

Material safety data sheet
According to EU Regulation 1907/2006 in the current version
Vitamin A Palmitate

1. Identification of the substance/mixture and company

Trade name: Vitamin A Palmitate
Min. 1.0 million IU vitamin A (=300,000 RE) per gram
INCI Retinyl palmitate, Helianthus annuus seed oil, Tocopherol
CAS No. : 79-81-2
EINECS No. : 201-228-5
REACH pre-registration No. : -
Utilization: Raw material for cosmetic or professional use
Supplier company identification: Elemental SRL, Piața Cazărmii no.15, 410188-Oradea, jud.Bihor, Romania
Tel/Fax: +40259-436.755, www.elemental.eu
Emergency: RO: număr național pentru cazuri de urgență: 021 3183606 Institutul de Sănătate Publică București.
International emergency number: +49 180 2273-112

2. Hazards Identification

2.1 Classification of the substance or mixture

According to UN GHS criteria:

Skin Corr./Irrit. 3

Skin Sens. 1B

Repr. 1B (unborn child)

Aquatic Chronic 4

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 (GHS):



Pictogram:

Signal Word: Danger

Hazard Statement:

H316 Causes mild skin irritation.

H317 May cause an allergic skin reaction.

H360 May damage the unborn child.

H413 May cause long lasting harmful effects to aquatic life.

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Precautionary Statements (Prevention):

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
P201 Obtain special instructions before use.
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):

P303 + P361 IF ON SKIN (or hair): Wash with plenty of soap and water.
P308 + P311 IF exposed or concerned: Call a POISON CENTER or doctor/physician.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P332 + P313 If skin irritation occurs: Get medical advice/attention.

Precautionary Statements (Storage):

P405 Store locked up.

Precautionary Statements (Disposal):

P501 Dispose of contents/container to hazardous or special waste collection point.

According to UN GHS criteria:

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

Other hazards according to UN GHS criteria:

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.

3. Declaration of 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 UN GHS criteria:

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Substance	CAS	EINECS/EC	Hazard symbols	Percent %
Retinyl palmitate	79-81-2	201-228-5	Skin Corr./Irrit. 3 Repr. 1B (unborn child) Aquatic Chronic 4 H316, H360, H413	>= 50 - < 75
3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	10191-41-0	233-466-0	Skin Sens. 1B H317	>= 1 - < 3

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

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, consult an eye specialist.

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 labeling (see section 2) and/or in section 11, (Further) symptoms and / or effects are not known so far.

4.3 Indication of any immediate medical attention and special treatment needed

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

5. Fire fighting measures

5.1 Extinguishing media

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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, carbon oxides, harmful vapors. 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.

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 vapor/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.

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.

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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.

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.

8. Exposure controls / personal protection

8.1 Control parameters

Components with occupational exposure limits: 8001-21-6: Sunflower oil

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: 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:

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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.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form: oily
Color: yellow
Odor: mild
Odor threshold: Not determined due to potential health hazard by inhalation.
pH value: not determined
Freezing point: not determined
Boiling point: The substance / product decomposes therefore not determined.
Flash point: > 100 °C (DIN 51758)
Evaporation rate: negligible
Flammability: hardly combustible (derived from flash point)
Lower explosion limit: For liquids not relevant for classification and labeling.
Upper explosion limit: For liquids not relevant for classification and labeling.
Ignition temperature: approx. 265 °C (DIN 51794)
Vapor pressure: negligible
Density: 0,88 g/cm³ (20 °C)
Relative vapor density (air): negligible
Solubility in water: insoluble
Solubility (qualitative) solvent(s): soluble in hydrocarbons, chlorinated hydrocarbons, ether, fats, oils
Partitioning coefficient n-octanol/water (log K_{ow}): not applicable for mixtures
Self ignition: Risk of self-ignition when a large surface area is produced due to fine dispersion.
Thermal decomposition: No decomposition if stored and handled as prescribed/indicated.
Viscosity, dynamic: 27 mPa.s (60°C)
Explosion hazard: Based on the chemical structure there is no indicating of explosive properties.
Fire promoting properties: Based on its structural properties the product is not classified as oxidizing.

9.1 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.

10. Stability and reactivity

10.1 Reactivity

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

10.2 Possibility of hazardous reactions

When finely distributed, self-ignition is possible.

10.3 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.

10.4 Incompatible materials

Substances to avoid: atmospheric oxygen, atmospheric moisture

10.5 Hazardous decomposition products

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

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.

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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.
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Respiratory/Skin sensitization:
Assessment of sensitization: May cause sensitization by skin contact.

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.
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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.

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

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Aspiration hazard:
No data available.

11.2 Other relevant toxicity information:

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

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, <i>Leuciscus idus</i> (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, <i>Brachydanio rerio</i>
		The details of the toxic effect relate to the nominal concentration.
Information on: Retinyl palmitate	Aquatic invertebrates:	EC50 (48 h) > 100 mg/l, <i>Daphnia magna</i> (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, <i>Daphnia magna</i>
		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), <i>Scenedesmus subspicatus</i> (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)

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12.2 Persistence and degradability

Information on: Retinyl palmitate	Assessment biodegradation and elimination (H ₂ O):	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 (H ₂ O):	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: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	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 Other adverse effects

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

12.6 Additional information

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

13. Disposal considerations

13.1. Waste treatment methods

Observe national and local legal requirements.

14. Transport information

14.1. UN number

NA

14.2. UN proper shipping name

NA

14.3. Transport hazard class(es)

NA

14.4. Packing group

NA

14.5. Environmental hazards

NA

14.6. Special precautions for user

NA

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

NA

15. Regulatory information

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

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

16. Additional information

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

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16.1 Full text of classifications, hazard symbols and hazard statements, if mentioned in section 2 or 3

Skin Corr./Irrit. Skin corrosion/irritation
Skin Sens. Skin sensitization
Repr. Reproductive toxicity
Aquatic Chronic Hazardous to the aquatic environment - chronic
H316 Causes mild skin irritation.
H360 May damage the unborn child.
H413 May cause long lasting harmful effects to aquatic life.
H317 May cause an allergic skin reaction.

16.2 Abbreviations

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS: Chemical Abstracts Service (division of the American Chemical Society).
CLP: Classification, Labeling, Packaging.
DNEL: Derived No Effect Level.
EINECS: European Inventory of Existing Commercial Chemical Substances.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IATA: International Air Transport Association.
IATA-DGR: Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO: International Civil Aviation Organization.
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG: International Maritime Code for Dangerous Goods.
INCI: International Nomenclature of Cosmetic Ingredients.
LTE: Long-term exposure.
PNEC: Predicted No Effect Concentration.
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail.
STE: Short-term exposure.
STEL: Short Term Exposure limit.
STOT: Specific Target Organ Toxicity.

Disclaimer:

This material safety data sheet does not constitute a guarantee of the properties of the product and is not a contractual legal report. The information is given in good faith on the basis of our best knowledge of the product at the indicated time. However, we cannot accept responsibility or liability for any consequences arising from its use, no warranty for correctness and completeness is given. We caution the users against the incurred possible risks when the product is used at other ends than the use for which it was initially planned. It is the user's responsibility during handling, storage and product use to consult the main regulatory texts in force regarding workers and environment protection.