

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

**0418579**

Version 7.0

Revision Date 12.07.2017

Print Date 06.08.2019

**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 pharmaceutical products, Ingredient for personal care 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/

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

**0418579**

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**Response:**  
P308 + P313 eye protection/ face protection.  
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- $\alpha$ -tocopherol. May produce an allergic reaction.

**2.3 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**

Synonyms : Retinol, hexadecanoate

Brief description of the product : Substance  
Stabilized product

Molecular formula : C<sub>36</sub> H<sub>60</sub> O<sub>2</sub>

**3.1 Substances**

**Hazardous components**

Chemical name	CAS-No. EC-No.	Concentration (% w/w)
retinyl palmitate	79-81-2 201-228-5	>= 90 - <= 100
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	10191-41-0 233-466-0	>= 1 - < 2.5

**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.  
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.

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

**0418579**

Version 7.0

Revision Date 12.07.2017

Print Date 06.08.2019

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.

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**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.

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**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.  
Ensure adequate ventilation.

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

**0418579**

Version 7.0

Revision Date 12.07.2017

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### 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, 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.

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## 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.  
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 : 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

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

**0418579**

Version 7.0

Revision Date 12.07.2017

Print Date 06.08.2019

retinyl palmitate	79-81-2	TWA	0.37 mg/m <sup>3</sup>	DSM Internal Limit
	established for men			
		TWA	0.09 mg/m <sup>3</sup>	DSM Internal Limit
	established for women			

**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 <sup>3</sup>
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 : characteristic

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

**0418579**

Version 7.0

Revision Date 12.07.2017

Print Date 06.08.2019

Odour Threshold	: No information available.
pH	: No data available
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 <sup>3</sup> (at 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
Thermal decomposition	: No data available
Viscosity, dynamic	: not determined
Explosive properties	: Not explosive
Oxidizing properties	: Not oxidizing

## 9.2 Other information

Molecular weight : 524.87 g/mol

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## 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

Exposure to air.  
Heat  
Exposure to light.  
Exposure to moisture

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

**0418579**

Version 7.0

Revision Date 12.07.2017

Print Date 06.08.2019

### 10.5 Incompatible materials

Oxidizing agents  
Strong acids and strong bases

Copper  
Copper alloys  
Iron  
Iron salts

### 10.6 Hazardous decomposition products

No decomposition if used as directed.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

- 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)
- 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)

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

**0418579**

Version 7.0

Revision Date 12.07.2017

Print Date 06.08.2019

- 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)
- Experience with human exposure : 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 : 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)
- Further information : Danger of cumulative effects.
- Aspiration toxicity : No aspiration toxicity classification

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## 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 : Desmodemus 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)



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

**0418579**

Version 7.0

Revision Date 12.07.2017

Print Date 06.08.2019

Photodegradation : Decomposes rapidly in contact with light.  
55 min

### 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)

### 12.5 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.

### 12.6 Other adverse effects

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

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## 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.

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## 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

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

**0418579**

Version 7.0

Revision Date 12.07.2017

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**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**

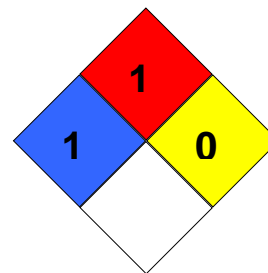
Not applicable for product as supplied.

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**SECTION 15: Regulatory information**

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

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



**15.2 Chemical safety assessment**

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

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**SECTION 16: Other information**

**Full text of other abbreviations**

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



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

0418579

Version 7.0

Revision Date 12.07.2017

Print Date 06.08.2019

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.

GB / EN

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according to Regulation (EC) No. 1907/2006

**Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)****0418579**

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**Annex**

	<b>Title of Exposure Scenario</b>
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"

## ES 1: Formulation liquid

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### 1. Scenario description

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

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### 2.1 Contributing scenario controlling environmental exposure for: ERC2

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#### 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.
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**

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	<= 0.034 mg/kg bw/d	<= 0.021
see above	ECETOC TRA	Worker (Industrial)	Inhalation exposure	<= 0.025 mg/m <sup>3</sup>	<= 0.045

see above	ECETOC TRA	Worker (Pro- fessional)	Inhalation exposure	$\leq 0.050 \text{ mg/m}^3$	$\leq 0.091$
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#### **4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario**

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EUSES = EUSES version 2.1.1

## ES 2: Formulation solid

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### 1. Scenario description

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

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### 2.1 Contributing scenario controlling environmental exposure for: ERC2

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#### 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.

#### 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 m <sup>3</sup> /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.

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

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### **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.

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

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### **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 %)

### **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.

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### 3. Exposure estimation and reference to its source

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#### 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 <sup>3</sup>	<= 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 <sup>3</sup>	<= 0.46

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

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EUSES = EUSES version 2.1.1

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

**0418579**

Version 7.0

Revision Date 12.07.2017

Date of last issue: 02.07.2014

**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 m<sup>3</sup>/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 Scenario	Exposure Assessment Meth-	Specific conditions	Compartment	Value	Level of Exposure (PEC)	RCR
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**Vitamin A Palmitate 1.7 MIU/g (stabilized with tocopherol)**

**0418579**

Version 7.0

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Date of last issue: 02.07.2014

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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.

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

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EUSES = EUSES version 2.1.1