

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

ORIGINAL



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

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

1.1 Product identifier

Trade name : Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

REACH Registration Number : 01-2119480425-37-0001

Substance name : all-trans-3,7-dimethyl-9-(2,6,6-trimethyl-1-cyclohexene-1-yl)-2,4,6,8-nonatetraene-1-yl palmitate

CAS-No. : 79-81-2

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 personal care products

1.3 Details of the supplier of the safety data sheet

Company : DSM Nutritional Products Ltd.
PO Box 2676
CH-4002Basel

Telephone : +41618158888

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.

Long-term (chronic) aquatic hazard, 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/



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

eye protection/ face protection/ hearing protection.

Response:

P308 + P313

IF exposed or concerned: Get medical advice/ attention.

Disposal:

P501

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

Additional Labelling:

EUH208

Contains dl- α -tocopherol. May produce an allergic reaction.

2.3 Other hazards

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.

Ecological information The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

Synonyms : Retinol, hexadecanoate

Brief description of the product : Substance
Stabilized product

Molecular formula : C36 H60 O2

3.1 Substances

Hazardous components

Chemical name	CAS-No. EC-No.	Concentration (% w/w)
retinyl palmitate	79-81-2 201-228-5	$\geq 90 - \leq 100$
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	10191-41-0 233-466-0	$\geq 1 - < 5$

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.



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

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. |

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) |
|----------|---|--|

- | | | |
|-------|---|------------------------------|
| Risks | : | May damage the unborn child. |
|-------|---|------------------------------|

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. |
|---------------------------------------|---|-------------|



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

5.3 Advice for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus for firefighters

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

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : 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).

6.2 Environmental precautions

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

Methods for 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.

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 : Handle substance within a predominantly closed system provided with extract ventilation.

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 : 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.



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

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 under inert gas.

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

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
retinyl palmitate	79-81-2	TWA	0.247 mg/m ³	DSM Internal Limit
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	10191-41-0	TWA	7.3 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



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

- | | |
|--------------------------|--|
| 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
May crystallize, even at room temperature. |
| Colour | : yellow - brownish |
| Odour | : characteristic |
| Odour Threshold | : No information available. |
| pH | : substance/mixture is non-soluble (in water) |
| Melting point/range | : ca. 26 °C |
| Flash point | : ca. 194 °C (closed cup) |
| Evaporation rate | : not determined |
| Flammability (solid, gas) | : The substance or mixture does not emit flammable gases in contact with water. |
| Lower explosion limit | : not determined |
| Upper explosion limit | : not determined |
| Vapour pressure | : < 0.001 hPa (25 °C; calculated (citation from literature)) |
| Relative vapour density | : not determined |
| Density | : 0.92 g/cm ³ (20 °C) |
| Water solubility | : < 0.0001 mg/l (25 °C; calculated (citation from literature))
insoluble |
| Solubility in other solvents | : Ethanol: slightly soluble
Ether: soluble
Peanut oil: soluble |
| Partition coefficient: n-octanol/water | : log Pow 15.5 (25 °C; calculated (citation from literature)) |
| Ignition temperature | : > 250 °C |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : not determined |

9.2 Other information

- | | |
|----------------------|-----------------|
| Explosive properties | : Not explosive |
| Oxidizing properties | : Not oxidizing |
| Molecular weight | : 524.87 g/mol |

SECTION 10: Stability and reactivity



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

10.1 Reactivity

No hazards to be specially mentioned.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

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

Conditions to avoid : Exposure to air.
Heat
Exposure to light.
Exposure to moisture

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Strong acids and strong bases

Copper
Copper alloys
Iron
Iron salts

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke).

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity : LD50 (Rat): > 2,500 mg/kg
: LD50 (Mouse): 6,060 mg/kg

Skin irritation : Mild skin irritation (Rabbit, OECD Test Guideline 404)
: no phototoxic skin reaction (Guinea pig)

Eye irritation : No eye irritation (Rabbit, OECD Test Guideline 405)

Sensitisation : Did not cause sensitisation on laboratory animals. (Guinea pig, Maximisation Test, OECD Test Guideline 406)
Test substance: active ingredient
: 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.
: no photoallergenic skin reaction (Guinea pig)



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

Genotoxicity in vitro	: not mutagenic (Ames test)
Genotoxicity in vivo	: not genotoxic (In vivo micronucleus test, Mouse)
Carcinogenicity	: No indication for carcinogenicity known.
Teratogenicity	: embryotoxic Teratogenic (several species)
STOT - single exposure (Acute exposure)	: The substance or mixture is not classified as specific target organ toxicant, single exposure.
STOT - repeated exposure	: NOAEL (Oral, Rat) : 1.43 - 3.32 mg/kg bw/d Test substance: retinyl acetate Sub-chronic toxicity study (90-day)
Aspiration toxicity	: No aspiration toxicity classification

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
------------	---

Experience with human exposure

Components:

retinyl palmitate:

General Information	: 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
Ingestion	: 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)



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

Further information

Components:

retinyl palmitate:

Remarks : Danger of cumulative effects.

SECTION 12: Ecological information

12.1 Toxicity

- Toxicity to fish : Leuciscus idus (Golden orfe)
LC50 (96 h) > 10,000 mg/l
Test substance: retinyl propionate
(nominal concentration)
(DIN 38412)
- Toxicity to algae : Desmodesmus subspicatus (green algae)
ErC50 (72 h) 153 mg/l
(nominal concentration)
(DIN 38412)
: ErC10 (72 h) 4.4 mg/l
(nominal concentration)
- Toxicity to bacteria : activated sludge
EC20 (0.5 h) > 1,000 mg/l
(nominal concentration)
(OECD Test Guideline 209)

12.2 Persistence and degradability

- Biodegradability : Not readily biodegradable.
40 - 50 % (28 d)
(OECD Test Guideline 301F)
- Photodegradation : Decomposes rapidly in contact with light.
Half-life (direct photolysis): 55 min (calculated value)

12.3 Bioaccumulative potential

- Bioaccumulation : Bioconcentration factor (BCF): 3.16
Method: calculated value
Accumulation in aquatic organisms is unlikely.
- Partition coefficient: n-octanol/water : log Pow 15.5 (25 °C ; calculated (citation from literature))

12.4 Mobility in soil

- Distribution among environmental compartments : Adsorption, Soil
log Koc 9.0 (calculated value)
- Stability in soil : Adsorbs on soil.

12.5 Results of PBT and vPvB assessment



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

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.

12.6 Endocrine disrupting properties

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Product:

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

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 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

14.1 UN number or ID number

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.4 Packing group

ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	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 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Conditions of restriction for the following entries should be considered: Number on list 3
--	---	---

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	:	Not applicable
---	---	----------------

Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable
----------------------------	---	--

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

15.2 Chemical safety assessment

retinyl palmitate: A Chemical Safety Assessment has been carried out for this substance.



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; 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; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

DNEL - Derived No-Effect Level; NFPA - National Fire Protection Association (USA); PNEC - Predicted No-Effect Concentration; STEL - Short term exposure limit; TLV-C - Ceiling Limit Value; TWA - Time Weighted Average; WEL - Workplace Exposure Limit.

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.

IE / EN



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

Annex

	Title of Exposure Scenario
ES 1:	Formulation liquid
ES 2:	Formulation solid
ES 3:	Private use of cosmetics and personal care products

Abbreviations

ART = Advanced REACH Tool

ECETOC TRA = European Centre for Ecotoxicology and Toxicology Of Chemicals - Targeted Risk Assessment

ES = Exposure scenario

EUSES = European Union System for the Evaluation of Substances

PEC = Predicted exposure concentration

RCR = Risk characterisation ratio: "Level of Exposure/DNEL" or "PEC/PNEC"



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

ES 1: Formulation liquid

1. Scenario description

Main User Groups	: SU 3: Industrial uses: Uses of substances as such or in preparations at industrial sites
Sectors of end-use	: SU 10: Formulation
Chemical product category	: PC39: Cosmetics, personal care products
Process categories	: PROC1: Use in closed process, no likelihood of exposure PROC2: Use in closed, continuous process with occasional controlled exposure PROC3: Use in closed batch process (synthesis or formulation) PROC5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact) PROC8a: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities PROC8b: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities PROC9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC14: Production of preparations or articles by tableting, compression, extrusion, pelletisation PROC15: Use as laboratory reagent
Environmental Release Categories	: ERC2: Formulation of preparations

2.1 Contributing scenario controlling environmental exposure for: ERC2

Product characteristics

Viscosity, dynamic	: Very viscous
Daily amount per site (Msafe)	: 11,250 kg
Remarks	: Msafe is the maximum amount of substance or product which may be used safely under the conditions defined in the environmental part of the exposure scenario.

Environment factors not influenced by risk management

Dilution Factor (River)	: 10
Dilution Factor (Coastal Areas)	: 100

Other given operational conditions affecting environmental exposure

Emission or Release Factor: Air	: 2.5 %
Emission or Release Factor: Water	: 2 %
Emission or Release Factor: Soil	: 0 %

Technical conditions and measures / Organizational measures

Air	: Exhaust ventilation equipped with scrubbers.
Water	: All contaminated waste water must be processed in an industrial or municipal wastewater treatment plant that incorporates both primary and secondary treatments.



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

Soil : Avoid subsoil penetration.

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant : Municipal sewage treatment plant
Flow rate of sewage treatment : 2,000 m3/d
plant effluent
Sludge Treatment : Can be landfilled or incinerated, when in compliance with local regulations.

Conditions and measures related to external treatment of waste for disposal

Disposal methods : Dispose of as hazardous waste in compliance with local and national regulations.

2.2 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15

Product characteristics

Concentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 5%.
Physical Form (at time of use) : Liquid mixture, Low volatile liquid

Frequency and duration of use

Frequency of use : <= 8 hours/day

Other operational conditions affecting workers exposure

Outdoor / Indoor : Indoor use

Technical conditions and measures

Handle substance within a predominantly closed system provided with extract ventilation.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear chemically resistant gloves (tested to EN374) in combination with specific activity training. (Effectiveness (of a measure): 95 %)
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. Smoking, eating and drinking should be prohibited in the application area.

3. Exposure estimation and reference to its source

Environment

Contributing Scenario	Exposure Assessment Method	Specific conditions	Compartment	Value	Level of Exposure (PEC)	RCR
ERC2	EUSES		Fresh water		< 0.0007 mg/l	< 0.007
ERC2	EUSES		Marine water		< 0.0008 mg/l	< 0.08
ERC2	EUSES		Sewage treatment plant		< 10 mg/l	< 1.0

Workers



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

Contributing Scenario	Exposure Assessment Method	Specific conditions	Value	Level of Exposure	RCR
PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15	ECETOC TRA	Worker (Industrial), Worker (Professional)	Dermal: long-term, systemic	$\leq 0.034 \text{ mg/kg bw/d}$	≤ 0.021
see above	ECETOC TRA	Worker (Industrial)	Inhalation exposure	$\leq 0.025 \text{ mg/m}^3$	≤ 0.045
see above	ECETOC TRA	Worker (Professional)	Inhalation exposure	$\leq 0.050 \text{ mg/m}^3$	≤ 0.091

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

EUSES = EUSES version 2.1.1



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

ES 2: Formulation solid

1. Scenario description

Main User Groups	: SU 3: Industrial uses: Uses of substances as such or in preparations at industrial sites
Sectors of end-use	: SU 10: Formulation
Chemical product category	: PC39: Cosmetics, personal care products
Process categories	: PROC1: Use in closed process, no likelihood of exposure PROC2: Use in closed, continuous process with occasional controlled exposure PROC3: Use in closed batch process (synthesis or formulation) PROC5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact) PROC8a: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities PROC8b: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities PROC9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC14: Production of preparations or articles by tableting, compression, extrusion, pelletisation PROC15: Use as laboratory reagent
Environmental Release Categories	: ERC2: Formulation of preparations

2.1 Contributing scenario controlling environmental exposure for: ERC2

Product characteristics

Daily amount per site (Msafe)	: 11,250 kg
Remarks	: Msafe is the maximum amount of substance or product which may be used safely under the conditions defined in the environmental part of the exposure scenario.

Environment factors not influenced by risk management

Dilution Factor (River)	: 10
Dilution Factor (Coastal Areas)	: 100

Other given operational conditions affecting environmental exposure

Emission or Release Factor: Air	: 2.5 %
Emission or Release Factor: Water	: 2 %
Emission or Release Factor: Soil	: 0 %

Technical conditions and measures / Organizational measures

Air	: Exhaust ventilation equipped with filters.
Water	: All contaminated waste water must be processed in an industrial or municipal wastewater treatment plant that incorporates both primary and secondary treatments.
Soil	: Avoid subsoil penetration.



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

Conditions and measures related to municipal sewage treatment plant

- Type of Sewage Treatment Plant : Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent : 2,000 m3/d
Sludge Treatment : Can be landfilled or incinerated, when in compliance with local regulations.

Conditions and measures related to external treatment of waste for disposal

- Disposal methods : Dispose of as hazardous waste in compliance with local and national regulations.

2.2 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC15

Product characteristics

- Concentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 5%.
Physical Form (at time of use) : Solid, high dustiness

Frequency and duration of use

- Frequency of use : <= 8 hours/day

Other operational conditions affecting workers exposure

- Outdoor / Indoor : Indoor use

Technical conditions and measures

None.

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear chemically resistant gloves (tested to EN374) in combination with specific activity training. (Effectiveness (of a measure): 95 %)

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. Smoking, eating and drinking should be prohibited in the application area.

2.3 Contributing scenario controlling worker exposure for: PROC5, PROC8a, PROC8b, PROC9, PROC14

Product characteristics

- Concentration of the Substance in Mixture/Article : Covers the percentage of the substance in the product up to 5%.
Physical Form (at time of use) : Solid, high dustiness

Frequency and duration of use

- Frequency of use : <= 8 hours/day

Other operational conditions affecting workers exposure

- Outdoor / Indoor : Indoor use

Technical conditions and measures

Provide appropriate exhaust ventilation at places where dust is formed. (Effectiveness (of a measure): 90 %)



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

Organisational measures to prevent /limit releases, dispersion and exposure

Ensure operatives are trained to minimise exposures.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear chemically resistant gloves (tested to EN374) in combination with specific activity training. (Effectiveness (of a measure): 95 %)

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. Smoking, eating and drinking should be prohibited in the application area.

3. Exposure estimation and reference to its source

Environment

Contributing Scenario	Exposure Assessment Method	Specific conditions	Compartment	Value	Level of Exposure (PEC)	RCR
ERC2	EUSES		Fresh water		< 0.0007 mg/l	< 0.007
ERC2	EUSES		Marine water		< 0.0008 mg/l	0.08
ERC2	EUSES		Sewage treatment plant		< 10 mg/l	< 1.0

Workers

Contributing Scenario	Exposure Assessment Method	Specific conditions	Value	Level of Exposure	RCR
PROC1, PROC2, PROC3, PROC15	ECETOC TRA	Worker (Industrial), Worker (Professional)	Dermal: long-term, systemic	< 0.004 mg/kg bw/d	<= 0.002
PROC1, PROC2, PROC3, PROC15	ECETOC TRA	Worker (Industrial), Worker (Professional)	Inhalation exposure	<= 0.25 mg/m ³	<= 0.46
PROC5, PROC8a, PROC8b, PROC9, PROC14	ECETOC TRA	Worker (Industrial), Worker (Professional)	Dermal: long-term, systemic	<= 0.034 mg/kg bw/d	<= 0.021
PROC5, PROC8a, PROC8b, PROC9, PROC14	ECETOC TRA	Worker (Industrial), Worker (Professional)	Inhalation exposure	<= 0.25 mg/m ³	<= 0.46

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

EUSES = EUSES version 2.1.1



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

ES 3: Private use of cosmetics and personal care products

1. Scenario description

Main User Groups : **SU 21:** Consumer uses: Private households (= general public = consumers)
Sectors of end-use : **SU 21:** Consumer uses: Private households (= general public = consumers)
Chemical product category : **PC39:** Cosmetics, personal care products
Environmental Release Categories : **ERC8a:** Wide dispersive indoor use of processing aids in open systems

2.1 Contributing scenario controlling environmental exposure for: ERC8a

Product characteristics

Viscosity, dynamic : not determined

Amount used

Annual amount for wide disperse uses : 100 t
Remarks : amount used for the exposure estimation

Frequency and duration of use

Continuous exposure : 365 days/year

Environment factors not influenced by risk management

Dilution Factor (River) : 10
Dilution Factor (Coastal Areas) : 100

Other given operational conditions affecting environmental exposure

Continuous use/release
Number of emission days per year : 365
Emission or Release Factor: Water : 90 %

Conditions and measures related to municipal sewage treatment plant

Type of Sewage Treatment Plant : Municipal sewage treatment plant
Flow rate of sewage treatment plant effluent : 2,000 m3/d
Sludge Treatment : Can be applied on agricultural soil, when in compliance with local regulations.

2.2 Contributing scenario controlling consumer exposure for: PC39

Frequency and duration of use

Frequency of use : 365 days/year
Remarks : Continuous use/release



3. Exposure estimation and reference to its source

Environment

Contributing	Exposure	Specific	Compartment	Value	Level of Exposure	RCR
--------------	----------	----------	-------------	-------	-------------------	-----

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

Scenario	Assessment Method	conditions			(PEC)	
ERC8a	EUSES		Fresh water		0.13 E-06 mg/l	0.000001
ERC8a	EUSES		Marine water		0.15 E-06 mg/l	0.000015
ERC8a	EUSES		Sewage treatment plant		0.0019 mg/l	0.00019

Risk to consumers' health does not need to be assessed as this is already covered by the Cosmetic Directive 76/768/EEC.

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

EUSES = EUSES version 2.1.1



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)

0418579

Version 11.0

Revision Date 24.10.2024

Date of last issue: 27.01.2023

