

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

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/M 1.0 MIU/g (stabilized with tocopherol)

REACH Registration Number : 01-2119480425-37-0001 (retinyl palmitate)

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

Use of the Sub-
stance/Mixture : For the fortification of foods, Ingredient for pharmaceutical products, 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/ eye protection/ face protection.

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

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

Disposal:
P501

vice/ attention.

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

Hazardous components which must be listed on the label:

79-81-2 retinyl palmitate (vitamin A palmitate)

Additional Labelling:

EUH208 Contains dl- α -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

Brief description of the product : Mixture (preparation) containing active ingredient and auxiliary substances

3.1 Substances

Not applicable

3.2 Mixtures

Hazardous components

Chemical name	CAS-No. EC-No. Registration number	Classification	Concentration (% w/w)
retinyl palmitate (vitamin A palmitate)	79-81-2 201-228-5 01-2119480425-37	Repr. 1B; H360D Aquatic Chronic 4; H413	>= 50 - < 70
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol (dl- α -tocopherol)	10191-41-0 233-466-0	Skin Sens. 1B; H317 Aquatic Chronic 4; H413	>= 1 - < 2.5

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
After any accidental exposure women should seek medical advice from a physician.
- If inhaled : Move to fresh air.
Consult a physician after significant exposure.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.
If symptoms persist, call a physician.
- In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Headache, Irritability, Tiredness, Drowsiness, Nausea, Vomiting, Signs of increased intracranial pressure, Generalized desquamation of the skin (after ca. 24 hours)

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Alcohol-resistant foam
Dry chemical
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : None known.

5.3 Advice for firefighters

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

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

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

6.1 Personal precautions, protective equipment and emergency procedures

Evacuate personnel to safe areas.
Use personal protective equipment.
Ensure adequate ventilation.

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : Avoid exposure - obtain special instructions before use.
For personal protection see section 8.
Dispose of rinse water in accordance with local and national regulations.
Handle under inert gas.
Smoking, eating and drinking should be prohibited in the application area.
- Advice on protection against fire and explosion : Take necessary action to avoid static electricity discharge.
Product will burn under fire conditions.
- Hygiene measures : When using do not eat or drink. When using do not smoke.
Avoid contact with skin, eyes and clothing.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : 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	0.37 mg/m ³	DSM Internal Limit
	established for men			

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

	TWA	0.09 mg/m ³	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 ³
Exposure time: 8 h				

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

Substance name	Environmental Compartment	Value
retinyl palmitate	Fresh water	0.1 mg/l
	Fresh water sediment	
The equilibrium partitioning method is not applicable.		
	Marine water	0.01 mg/l
	Marine sediment	
The equilibrium partitioning method is not applicable.		
	Soil	
The equilibrium partitioning method is not applicable.		
	Sewage treatment plant	10 mg/l

8.2 Exposure controls

Personal protective equipment

- Eye protection : Safety glasses with side-shields
- Hand protection : Consider the hazard characteristics of this product and any special workplace conditions when selecting the appropriate type of protective gloves.
Glove material: for example nitrile rubber
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Respiratory protection : In the case of vapour formation use a respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : oily liquid
- Colour : yellow - brownish
- Odour : No information available.
- Odour Threshold : No information available.
- pH : No data available

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

Melting point/range	: not determined
Boiling point/boiling range	: not determined
Flash point	: ca. 195 °C (DIN 51758) Test performed using a similar product.
Evaporation rate	: not determined
Lower explosion limit	: not determined
Upper explosion limit	: not determined
Vapour pressure	: not determined
Relative vapour density	: Not applicable
Density	: not determined
Water solubility	: insoluble
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Ignition temperature	: ca. 355 °C (DIN 51794) Test performed using a similar product.
Thermal decomposition	: No data available
Viscosity, dynamic	: not determined
Explosive properties	: Not explosive
Oxidizing properties	: No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No hazards to be specially mentioned.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

Heat
Exposure to air.

10.5 Incompatible materials

Oxidizing agents
Strong acids and strong bases

10.6 Hazardous decomposition products

No decomposition if used as directed.

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
(Calculation method)
- Skin irritation
retinyl palmitate : Mild skin irritation (Rabbit, OECD Test Guideline 404)

no phototoxic skin reaction (Guinea pig)
- 3,4-dihydro-2,5,7,8-
tetramethyl-2-(4,8,12-
trimethyltridecyl)-2H-
benzopyran-6-ol : Mild skin irritation (Rabbit)
- Eye irritation
3,4-dihydro-2,5,7,8-
tetramethyl-2-(4,8,12-
trimethyltridecyl)-2H-
benzopyran-6-ol : slight irritation (Rabbit, Draize Test)
temporary redness
- Sensitisation : 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)
Test substance: active ingredient
- Genotoxicity in vivo
retinyl palmitate : not genotoxic (In vivo micronucleus test, Mouse)
- Carcinogenicity : No indication for carcinogenicity known.
- Teratogenicity
retinyl palmitate : Teratogenic
embryotoxic
(several species)
- STOT - single exposure (A-
cute exposure) : The substance or mixture is not classified as specific target
organ toxicant, single exposure.
- STOT - repeated exposure : This information is not available.

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

Experience with human exposure
retinyl palmitate : RDA (Recommended Daily Allowance) 0.8 mg pure vitamin A (retinol) per day established for men
RDA (Recommended Daily Allowance) ca. 0.7 mg pure vitamin A (retinol) per day established for women

Experience with human exposure: Ingestion
retinyl palmitate : Acute overdose produces the following symptoms: Headache, Irritability, Tiredness, Drowsiness, Nausea, Vomiting, Signs of increased intracranial pressure, Generalized desquamation of the skin (after ca. 24 hours)

Further information
retinyl palmitate : Danger of cumulative effects.

Aspiration toxicity : No aspiration toxicity classification

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to algae : Desmodesmus subspicatus (green algae)
ErC50 (72 h) 153 mg/l
Test substance: Active ingredient
(nominal concentration)
(DIN 38412)

12.2 Persistence and degradability

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

3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol : Not readily biodegradable.
8 % (28 d)
(OECD Test Guideline 301F)

Photodegradation
retinyl palmitate : Decomposes rapidly in contact with light.

No data is available on the product itself.

12.3 Bioaccumulative potential

Bioaccumulation : No data available

Partition coefficient: n-octanol/water : Not applicable

12.4 Mobility in soil

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

Distribution among environmental compartments : No data available

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.

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

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

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

Not applicable for product as supplied.

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

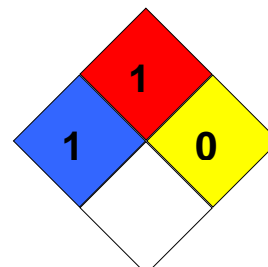
Revision Date 14.07.2017

Print Date 06.08.2019

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.

SECTION 16: Other information

Full text of H-Statements

H317 : May cause an allergic skin reaction.
H360D : May damage the unborn child.
H413 : May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Aquatic Chronic : Chronic aquatic toxicity
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

**Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)****5008530**

Version 7.0

Revision Date 14.07.2017

Print Date 06.08.2019

Annex

	Title of Exposure Scenario
ES 1:	Formulation liquid (retinyl palmitate - pure substance)
ES 2:	Formulation solid (retinyl palmitate - pure substance)
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 (retinyl palmitate - pure substance)

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.
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 m ³ /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 ³	<= 0.045

see above	ECETOC TRA	Worker (Pro- fessional)	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

ES 2: Formulation solid (retinyl palmitate - pure substance)

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.

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 ³ /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 %)

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

Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Date of last issue: 06.07.2015

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 Scenario	Exposure Assessment Meth-	Specific conditions	Compartment	Value	Level of Exposure (PEC)	RCR

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Vitamin A Palmitate/M 1.0 MIU/g (stabilized with tocopherol)

5008530

Version 7.0

Revision Date 14.07.2017

Date of last issue: 06.07.2015

	od					
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