

Vitamin A palmitate (ca. 1 mio i.u/g)

Safety Data Sheet

646407

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 2.1

Date of issue: 09/09/2014 Revision date: 07/12/2017

Supersedes 24/02/2017

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

1.1. Product identifier

Product form : Mixture
 Product name : Vitamin A palmitate (ca. 1 mio i.u/g)
 Product code : 646407

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : Industrial
 For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - The Netherlands
 T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31(0)23-5319093 (M-F 09:00-17:00)
 +31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Reproductive toxicity, Category 1A H360D

Full text of hazard classes and H-statements : see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Repr.Cat.1; R61

Full text of R-phrases: see section 16

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Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS08

Signal word (CLP)

: Danger

Hazardous ingredients

: Retinolpalmitat

Hazard statements (CLP)

: H360D - May damage the unborn child

Precautionary statements (CLP)

: P202 - Do not handle until all safety precautions have been read and understood
 P280 - Wear protective gloves/protective clothing/eye protection/face protection
 P308+P313 - IF exposed or concerned: Get medical advice/attention

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : DL-alpha-tocopherol 1.5%, peanut oil: 43.5%

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Retinolpalmitat	(CAS-No.) 97-81-2 (EC-No.) 204-884-2 (EC Index-No.) 201-228-5	55	Repr.Cat.1; R61	Repr. 1A, H360D

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

: Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention.

First-aid measures after inhalation

: Assure fresh air breathing. Allow the victim to rest. Seek medical advice (show the label where possible).

First-aid measures after skin contact

: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

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- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. Ensure adequate flushing of eyes by separating eyelids with the fingers.
- First-aid measures after ingestion : Rinse mouth. Drink plenty of water. Obtain emergency medical attention. Induce vomiting if person is conscious.

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

- Symptoms/effects : May damage the unborn child.

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

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Do not breathe gas/fumes/vapour/spray.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

Reference to other sections (8, 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Unopened container before use heat in a water bath at +65 ° C to +70 ° C with occasional shaking.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : TRGS 514 "Storage of toxic and very toxic substances ..." observe.
Storage conditions : Keep container closed when not in use. Keep only in the original container in a cool, well-ventilated place. Store under nitrogen.
Incompatible materials : Direct sunlight.
Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Wear appropriate mask. Dustmask with filtertype P3

Other information:

Do not eat, drink or smoke during use. Wash hands before break and at end of works. May damage fertility. May damage the unborn child.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Liquid
Colour	: Yellow.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 0.95 g/cm ³
Solubility	: Slightly miscible.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Oxidizing agent. Bases. acids. Oxygen. copper. Iron.

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10.6. Hazardous decomposition products

release of harmful/irritant gases/vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

LD/LC50-values relevant for classification	2500 mg / kg mouse; retinol acetate oral 2740 mg / kg rat 4100 mg / kg mouse
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Skin corrosion/irritation : Not classified

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified

Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : May damage the unborn child.

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Vitamin A palmitate (ca. 1 mio i.u/g)	
LC50 fish 1	43 mg/l 96 h.
EC50 Daphnia 1	46 mg/l 48 h.

12.2. Persistence and degradability

Vitamin A palmitate (ca. 1 mio i.u/g)	
Persistence and degradability	Not readily biodegradable.

12.3. Bioaccumulative potential

Vitamin A palmitate (ca. 1 mio i.u/g)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

Vitamin A palmitate (ca. 1 mio i.u/g)	
Ecology - soil	Poorly soluble in water.

12.5. Results of PBT and vPvB assessment

No additional information available

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12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

No data available

- Air transport

No data available

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

No additional information available

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15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
7.2	Storage temperature	Modified	Storage condition altered to ambient
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Respiratory protection	Modified	Added additional information (type of clothing related to concentration levels)
8.2	Appropriate engineering controls	Added	

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : REACH Disclaimer:
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

Full text of R-, H- and EUH-statements:

Repr. 1A	Reproductive toxicity, Category 1A
H360D	May damage the unborn child
R61	May cause harm to the unborn child

SDS EU (REACH Annex II) Version 2017

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product