

Vitamin A Palmitate 1.0 MIU/g + Vitamin D3 100'000 IU/g**5011558**

Version 4.2

Revision Date 01/11/2021

Date of last issue: 10/15/2020

SECTION 1. IDENTIFICATION

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

Manufacturer or supplier's details

Company name of supplier : DSM Nutritional Products

Address : 45 Waterview Blvd
Parsippany NJ 07054-1298

Telephone : (908) 475-7373
Telefax : (908) 475-7406

Emergency telephone number : 1-800-424-9300 (24 HR CHEMTREC, CA & US); Outside CA & US +1-703-572-3887 (COLLECT CALLS ACCEPTED)

E-mail address of person responsible for the SDS : sds.nutritionalproducts@dsm.com

Recommended use of the chemical and restrictions on use

Recommended use : For the fortification of foods

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360 May damage fertility or 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.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

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posal plant.

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

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
retinyl palmitate	79-81-2	≥ 50 - < 70
cholecalciferol	67-97-0	≥ 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. 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.
- 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 : Rinse mouth with 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.
- Most important symptoms and effects, both acute and delayed : Headache
Irritability
Tiredness
Drowsiness
Nausea
Vomiting
Signs of increased intracranial pressure
Generalized desquamation of the skin (after ca. 24 hours)
- Notes to physician : Treat symptomatically.

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SECTION 5. FIREFIGHTING MEASURES

- 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
- Specific hazards during fire-fighting : None known.
- 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.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Evacuate personnel to safe areas.
Use personal protective equipment.
Ensure adequate ventilation.
When the spilled material is cleaned up with an absorbent 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).
- 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.
- 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.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Take necessary action to avoid static electricity discharge.
Product will burn under fire conditions.
- 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.
Smoking, eating and drinking should be prohibited in the application area.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sun-

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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.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
retinyl palmitate	79-81-2	TWA	0.09 mg/m ³	DSM Internal Limit
cholecalciferol	67-97-0	TWA	0.005 mg/m ³	DSM Internal Limit

Personal protective equipment

- Respiratory protection : In the case of vapour formation use a respirator with an approved filter.
- Hand protection
Remarks : 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
- 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

- Appearance : oily liquid
- Colour : yellow - brownish
- Odour : characteristic
- Odour Threshold : No information available.
- pH : No data available
- Melting point/range : not determined
- Boiling point/boiling range : not determined
- Flash point : ca. 381 °F (194 °C) (closed cup)
Test performed using a similar product.
- Evaporation rate : not determined
- Lower explosion limit : not determined

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Upper explosion limit	: not determined
Vapour pressure	: not determined
Relative vapour density	: Not applicable
Density	: 0.92 g/cm ³ (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

Other information

No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No hazards to be specially mentioned.
Chemical stability	: Stable under recommended storage conditions.
Possibility of hazardous reactions	: In case of extensive air contact (e.g. soaked rags, moistened clothes) an exothermic autooxidation (self-ignition) is possible.
Conditions to avoid	: Heat Exposure to air. Exposure to light.
Incompatible materials	: Oxidizing agents Strong acids and strong bases
Hazardous decomposition products	: Carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke).

SECTION 11. TOXICOLOGICAL INFORMATION

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 retinyl palmitate	: Mild skin irritation (Rabbit, OECD Test Guideline 404)

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no phototoxic skin reaction (Guinea pig)

cholecalciferol	: slight irritation (Rabbit)
Sensitisation	: Did not cause sensitisation on laboratory animals. (Guinea pig, Maximisation Test, OECD Test Guideline 406) Information refers to the main component.
	: Did not cause sensitization. (Mouse, Local Lymph Node Assay (LLNA), OECD Test Guideline 429) Tested with a similar product containing 1.5% dl-alpha-tocopherol.
Genotoxicity in vivo retinyl palmitate	: not genotoxic (In vivo micronucleus test, Mouse)
cholecalciferol	: not genotoxic (Rat, Bone marrow, Mutagenicity (micronucleus test))
Carcinogenicity	: This information is not available.
IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
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)

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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 - 0.015 mg/day

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**Toxicity**

Toxicity to algae : *Desmodesmus subspicatus* (green algae)
ErC50 (72 h) 153 mg/l
(nominal concentration)
Information refers to the main component.
(DIN 38412)

Persistence and degradability

Biodegradability
retinyl palmitate : Not readily biodegradable.
40 - 50 % (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.
Half-life (direct photolysis): 55 min (calculated value)

No data is available on the product itself.

Bioaccumulative potential

Bioaccumulation : Bioconcentration factor (BCF): 3.16
Method: calculated value

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Accumulation in aquatic organisms is unlikely.
Information refers to the main component.

Partition coefficient: n-octanol/water : Not applicable

Mobility in soil

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

Results of PBT and vPvB assessment

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects

Regulation 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : May cause long-term adverse effects in the aquatic environment.

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : User must determine if any wastes generated exhibit hazardous characteristics as per 40 CFR Part 261 or other national / local legislation.

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 accordance with local regulations).
Discharge into the environment must be avoided.
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**International Regulations****UNRTDG**

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Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

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retinyl palmitate
Corn oil79-81-2
8001-30-7**Maine Chemicals of High Concern**

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

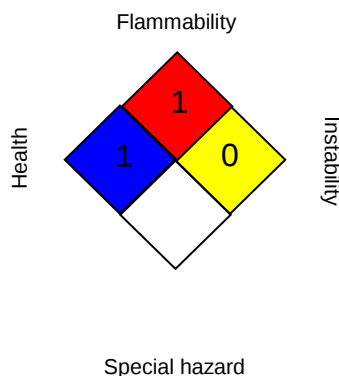
Washington Chemicals of High Concern

Product does not contain any listed chemicals

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION**Further information****NFPA 704:****HMIS® IV:**

HEALTH	*	1
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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 -

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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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

ACGIH = American Conference of Governmental Industrial Hygienists. CFR = Code of Federal Regulations. EPA = Environmental Protection Agency. NIOSH = National Institute of Occupational Safety and Health. OSHA = Occupational Safety and Health Administration. STEL = Short term exposure limit. TLV = Threshold Limit Value. TLV-C = Ceiling Limit Value. TWA = Time Weighted Average.

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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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