

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Dry Vitamin D3, Type 100 CWS

0418188

Version 2.0

Revision Date 12.07.2011

Print Date 26.06.2014

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name : Dry Vitamin D3, Type 100 CWS

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)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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

Harmful R20: Harmful by inhalation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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.

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.	Classification	Classification	Concentration
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	EC-No. Registration number	(67/548/EEC)	(REGULATION (EC) No 1272/2008)	[%]
cholecalciferol (Vitamin D3)	67-97-0 200-673-2	T; R24/25-R48/25 T+; R26	Acute Tox. 2; H330 Acute Tox. 3; H311 Acute Tox. 2; H300 STOT RE 1; H372	>= 0,1 - < 1
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. 1; 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.

Further ingredients

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

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.
- If inhaled : Move to fresh air in case of accidental inhalation of dust or fumes from overheating or combustion.
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 eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Induce vomiting if person is conscious.
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 : No specific symptoms known.

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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 : Water
Foam

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.
Consider dust explosion hazard.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.
Ensure adequate ventilation.
Avoid dust formation.
Avoid breathing dust.

6.2 Environmental precautions

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

6.3 Methods and materials 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.

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of respirable particles.
Avoid exceeding of the given occupational exposure limits (see section 8).
For personal protection see section 8.

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Provide sufficient air exchange and/or exhaust in work rooms. 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Protect from humidity.
Protect against light.
: Keep container tightly closed and dry.
Storage temperature : < 15 °C

7.3 Specific end uses

Specific use(s) : not applicable

8. Exposure controls/personal protection

8.1 Control parameters

Components	CAS-No.	Value	Control parameters	Update	Basis
sucrose	57-50-1	TWA	10 mg/m ³	2005-04-06	GB EH40
		STEL	20 mg/m ³	2005-04-06	GB EH40
Starch	9005-25-8	TWA	10 mg/m ³	2005-04-06	GB EH40
		Inhalable			
		TWA	4 mg/m ³	2005-04-06	GB EH40
		Respirable			
		: 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. Advice on control is given in EH44 and in the great majority of workplaces reasonable control measures will normally keep exposure below these levels. However some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limit.			
Components	CAS-No.	Value	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 the case of dust or aerosol formation use respirator with an approved filter.
Hand protection : Glove material: for example nitrile rubber

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

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: free flowing particles
Colour	: off-white - 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)	: Not classified as supporting combustion according to the transport regulations.
Vapour pressure	: not applicable
Relative vapour density	: not applicable
Density	: not determined
Water solubility	: dispersible
Partition coefficient: n-octanol/water	: not applicable
Autoignition temperature	: no data available
Thermal decomposition	: Decomposes on heating. Potential for exothermic hazard
Explosive properties	: no data available
Oxidizing properties	: no data available

9.2 Other information

Combustibility index for deposited dust	: 3 (22 °C)
	: 3 (100 °C)
Dust explosion class	: St(H)1 (Milled sample, Median value of the tested sample 0,102 mm, Loss on drying 3,0 %; The value was determined in the modified Hartmann tube.)
Minimum ignition energy	: 30 - 100 mJ (Milled sample, Median value of the tested sample 0,102 mm, Loss on drying 3,0 %, EN 13821) The Minimum ignition energy (MIE) of a dust/air mix depends

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	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. 1E+12 Ohmm (Product sample, Median value of the tested sample 0,277 mm, Loss on drying 5,2 %) The material can accumulate static charge and can therefore cause electrical ignition.
Minimum ignition temperature of a dust/air mix	: >= 360 °C (Median value of the tested sample 0,277 mm) Product sample, determined in the BAM oven

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.

11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity
cholecalciferol : LD50 (rat): 5 - 50 mg/kg
(OECD Test Guideline 423)

Acute inhalation toxicity
cholecalciferol : LC50 (rat, 4 h): 0,13 - 0,18 mg/l

Skin corrosion/irritation : Prolonged skin contact may cause skin irritation.

Serious eye damage/eye irritation : Dust contact with the eyes can lead to mechanical irritation.

Respiratory or skin sensitization

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3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	: no photoallergenic skin reaction (guinea pig, OECD Test Guideline 432)
	: Causes sensitization. (guinea pig, Maximisation Test, OECD Test Guideline 406)
Genotoxicity in vivo cholecalciferol	: not genotoxic (rat, Bone marrow, Mutagenicity (micronucleus test))
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)
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
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
Surface tension
3,4-dihydro-2,5,7,8- : 8,1 mN/m (430 °C)

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tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol

12.5 Results of PBT and vPvB assessment

Assessment : This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
: This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

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

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.2 Proper shipping name

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.3 Transport hazard class

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

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Not dangerous goods

IATA

Not dangerous goods

14.4 Packing group

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.5 Environmental hazards

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.6 Special precautions for user

Not classified as dangerous in the meaning of transport regulations.

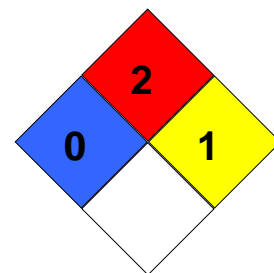
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

not applicable

15. Regulatory information

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

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



15.2 Chemical Safety Assessment

not applicable

16. Other information

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

R20 Harmful by inhalation.
R24/25 Toxic in contact with skin and if swallowed.
R26 Very toxic by inhalation.
R43 May cause sensitization by skin contact.
R48/25 Toxic: danger of serious damage to health by prolonged exposure if swallowed.

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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.
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.

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. 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.