure cholecalciferol : Causes damage to organs through prolonged or repeated exposure.
- Experience with human exposure cholecalciferol : RDA (Recommended Daily Allowance) 0,005 - 0,01 mg
- Experience with human exposure: Ingestion cholecalciferol : Acute overdose produces the following symptoms:
Nausea, Vomiting, Headache, Weakness, Abdominal pain,
Dry mouth, Metallic taste, Loss of appetite

12. Ecological information**12.1 Toxicity**

No data is available on the product itself.

12.2 Persistence and degradability

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

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3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol : Not readily biodegradable.
8 % (28 d)
(OECD Test Guideline 301F)

No data is available on the product itself.

12.3 Bioaccumulative potential

Bioaccumulation : No data available
Partition coefficient: n-octanol/water : not applicable

12.4 Mobility in soil

Distribution among environmental compartments : No data available

12.5 Results of PBT and vPvB assessment

Assessment : not determined

12.6 Other adverse effects

Additional ecological information : There is no data available for this product.

13. Disposal considerations

13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.
Do not dispose of waste into sewer.
Offer surplus and non-recyclable solutions to a licensed disposal company.

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

14. Transport information

14.1 UN number

ADR : 2810
RID : 2810
IMDG : 2810
IATA : 2810

14.2 Proper shipping name

ADR : TOXIC LIQUID, ORGANIC, N.O.S. (cholecalciferol)
RID : TOXIC LIQUID, ORGANIC, N.O.S. (cholecalciferol)
IMDG : TOXIC LIQUID, ORGANIC, N.O.S. (cholecalciferol)
IATA : Toxic liquid, organic, n.o.s. (cholecalciferol)

14.3 Transport hazard class

ADR : 6.1
RID : 6.1
IMDG : 6.1
IATA : 6.1

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14.4 Packing group**ADR**

Packaging group : III
Classification Code : T1
Hazard Identification Number : 60
Labels : 6.1
Tunnel restriction code : (E)

RID

Packaging group : III
Classification Code : T1
Hazard Identification Number : 60
Labels : 6.1

IMDG

Packaging group : III
Labels : 6.1
EmS Number : F-A, S-A

IATA

Packing instruction (cargo aircraft) : 663
Packaging group : III
Labels : 6.1

14.5 Environmental hazards**ADR**

Environmentally hazardous : no

RID

Environmentally hazardous : no

IMDG

Marine pollutant : no

IATA

Environmentally hazardous : no

14.6 Special precautions for user

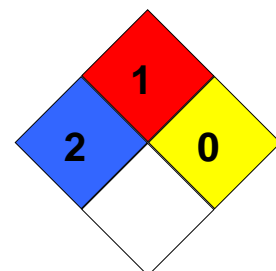
No additional requirements.

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

Remarks : not applicable

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

NFPA Classification : Health hazard: 2
Fire Hazard: 1
Reactivity Hazard: 0



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15.2 Chemical Safety Assessment

not applicable

16. Other information

Full text of R-phrases referred to under sections 2 and 3

R23	Toxic by inhalation.
R24/25	Toxic in contact with skin and if swallowed.
R26	Very toxic by inhalation.
R43	May cause sensitisation by skin contact.
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed.
R53	May cause long-term adverse effects in the aquatic environment.

Full text of H-Statements referred to under sections 2 and 3.

H300	Fatal if swallowed.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H317	May cause an allergic skin reaction.
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.
H413	May cause long lasting harmful effects to aquatic life.

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.

Abbreviations: 67/548/EEC= Dangerous Substances Directive. 1999/45/EC= Dangerous Preparations Directive. Regulation (EC) No. 1272/2008= Regulation on classification, labelling and packaging of substances and mixtures. DNEL= Derived No-Effect Level. PNEC= Predicted No-Effect Concentration. NFPA= National Fire Protection Association (USA). IATA= International Air Transport Association. IMDG= International Maritime Dangerous Goods. RID= International Rule for Transport of Dangerous Substances by Railway; ADR= European Agreement concerning the International Carriage of Dangerous Goods by Road. TWA= Time Weighted Average. STEL= Short term exposure limit. WEL = Workplace Exposure Limit.