

**Vitamin A Palmitate 1.0 MIU/g + Vitamin D3
100'000 IU/g**

5011558

Version 5.0

Revision Date 18.10.2016

Date of last issue: 07.07.2014

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

1.1 Product identifier

Trade name : Vitamin A Palmitate 1.0 MIU/g + Vitamin D3 100'000 IU/g

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

Use of the Sub-
stance/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 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)

Reproductive toxicity, Category 1B H360D: May damage the unborn child.
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	:	H360D May damage the unborn child. H413 May cause long lasting harmful effects to aquatic life.
Precautionary statements	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention. Disposal:

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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.

Other hazards

In case of extensive air contact (e.g. soaked rags, moistened clothes) an exothermic autooxidation (self-ignition) is possible.

Women of childbearing age must avoid any overexposure.

SECTION 3: Composition/information on ingredients

Brief description of the product : Mixture (preparation) containing active ingredients 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)
retinyl palmitate (vitamin A palmitate)	79-81-2 201-228-5 01-2119480425-37	Repr. 1B; H360D Aquatic Chronic 4; H413	>= 50 - < 70
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	>= 0.25 - < 1
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	>= 0.25 - < 1

For explanation of abbreviations see section 16.

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.
After any accidental exposure women should seek medical advice from a physician.

If inhaled : Move to fresh air.
Consult a physician after significant exposure.

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.

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according to Regulation (EC) No. 1907/2006



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|------------------------|---|
| 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.
If symptoms persist, call a physician.
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. |
|-----------|--------------------------|

SECTION 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 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. |

SECTION 6: Accidental release measures

When the spilled material is cleaned up with an absorbant material, attention should be paid to the possibility of exothermic autooxidation (self-ignition) in the presence of air, even at room temperature: store in the absence of air (e.g. in water) and send for incineration (or dispose of in accordance with local regulations).

6.1 Personal precautions, protective equipment and emergency procedures

- Evacuate personnel to safe areas.
Use personal protective equipment.

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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 material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, saw-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 exposure - obtain special instructions before use.
For personal protection see section 8.
Dispose of rinse water in accordance with local and national regulations.
handle under inert gas
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.

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 : Protect against light.
Keep under inert gas.

Keep container tightly closed and dry.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Recommended storage temperature : < 15 °C

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
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retinyl palmitate	79-81-2	TWA	0.37 mg/m ³	DSM Internal Limit
	established for men			
		TWA	0.09 mg/m ³	DSM Internal Limit
	established for women			
cholecalciferol	67-97-0	TWA	0.005 mg/m ³	DSM Internal Limit

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
retinyl palmitate	Workers	Skin contact	Systemic effects, long-term	1.6 mg/kg bw/d
	Workers	Inhalation	Systemic effects, long-term	0.55 mg/m ³
Exposure time: 8 h				

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
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.		
	Soil	
The equilibrium partitioning method is not applicable.		
	Sewage treatment plant	10 mg/l

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

: In the case of vapour formation use a respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : oily liquid

Colour : yellow - brownish

Odour : No information available.

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Odour Threshold	: No information available.
pH	: No data available
Melting point/range	: not determined
Boiling point/boiling range	: not determined
Flash point	: ca. 194 °C (closed cup) Test performed using a similar product.
Evaporation rate	: not determined
Lower explosion limit	: not determined
Upper explosion limit	: not determined
Vapour pressure	: not determined
Relative vapour density	: Not applicable
Density	: 0.92 g/cm ³ (at 20 °C)
Water solubility	: insoluble
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Ignition temperature	: not determined
Thermal decomposition	: No data available
Viscosity, dynamic	: not determined
Explosive properties	: Not explosive
Oxidizing properties	: No data available

9.2 Other information

No data available

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

In case of extensive air contact (e.g. soaked rags, moistened clothes) an exothermic autooxidation (self-ignition) is possible.

10.4 Conditions to avoid

Heat
Exposure to air.

10.5 Incompatible materials

Strong acids and strong bases
Strong oxidizing agents

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10.6 Hazardous decomposition products

No decomposition if used as directed.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity	: LD50 (Rat): > 2,000 mg/kg (calculated from LD50 of components)
Acute inhalation toxicity	: Acute toxicity estimate : > 10 mg/l (Calculation method)
Acute dermal toxicity	: Acute toxicity estimate : > 5,000 mg/kg (Calculation method)
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 (Rabbit)
cholecalciferol	: slight irritation (Rabbit)
Eye irritation 3,4-dihydro-2,5,7,8- tetramethyl-2-(4,8,12- trimethyltridecyl)-2H- benzopyran-6-ol	: slight irritation (Rabbit, Draize Test) temporary redness
Sensitisation retinyl palmitate	: Did not cause sensitisation on laboratory animals. (Guinea pig, Maximisation Test, OECD Test Guideline 406)
3,4-dihydro-2,5,7,8- tetramethyl-2-(4,8,12- trimethyltridecyl)-2H- benzopyran-6-ol	: Causes sensitisation. (Guinea pig, Maximisation Test, OECD Test Guideline 406) no photoallergenic skin reaction (Guinea pig, OECD Test Guideline 432)
Genotoxicity in vivo retinyl palmitate	: not genotoxic (In vivo micronucleus test, Mouse)
cholecalciferol	: not genotoxic (Rat, Bone marrow, Mutagenicity (micronucleus test))

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- Carcinogenicity : This information is not available.
- Teratogenicity
retinyl palmitate : Teratogenic
embryotoxic
(several species)
- 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 - single exposure (Acute exposure) : The substance or mixture is not classified as specific target organ toxicant, single exposure.
- 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
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
- cholecalciferol : RDA (Recommended Daily Allowance) 0.005 - 0.01 mg
- 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)
- cholecalciferol : Acute overdose produces the following symptoms:
Nausea, Vomiting, Headache, Weakness, Abdominal pain, Dry mouth, Metallic taste, Loss of appetite
- Further information
retinyl palmitate : Danger of cumulative effects.
- Aspiration toxicity : No aspiration toxicity classification

SECTION 12: Ecological information

12.1 Toxicity

- Toxicity to algae : *Desmodesmus subspicatus* (green algae)
ErC50 (72 h) 153 mg/l
(nominal concentration)
Information refers to the main component.

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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)
- cholecalciferol : Not readily biodegradable.
<= 7 % (28 d)
(OECD Test Guideline 301C)
- Photodegradation
retinyl palmitate : Decomposes rapidly in contact with light.

No data is available on the product itself.

12.3 Bioaccumulative potential

- Bioaccumulation : Bioconcentration factor (BCF): 3.16
Method: calculated value
Accumulation in aquatic organisms is unlikely. Information refers
to the main component.
- Partition coefficient: n-
octanol/water : Not applicable

12.4 Mobility in soil

- Distribution among environ-
mental compartments : Adsorption, Soil
log Koc 9.0 (calculated value)
Information refers to the main component.

12.5 Results of PBT and vPvB assessment

- Assessment : not determined

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 : Organic materials (e.g. rags, paper, wood) which are soaked
with this product can heat up and catch fire in the presence of
air, even at room temperature: store in the absence of air (e.g.
in water) and send it for incineration (or dispose of in accord-
ance with local regulations).
Discharge into the environment must be avoided.

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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.

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.

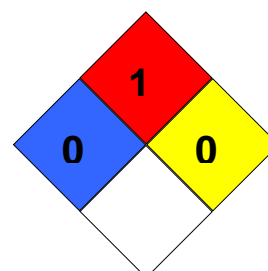
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

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: 0
Fire Hazard: 1
Reactivity Hazard: 0



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.

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H317	: May cause an allergic skin reaction.
H330	: Fatal if inhaled.
H360D	: May damage the unborn child.
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
Repr.	: Reproductive 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 - 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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