

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

1.1 Product identifier

Trade name : Dry Vitamin D3 100 CWS

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

Use of the Sub-stance/Mixture : Ingredient for pharmaceutical products, Ingredient/additive for dietary supplements, 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)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Additional Labelling:

EUH210 Safety data sheet available on request.
EUH208 Contains dl- α -tocopherol. May produce an allergic reaction.

2.3 Other hazards

Risk of dust explosion.

SECTION 3: Composition/information on ingredients

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

3.1 Substances

Not applicable

3.2 Mixtures

Hazardous components

Chemical name	CAS-No. EC-No. Registration number	Classification	Concentration (% w/w)

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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	Skin Sens. 1B; H317 Aquatic Chronic 4; H413	$\geq 0.1 - < 0.25$
Substances with a workplace exposure limit :			
cholecalciferol (Vitamin D3)	67-97-0 200-673-2	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 3; H311 STOT RE 1; H372 Aquatic Chronic 4; H413	$\geq 0.25 - < 1$

For explanation of abbreviations see section 16.

Further ingredients

Chemical name	CAS-No. EC-No. Registration number	GHS Classification	Concentration [%]
sucrose	57-50-1 200-334-9		$\geq 30 - < 60$
Starch	9005-25-8 232-679-6		$\geq 10 - < 30$

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : No hazards which require special first aid measures.
- If inhaled : Move to fresh air.
If symptoms persist, call a physician.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.
- 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 swallowed : Induce vomiting if person is conscious.
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.

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 : Consider dust explosion hazard.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.
Avoid dust formation.

6.2 Environmental precautions

Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust.

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 : For personal protection see section 8.

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 : Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of work-day.

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 container tightly closed and dry.

Advice on common storage : No special restrictions on storage with other products.

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
sucrose	57-50-1	TWA	10 mg/m ³	GB EH40
		STEL	20 mg/m ³	GB EH40
starch	9005-25-8	TWA (inhalable dust)	10 mg/m ³	GB EH40
		TWA (Respirable dust)	4 mg/m ³	GB EH40
The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m ⁻³ 8-hour TWA of inhalable dust or 4 mg.m ⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limit.				
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 : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Respiratory protection : No personal respiratory protective equipment normally required.
In case of high dust concentration use a dust mask applicable to local conditions.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : free flowing particles
- Colour : off-white - 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 : Not applicable
- Flammability (solid, gas) : May form combustible dust concentrations in air.
- Vapour pressure : Not applicable
- Relative vapour density : Not applicable
- Density : not determined
- Water solubility : dispersible
- Partition coefficient: n-octanol/water : Not applicable

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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	: 3 (23 °C)
	: 3 (100 °C)
Dust explosion class	: St(H)1 (Milled sample, Median value of the tested sample 0.073 mm, Loss on drying 3.8 %; The value was determined in the modified Hartmann tube.)
Minimum ignition energy	: 30 - 100 mJ (Milled sample, Median value of the tested sample 0.073 mm, Loss on drying 3.8 %, EN 13821) 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	: ca. 8E+11 Ohmm (Product sample, Median value of the tested sample 0.245 mm, Loss on drying 4.2 %) The material can accumulate static charge and can therefore cause electrical ignition.
Minimum ignition temperature of a dust/air mix	: 370 °C (Median value of the tested sample 0.073 mm) determined in the BAM oven

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

Dust may form explosive mixture in air.

10.4 Conditions to avoid

Heat

10.5 Incompatible materials

Strong acids and strong bases
Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if used as directed.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity	: Acute toxicity estimate : > 5,000 mg/kg (Calculation method)
Acute inhalation toxicity	: Acute toxicity estimate : > 20 mg/l (Calculation method)
Acute dermal toxicity	: Acute toxicity estimate : > 5,000 mg/kg (Calculation method)
Skin irritation	: No data available
Eye irritation	: Dust contact with the eyes can lead to mechanical irritation.
Sensitisation	: No data available
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 Gui- deline 414)
STOT - single exposure (A- cute exposure)	: The substance or mixture is not classified as specific target organ toxicant, single exposure.
STOT - repeated exposure	: This information is not available.
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
Aspiration toxicity	: No aspiration toxicity classification

SECTION 12: Ecological information

12.1 Toxicity

No data is available on the product itself.

12.2 Persistence and degradability

Biodegradability
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)

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

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 environ-
mental compartments : No data available

12.5 Results of PBT and vPvB assessment

Assessment : not determined

12.6 Other adverse effects

Additional ecological informa-
tion : There is no data available for this product.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : 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.
Empty containers should be taken to an approved waste han-
dling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

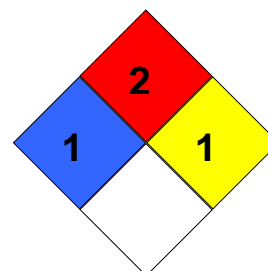
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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



15.2 Chemical safety assessment

Not applicable

SECTION 16: Other information

Full text of H-Statements

H300 : Fatal if swallowed.
H311 : Toxic in contact with skin.
H317 : May cause an allergic skin reaction.
H330 : Fatal if inhaled.
H372 : Causes damage to organs through prolonged or repeated exposure.
H413 : May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Chronic aquatic toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

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 -

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



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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 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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