

Safety Data Sheet

BASF Safety data sheet according to Regulation (EC) No. 1907/2006 as amended from time to time.
Date / Revised: 04.06.2018
Product: **Vitamin A-Palmitate 1.0 Mio IU/G stabilized with Tocopherol**

Version: 3.0

SECTION 1: Identification of the substance/mixture

1.1. Product identifier

Vitamin A-Palmitate 1.0 Mio IU/G stabilized with Tocopherol

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

Relevant identified uses: food additive(s)

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

According to Regulation (EC) No 1272/2008 [CLP

Skin Sens. 1B

Repr. 1B (unborn child)

Aquatic Chronic 4

H317, H360D, H413

For the classifications not written out in full in this section the full text can be found in section 16.

2.2. Label elements

Globally Harmonized System, EU (GHS)

Pictogram:



Signal Word:

Danger

Hazard Statement:

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

Precautionary Statements (Prevention):

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P273	Avoid release to the environment.
P202	Do not handle until all safety precautions have been read and understood.
P272	Contaminated work clothing should not be allowed out of the workplace.

Precautionary Statements (Response):

P308 + P311	IF exposed or concerned: Call a POISON CENTER or doctor/physician.
P303 + P352	IF ON SKIN (or hair): Wash with plenty of soap and water.
P333 + P311	If skin irritation or rash occurs: Call a POISON CENTER or doctor/physician.
P362 + P364	Take off contaminated clothing and wash it before reuse.

Precautionary Statements (Storage):

P405	Store locked up.
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Precautionary Statements (Disposal):

P501	Dispose of contents/container to hazardous or special waste collection point.
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According to Regulation (EC) No 1272/2008 [CLP]

Hazard determining component(s) for labelling: Retinyl palmitate, 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol

2.3. Other hazards

According to Regulation (EC) No 1272/2008 [CLP]

When finely distributed, self-ignition is possible. The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

SECTION 3: Composition/Information on Ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Chemical nature

Preparation based on: Retinyl palmitate dissolved in: Sunflower oil stabilized with: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol

Hazardous ingredients (GHS)
according to Regulation (EC) No. 1272/2008

Retinyl palmitate

Content (W/W): $\geq 50\%$ - $< 75\%$	Repr. 1B (unborn child)
CAS Number: 79-81-2	Aquatic Chronic 4
EC-Number: 201-228-5	H360D, H413
REACH registration number: 01-2119480425-37	

3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol

Content (W/W): $\geq 1\%$ - $< 3\%$	Skin Sens. 1B
CAS Number: 10191-41-0	H317
EC-Number: 233-466-0	
REACH registration number: 01-2120086658-39	

For the classifications not written out in full in this section, including the hazard classes and the hazard statements, the full text is listed in section 16.

SECTION 4: First-Aid Measures

4.1. Description of first aid measures

First aid personnel should pay attention to their own safety. If the patient is likely to become unconscious, place and transport in stable sideways position (recovery position). Immediately remove contaminated clothing.

If inhaled:

Keep patient calm, remove to fresh air, seek medical attention.

On skin contact:

Immediately wash thoroughly with soap and water, seek medical attention.

On contact with eyes:

Wash affected eyes for at least 15 minutes under running water with eyelids held open.

On ingestion:

Immediately rinse mouth and then drink 200-300 ml of water, seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms: The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11., Further important symptoms and effects are so far not known.

4.3. Indication of any immediate medical attention and special treatment needed

Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

SECTION 5: Fire-Fighting Measures

5.1. Extinguishing media

Suitable extinguishing media:
water spray, carbon dioxide, dry powder, foam

Unsuitable extinguishing media for safety reasons:
water jet

5.2. Special hazards arising from the substance or mixture

acrylaldehyde; acrolein; prop-2-enal, carbon oxides, harmful vapours
The substances/groups of substances mentioned can be released in case of fire. Evolution of fumes/fog.

5.3. Advice for fire-fighters

Special protective equipment:

Wear self-contained breathing apparatus and chemical-protective clothing.

Further information:

In case of combustion evolution of toxic gases/vapours possible. Cool endangered containers with water-spray. Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective clothing. Information regarding personal protective measures see, section 8. Ensure adequate ventilation. Do not breathe vapour/aerosol/spray mists. Avoid contact with the skin, eyes and clothing.

6.2. Environmental precautions

Do not discharge into drains/surface waters/groundwater. Inform authorities in the event of product spillage to water courses or sewage systems.

6.3. Methods and material for containment and cleaning up

For small amounts: Pick up with suitable absorbent material. After taking up material in containers, cover immediately with water layer.

For large amounts: Dike spillage. Pump off product.

Dispose of absorbed material in accordance with regulations. Mop up spills with non-flammable adsorbents (e.g. vermiculite, spill mats). Soiled textiles / cleaning rags / adsorbents and Silica are capable of self ignition and should be wetted with water and must be disposed of in a safe manner.

6.4. Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Avoid aerosol formation. Wear suitable protective clothing and eye/face protection. Avoid contact with the skin, eyes and clothing. Keep container tightly sealed. Ensure that there is no crystallized product in the container before use. Processing machines must be fitted with local exhaust ventilation.

Protection against fire and explosion:

Risk of self-ignition when a large surface area is produced due to fine dispersion. Soiled textiles / cleaning rags / adsorbents and Silica are capable of self-ignition and should be wetted with water and must be disposed of in a safe manner. Take precautionary measures against static discharges. Avoid all sources of ignition: heat, sparks, open flame. If exposed to fire, keep containers cool by spraying with water.

Control of exposure and risk management measures

Emission factor air:	5 %
Emission factor water:	0.003 %
Emission factor soil:	0 %

Exposure estimate and reference to its source

Assessment method:	ECETOC TRA v2.0 Environment
Maximum amount of safe use:	100,000 kg/d
Remarks:	Risk from environmental exposure is driven by marine water.

7.2. Conditions for safe storage, including any incompatibilities

Segregate from oxidants.

Suitable materials for containers: High density polyethylene (HDPE), Low density polyethylene (LDPE)

Further information on storage conditions: Keep container tightly closed and dry; store in a cool place. Protect from air. Protect from the effects of light. Keep under nitrogen.

7.3. Specific end use(s)

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

Components with occupational exposure limits

No occupational exposure limits known.

PNEC

Data refer to the lead substance

Components with PNEC

79-81-2: Retinyl palmitate

freshwater:	0.1 mg/l
marine water:	0.01 mg/l
intermittent release:	1 mg/l
sediment (freshwater):	595000 mg/kg
sediment (marine water):	5950000 mg/kg
soil:	2100000 mg/kg
STP:	10 mg/l

DNEL

Data refer to the lead substance

Components with DNEL

79-81-2: Retinyl palmitate

worker: Long-term exposure- systemic effects, dermal: 1.6 mg/kg

8.2. Exposure controls

Personal protective equipment

Respiratory protection:

Respiratory protection in case of vapour/aerosol release. Particle filter with high efficiency for solid and liquid particles (e.g., EN 143 or 149, Type P3 or FFP3).

Hand protection:

Wear chemically resistant gloves in combination with 'basic' employee training.

Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g., nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) etc. Supplementary note: The specifications are based on tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the permeation time determined through testing. Manufacturer's directions for use should be observed because of great diversity of types.

Eye protection:

Safety glasses with side-shields (frame goggles) (e.g., EN 166)

Body protection:

Body protection must be chosen depending on activity and possible exposure, e.g., apron, protecting boots, chemical-protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust).

General safety and hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is required additionally to the stated personal protection equipment. Under no circumstances should the product come into contact with the skin of pregnant women or be inhaled by them. Avoid contact with skin. No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

Environmental exposure controls

Do not discharge product into the environment without control.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Form:	oily
Colour:	yellow
Odour:	mild
Odour threshold:	Not determined due to potential health hazard by inhalation.
pH value:	insoluble not determined
Freezing point:	The substance / product decomposes therefore not determined

Flash point:	> 100 °C	(DIN 51758)
Evaporation rate:		
Flammability:	negligible	
Lower explosion limit:	hardly combustible	
Upper explosion limit:	For liquids not relevant for classification and labelling.	
Ignition temperature:	For liquids not relevant for classification and labelling.	
Vapour pressure:	approx. 265 °C	(DIN 51794)
Density:	negligible	
Relative vapour density (air):	0.88 g/cm ³ (20 °C)	
Solubility in water:	negligible	
Solubility (qualitative) solvent(s):	insoluble	
Partitioning coefficient n-octanol/water (log Kow):	hydrocarbons, chlorinated hydrocarbons, ether, fats, oils	
Self ignition:	soluble	
Thermal decomposition:	not applicable for mixtures	
Viscosity, dynamic:	Risk of self-ignition when a large surface area is produced due to fine dispersion.	
Explosion hazard:	No decomposition if stored and handled as prescribed/indicated.	
Fire promoting properties:	27 mPa.s (60 °C)	
	Based on the chemical structure there is no indicating of explosive properties.	
	Based on its structural properties the product is not classified as oxidizing.	

9.2. Other information

Self-heating ability:	not applicable, the product is a liquid
Grain size distribution:	The substance / product is marketed or used in a non-solid or granular form.

SECTION 10: Stability and Reactivity

10.1. Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

Corrosion to metals: Corrosive effects to metal are not anticipated.

10.2. Chemical stability

The product is stable if stored and handled as prescribed/indicated.

10.3. Possibility of hazardous reactions

When finely distributed, self-ignition is possible.

10.4. Conditions to avoid

Avoid light. Avoid all sources of ignition: heat, sparks, open flame. Avoid electro-static charge. See MSDS section 7 - Handling and storage.

10.5. Incompatible materials

Substances to avoid:
atmospheric oxygen, atmospheric moisture

10.6. Hazardous decomposition products

Hazardous decomposition products:
No hazardous decomposition products if stored and handled as prescribed/indicated.

SECTION 11: Toxicological Information

11.1. Information on toxicological effects

Acute toxicity

Assessment of acute toxicity:
Virtually nontoxic after a single ingestion.

Information on: Retinyl palmitate

*Experimental/calculated data:
LD50 rat (oral): > 2,000 mg/kg (BASF-Test)
No mortality was observed. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.*

Irritation

Assessment of irritating effects:
Skin contact causes slight irritation. May cause slight irritation to the eyes.

*Information on: Retinyl palmitate
Assessment of irritating effects:
Not irritating to the eyes. May cause slight irritation to the skin.*

*Information on: Sunflower oil
Assessment of irritating effects:
May cause slight irritation to the skin. May cause slight irritation to the eyes. May cause slight irritation to the respiratory tract. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.*

*Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol
Assessment of irritating effects:
Not irritating to the skin. Not irritating to the eyes.*

Respiratory/Skin sensitization

Assessment of sensitization:
May cause sensitization by skin contact.

The Essentially Natural Domain (Pty) Ltd | Reg. No. 2014/170069/07
Unit 14, Duville Business Park, 8 Arum Lily Street, Durbanville, Cape Town, South Africa 7550
www.essentiallynatural.co.za (T) 021 976 9116 (E) support@essentiallynatural.co.za

Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol
Assessment of sensitization:
Caused skin sensitization in animal studies.

Germ cell mutagenicity

Assessment of mutagenicity:
Based on available Data, the classification criteria are not met.

Information on: Retinyl palmitate
Assessment of mutagenicity:
In the majority of tests performed (bacteria/microorganisms/cell cultures) a mutagenic effect was not found. A mutagenic effect was also not observed in in-vivo assays. The product has not been fully tested. The statements have been derived in parts from products of a similar structure or composition.

Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol
Assessment of mutagenicity:
Results from a number of mutagenicity studies with microorganisms, mammalian cell culture and mammals are available. Taking into account all of the information, there is no indication that the substance is mutagenic.

Carcinogenicity

Assessment of carcinogenicity:
Based on available Data, the classification criteria are not met.

Information on: Retinyl palmitate
Assessment of carcinogenicity:
Results from a number of long-term carcinogenicity studies and short-term tests are available. Taking into account all of the information, there is no indication that the substance itself is carcinogenic. Literature data.

Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol
Assessment of carcinogenicity:
In long-term studies in rats in which the substance was given by feed, a carcinogenic effect was not observed. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Reproductive toxicity

Assessment of reproduction toxicity:
Not classified, due to lack of data.

Developmental toxicity

Assessment of teratogenicity:
May cause harm to the unborn child.

Information on: Retinyl palmitate
Assessment of teratogenicity:
May cause harm to the unborn child.

Specific target organ toxicity (single exposure)

Assessment of STOT single:

Based on available Data, the classification criteria are not met.

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)

Assessment of repeated dose toxicity:

Based on available Data, the classification criteria are not met.

Information on: Retinyl palmitate

Assessment of repeated dose toxicity:

Repeated exposure to large quantities may affect certain organs.

Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol

Assessment of repeated dose toxicity:

Repeated oral uptake of the substance did not cause substance-related effects.

Aspiration hazard

No data available.

Other relevant toxicity information

The product has not been tested. The statements on toxicology have been derived from the properties of the individual components.

SECTION 12: Ecological Information

12.1. Toxicity

Assessment of aquatic toxicity:

There is a high probability that the product is not acutely harmful to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Information on: Retinyl palmitate

Toxicity to fish:

*LC50 (96 h) > 10,000 mg/l, *Leuciscus idus* (DIN 38412 Part 15, static)*

The details of the toxic effect relate to the nominal concentration. The product has not been tested.

The statement has been derived from substances/products of a similar structure or composition.

Information on: Sunflower oil

Toxicity to fish:

*LC50 (96 h) > 1,000 mg/l, *Brachydanio rerio**

The details of the toxic effect relate to the nominal concentration.

Information on: Retinyl palmitate

Aquatic invertebrates:

*EC50 (48 h) > 100 mg/l, *Daphnia magna* (Screening test, static)*

The details of the toxic effect relate to the nominal concentration. The product has not been tested.

The statement has been derived from substances/products of a similar structure or composition.

Information on: Sunflower oil

Aquatic invertebrates:

EC50 (48 h) > 100 mg/l, Daphnia magna

The details of the toxic effect relate to the nominal concentration.

Information on: Retinyl palmitate

Aquatic plants:

EC50 (72 h) 152.94 mg/l (growth rate), Scenedesmus subspicatus (DIN 38412 Part 9, static)

The product has low solubility in the test medium. An aqueous solution prepared with solubilizers has been tested.

Information on: Sunflower oil

Aquatic plants:

EC50 > 100 mg/l, algae

The details of the toxic effect relate to the nominal concentration.

Information on: Retinyl palmitate

Microorganisms/Effect on activated sludge:

EC20 (30 min) > 1,000 mg/l, activated sludge, domestic (DIN EN ISO 8192-OECD 209-88/302/EEC, P. C, aerobic)

12.2. Persistence and degradability

Information on: Retinyl palmitate

Assessment biodegradation and elimination (H2O):

Not readily biodegradable (by OECD criteria). Moderately/partially biodegradable.

Information on: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol

Assessment biodegradation and elimination (H2O):

Not readily biodegradable (by OECD criteria). Biodegradable. -

12.3. Bioaccumulative potential

Information on: Retinyl palmitate

Assessment bioaccumulation potential:

The product will not be readily bioavailable due to its consistency and insolubility in water. No significant accumulation in organisms is expected as a result of the distribution coefficient of n-octanol/water (log Pow).

Information on: Sunflower oil

Bioaccumulation potential:

Because of the n-octanol/water distribution coefficient (log Pow) accumulation in organisms is possible.

12.4. Mobility in soil

Information on: Retinyl palmitate

Assessment transport between environmental compartments:

Volatility: The substance will not evaporate into the atmosphere from the water surface.

Adsorption in soil: Adsorption to solid soil phase is expected.

12.5. Results of PBT and vPvB assessment

According to Annex XIII of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Self classification

12.6. Other adverse effects

The product does not contain substances that are listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

12.7. Additional information

Other ecotoxicological advice:

The product has not been tested. The statements on ecotoxicology have been derived from the properties of the individual components.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods

Observe national and local legal requirements.

The UK Environmental Protection (Duty of Care) Regulations (EP) and amendments should be noted (United Kingdom).

This product and any uncleaned containers must be disposed of as hazardous waste in accordance with the 2005 Hazardous Waste Regulations and amendments (United Kingdom)

SECTION 14: Transport Information

Land transport

ADR

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

RID

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

Inland waterway transport

ADN	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user:	None known

Transport in inland waterway vessel

Not evaluated

Sea transport

IMDG

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user:	None known

Air transport

IATA/ICAO

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user:	None known

14.1. UN number

See corresponding entries for "UN number" for the respective regulations in the tables above.

14.2. UN proper shipping name

See corresponding entries for "UN proper shipping name" for the respective regulations in the tables above.

14.3. Transport hazard class(es)

See corresponding entries for "Transport hazard class(es)" for the respective regulations in the tables above.

14.4. Packing group

See corresponding entries for "Packing group" for the respective regulations in the tables above.

14.5. Environmental hazards

See corresponding entries for "Environmental hazards" for the respective regulations in the tables above.

14.6. Special precautions for user

See corresponding entries for "Special precautions for user" for the respective regulations in the tables above.

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

Regulation:	Not evaluated
Shipment approved:	Not evaluated
Pollution name:	Not evaluated
Pollution category:	Not evaluated
Ship Type:	Not evaluated

SECTION 15: Regulatory Information

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

Prohibitions, Restrictions and Authorizations

Annex XVII of Regulation (EC) No 1907/2006: Number on List: 3

If other regulatory information applies that is not already provided elsewhere in this safety data sheet, then it is described in this subsection.

The data should be considered when making any assessment under the Control of Substances Hazardous to Health Regulations (COSHH), and related guidance, for example, 'COSHH Essentials' (United Kingdom).

15.2. Chemical Safety Assessment

Assessment of safe use has been performed for the mixture and the result is documented in section 7 and 8 of the SDS

SECTION 16: Other Information

Assessment of the hazard classes according to UN GHS criteria (most recent version)

Skin Corr./Irrit. 3
Skin Sens. 1B
Aquatic Chronic 4
Repr. 1B (unborn child)

Any other intended applications should be discussed with the manufacturer. Corresponding occupational protection measurements must be followed.

Full text of the classifications, including the hazard classes and the hazard statements, if mentioned in section 2 or 3:

Skin Sens.	Skin sensitization
Repr.	Reproductive toxicity
Aquatic Chronic	Hazardous to the aquatic environment - chronic
H317	May cause an allergic skin reaction.
H360D	May damage the unborn child.
H413	May cause long lasting harmful effects to aquatic life.