

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Dry Vitamin A Palmitate, Type 250 CWS

0429937

Version 4.0

Revision Date 26.09.2011

Print Date 23.06.2014

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

1.1 Product identifier

Trade name : Dry Vitamin A Palmitate, Type 250 CWS

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

Use of the Substance/Mixture : For the fortification of foods, Ingredient for pharmaceutical products

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)

||| Reproductive toxicity, Category 1B H360D: May damage the unborn child.

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

Toxic to Reproduction Category 2 R61: May cause harm to the unborn child.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

||| Hazard pictograms :



||| Signal word : Danger

||| Hazard statements : H360D May damage the unborn child.

||| Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P281 Use personal protective equipment as required.

Response:
P308 + P313 IF exposed or concerned: Get medical

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advice/ attention.

Storage:
P405 Store locked up.

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

Hazardous components which must be listed on the label:
79-81-2 retinyl palmitate

Additional Labelling:

EUH208 Contains: dl- α -tocopherol: May produce an allergic reaction.
Restricted to professional users.

2.3 Other hazards

Risk of dust explosion.
Women of childbearing age must avoid any overexposure.

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 [%]
retinyl palmitate	79-81-2 201-228-5 01- 2119480425- 37	Repr.Cat.2; R61 Xi; R38 R53	Repr. 1B; H360D Aquatic Chronic 4; H413	>= 10 - < 15
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
tert-butyl-4-methoxyphenol	25013-16-5 246-563-8	Xi; R41 N; R51-R53	Eye Dam. 1; H318 Aquatic Chronic 2; H411	>= 0 - < 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

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Starch	9005-25-8 232-679-6			>= 10 - < 30
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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.
After any accidental exposure women should seek medical advice from a physician.
- 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.
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 : Headache, Irritability, Tiredness, Drowsiness, Nausea, Vomiting, Signs of increased intracranial pressure, Generalized desquamation of the skin (after ca. 24 hours)

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

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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

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 materials 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.

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of respirable particles.
Avoid exposure - obtain special instructions before use.
For personal protection see section 8.
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 : 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 against light.
Protect from humidity.
: Keep container tightly closed and dry.
Prevent unauthorized access.

Storage temperature : < 15 °C

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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/m3	2005-04-06	GB EH40
		STEL	20 mg/m3	2005-04-06	GB EH40
Starch	9005-25-8	TWA	10 mg/m3	2005-04-06	GB EH40
	Inhalable				
		TWA	4 mg/m3	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/m3 8-hour TWA of inhalable dust or 4 mg/m3 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
retinyl palmitate	79-81-2	TWA	0,37 mg/m3		DSM Internal Limit
	established for men				
		TWA	0,09 mg/m3		DSM Internal Limit
	established for women				

DNEL

retinyl palmitate

: Skin contact, Workers
Potential health effects: Systemic effects, long-term
Value: 1,6 mg/kg bw/d

Inhalation, Workers

Potential health effects: Systemic effects, long-term
Value: 0,55 mg/m3 (8 h)**PNEC**

retinyl palmitate

: Fresh water: 0,1 mg/l

Fresh water sediment: The equilibrium partitioning method is not applicable.

Marine water: 0,01 mg/l

Marine sediment: The equilibrium partitioning method is not applicable.

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Soil: The equilibrium partitioning method is not applicable.

Sewage treatment plant: 10 mg/l

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
: 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 : 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 : free flowing particles
- Colour : light 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

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Explosive properties : no data available

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 0,066 mm, Loss on drying 3,3 %; The value was determined in the modified Hartmann tube.)

Minimum ignition energy : 10 - 30 mJ (Milled sample, Median value of the tested sample 0,066 mm, Loss on drying 3,3 %, 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. 1E+12 Ohmm (Product sample, Median value of the tested sample 0,356 mm, Loss on drying 4,3 %)
The material can accumulate static charge and can therefore cause electrical ignition.

Minimum ignition temperature of a dust/air mix : 340 °C (Median value of the tested sample 0,356 mm) 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.

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11. Toxicological information**11.1 Information on toxicological effects**

- Acute oral toxicity
tert-butyl-4-methoxyphenol : LD50 (rat): 2 000 mg/kg
- Skin irritation
retinyl palmitate : Mild skin irritation (rabbit, OECD Test Guideline 404)
: no phototoxic skin reaction (guinea pig)
- 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol : Mild skin irritation (several species)
- Serious eye damage/eye irritation : Dust contact with the eyes can lead to mechanical irritation.
- Respiratory or skin sensitization
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
retinyl palmitate : not genotoxic (In vivo micronucleus test, mouse)
- Teratogenicity
retinyl palmitate : Teratogenic
embryotoxic
(several species)
- Further information
retinyl palmitate : Danger of cumulative effects.
- Experience with human exposure
retinyl palmitate : RDA (Recommended Daily Allowance) 0,8 mg pure vitamin A (retinol) per day established for men
RDA (Recommended Daily Allowance) ca. 0,7 mg pure vitamin A (retinol) per day established for women
- Experience with human exposure: Ingestion
retinyl palmitate : Acute overdose produces the following symptoms:
Headache, Irritability, Tiredness, Drowsiness, Nausea, Vomiting, Signs of increased intracranial pressure, Generalized desquamation of the skin (after ca. 24 hours)

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12. Ecological information

12.1 Toxicity

Toxicity to fish
tert-butyl-4-methoxyphenol : Oncorhynchus mykiss (rainbow trout)
LC50 (48 h) 1 mg/l

No data is available on the product itself.

12.2 Persistence and degradability

Biodegradability
retinyl palmitate : Not readily biodegradable.
40 - 50 % (28 d)
(OECD Test Guideline 301F)

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 : 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.

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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

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

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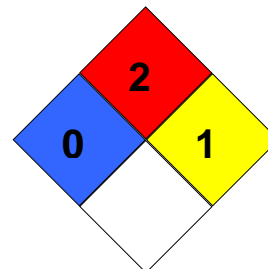
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not applicable

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

R38 Irritating to skin.
R41 Risk of serious damage to eyes.
R43 May cause sensitization by skin contact.
R51 Toxic to aquatic organisms.
R53 May cause long-term adverse effects in the aquatic environment.
R61 May cause harm to the unborn child.

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

H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H360D May damage the unborn child.
H411 Toxic to aquatic life with long lasting effects.
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.