Safety data sheet

1. Identification

Product identifier

Vitamin A-Palmitate 1.7

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

Relevant identified uses: feed additive(s), food additive(s), cosmetic ingredient

Details of the supplier of the safety data sheet

Company: RAWPHARMA BIZ PVT LTD 1101-CITY CENTRE-2 SCIENCE CITY ROAD, SOLA AHMEDABAD, 380060 GUJARAT, INDIA.

Telephone: 8320310672

E-mail address: info@rawpharmabiz.com

Website: www.rawpharmabiz.com

2. Hazards Identification

Classification of the substance or mixture

According to UN GHS criteria

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

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

Label elements

Globally Harmonized System (GHS)

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Signal Word: Danger Hazard Statement: H316 Causes mild skin irritation. H360 May damage the unborn child. H412 Harmful to aquatic life with long lasting effects. H402 Harmful to aquatic life. Precautionary Statements (Prevention): P280 Wear protective gloves/protective clothing/eye protection/face protection. 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. Precautionary Statements (Response): IF exposed or concerned: Call a POISON CENTER or doctor/physician. P332 + P308 + P311 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 labelling: Retinyl palmitate

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/bio accumulative/toxic) criteria or the vPvB (very persistent/very bio accumulative) criteria.

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3. Composition/Information on Ingredients Substances

Not applicable

Mixtures

Chemical nature

Retinyl palmitate

stabilized with 2,6-di-tert-Butyl-p-cresol

Hazardous ingredients (GHS)

According to UN GHS criteria

Retinyl palmitate

Content (W/W): >= 75 % - <= 100	Skin Corr./Irrit. 3
%	Repr. 1B (unborn child)
CAS Number: 79-81-2	Aquatic Chronic 4
EC-Number: 201-228-5	H316, H360, H413

2,6-di-tert-Butyl-p-cresol

Content (W/W): >= 1 % - < 2,5 %	Aquatic Acute 1
CAS Number: 128-37-0	Aquatic Chronic 1
EC-Number: 204-881-4	M-factor chronic: 1
	H400, H410

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

4. First-Aid Measures

Description of first aid measures Remove contaminated clothing.

If inhaled: Keep patient calm, remove to fresh air.

On skin contact: Wash off thoroughly with ample water. Consult a doctor if skin irritation persists.

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.

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.

Indication of any immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions).

5. Fire-Fighting Measures

Extinguishing media

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

Unsuitable extinguishing media for safety reasons: water jet

Special hazards arising from the substance or mixture

Burning produces harmful and toxic fumes.

Advice for fire-fighters Special protective equipment: Wear a self-contained breathing apparatus.

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Further information: Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental Release Measures

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Personal precautions, protective equipment, and emergency procedures

Handle in accordance with good industrial hygiene and safety practice.

Environmental precautions

Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

For small amounts: Pick up with suitable absorbent material (e.g., sand, sawdust, general-purpose binder, kieselguhr). Sweep/shovel up. After taking up material in containers, cover immediately with water layer.

For large amounts: Dike spillage. Vacuum up spilled product. Dispose of absorbed material in accordance with regulations.

7. Handling and Storage

Precautions for safe handling

Avoid aerosol formation. Processing machines must be fitted with local exhaust ventilation. Ensure that there is no crystallized product in the container before use.

Protection against fire and explosion:

Risk of self-ignition when a large surface area is produced due to fine dispersion. Take precautionary measures against static discharges. Avoid all sources of ignition: heat, sparks, open flame.

Conditions for safe storage, including any incompatibilities Segregate

from oxidants.

Suitable materials for containers: Stove-lacquer O 360, High density polyethylene (HDPE), Low density polyethylene (LDPE), Aluminum, Polypropylene (PP), Stove-lacquer 42 300 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.

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.

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8. Exposure Controls/Personal Protection

Control parameters

Components with occupational exposure limits

128-37-0: 2,6-di-tert-Butyl-p-cresol

Exposure controls

Personal protective equipment

Respiratory protection:

Respiratory protection in case of vapor/aerosol release. Particle filter with medium efficiency for solid and liquid particles (e.g., EN 143 or 149, Type P2 or FFP2)

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

Under no circumstances should the product come into contact with the skin of pregnant women or be inhaled by them. Handle in accordance with good industrial hygiene and safety practice. 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

Information on basic physical and chemical properties

Form: partially crystallized

Color: yellowish

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duct: Vitamin A-Palmita	ate 1.7 Mio IU/G stabilized with BHT	
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Odor:	aromatic	Date of print 16.04.207
0001.	alomatic	
Odor threshold:		
	Not determined due to potential health hazard by inhalation.	
pH value:	7	
Melting point:	approx. 26 °C	
Boiling point:	approx. 100 °C	(measured)
	The substance / product decomposes.	
Flash point:	194 °C	(DIN EN 22719; ISO 2719, closed cup)
Evaporation rate:		
	Value can be approximated from Henry's Law Constant or vapor pressure.	
Flammability: Lower explosion limit:	hardly combustible	(Derived from flash point)
·	For liquids not relevant for	
	classification and labelling., The	
	lower explosion point may be 5 - 15	
	°C below the flash point.	
Upper explosion limit:		
	For liquids not relevant for classification and labelling.	
Ignition temperature:	261 °C	(DIN EN 14522)
Vapor pressure:	approx. 8 mbar	
	(200 °C)	
Density:	921,1 kg/m3	(pyknometer)
B 1 4 1	(20 °C)	
Relative density:	0,9211	(pyknometer)
Deletion of a description	(20 °C)	
Relative vapor density	(air): not determined	
Calubility in water		
Solubility in water: Solubility (qualitative) s	Study technically not feasible. olvent(s): organic solvents soluble	
Partitioning coefficient	n-octanol/water (log Kow): 15,51 (25 °C)	(calculated)
Thermal decomposition	n: 465 °C (DTA)	
Viscosity, dynamic:	44 mPa.s	
	(60 °C)	
Explosion hazard:	not explosive	
Fire promoting propertie	es: not fire-propagating	

Other information

Self-heating ability: not applicable, the product is a liquid

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 pKA:
 The substance does not dissociate.

 Surface tension:
 Study technically not feasible.

 Grain size distribution:
 The substance / product is marketed or used in a non-solid or granular form.

10. Stability and Reactivity

Reactivity

Corrosion to metals: No corrosive effect on metal. Formation of Remarks: Forms no flammable gases in the flammable gases: presence of water.

Chemical stability

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

Possibility of hazardous reactions

When finely distributed, self-ignition is possible.

Conditions to avoid

> 60 °C Disregard of the conditions mentioned may result in undesirable decomposition reactions.

Incompatible materials

Substances to avoid: oxidizing agents

Hazardous decomposition products

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

11. Toxicological Information

Information on toxicological effects

Acute toxicity

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

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Experimental/calculated data: LD50 rat (oral): > 2.000 mg/kg 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: May cause slight irritation to the skin. Not irritating to the eyes.

Experimental/calculated data: Skin corrosion/irritation rabbit: Slightly irritating. (OECD Guideline 404)

Serious eye damage/irritation rabbit: non-irritant (OECD Guideline 405)

Respiratory/Skin sensitization

Assessment of sensitization: Skin sensitizing effects were not observed in animal studies.

Experimental/calculated data: Guinea pig maximization test guinea pig: non-sensitizing. (OECD Guideline 406)

Germ cell mutagenicity

Assessment of mutagenicity:

In most 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.

Carcinogenicity

Assessment of carcinogenicity: Results from a number of long-term carcinogenetic studies and short-term tests are available. Considering all of the information, there is no indication that the substance itself is carcinogenic. Literature data.

Reproductive toxicity

Assessment of reproduction toxicity: No reliable data are available concerning reproduction toxicity.

Developmental toxicity

Assessment of teratogenicity: The substance caused malformations/developmental toxicity in laboratory animals.

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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: Repeated exposure to large quantities may affect certain organs.

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.

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12. Ecological Information

Toxicity

Assessment of aquatic toxicity: Harmful to aquatic life with long lasting effects.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Information on: 2,6-di-tert-ButyI-p-cresol Assessment of aquatic toxicity:

Very toxic (acute effect) 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: 2,6-di-tert-Butyl-p-cresol Toxicity

to fish:

 $LC0 (96 h) \ge 0.57 mg/l$, Brachydanio rerio (OECD 203; ISO 7346; 84/449/EEC, C.1, semistatic) The statement of the toxic effect relates to the analytically determined concentration. Limit concentration test only (LIMIT test).

Information on: 2,6-di-tert-Butyl-p-cresol Aquatic invertebrates:

EC0 (48 h) 0,48 mg/l, Daphnia magna (OECD Guideline 202, part 1, static) The statement of the toxic effect relates to the analytically determined concentration.

Information on: 2,6-di-tert-Butyl-p-cresol Aquatic plants:

EC50 (72 h) > 0,40 mg/l (growth rate), Scenedesmus subspicatus (Guideline 92/69/EEC, C.3, static) The statement of the toxic effect relates to the analytically determined concentration.

Information on: 2,6-di-tert-Butyl-p-cresol Microorganisms/Effect on activated sludge: EC0 (3 h) 1.000 mg/l, activated sludge (DIN EN ISO 8192-OECD 209-88/302/EEC,P. C, aerobic)

Information on: 2,6-di-tert-Butyl-p-cresol Chronic toxicity to aquatic invertebrates:

No observed effect concentration (21 d) 0,316 mg/l, Daphnia magna (OECD Guideline 202, part 2, semistatic)

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Bio accumulative potential

Bioconcentration factor: 230 - 2.500 (56 d), Cyprinus Carpio (OECD Guideline 305 C)

Mobility in soil

Assessment transport between environmental compartments: Adsorption in soil: Adsorption to solid soil phase is expected.

Information on: 2,6-di-tert-Butyl-p-cresol 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.

Results of PBT and vPvB assessment

According to Annex XIII of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation,

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Authorization and Restriction of Chemicals (REACH): The product does not fulfill the criteria for PBT (Persistent/bio accumulative/toxic) and vPvB (very persistent/very bio accumulative). Self-classification

Other adverse effects

The substance is not listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

Additional information

Other ecotoxicological advice: The product has not been tested. The statement has been derived from the properties of the individual components.

13. Disposal Considerations

Waste treatment methods

Observe national and local legal requirements.

14. Transport Information

Land transport

ADR

	Not classified as	a dangerous g	jood under tra	ansport 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	None known user			

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		

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Packing group:Not applicableEnvironmental hazards:Not applicableSpecial precautions forNone known user

Inland waterway transport ADN

Not classified as a dangerous good under transport regulationsUN number:Not applicableUN proper shipping name:Not applicableTransport hazard class(es):Not applicablePacking group:Not applicableEnvironmental hazards:Not applicableSpecial precautions forNone known user:

<u>Transport in inland waterway vessel</u> Not evaluated

Sea transport

IMDG

Not classified as a dangerous good under transport regulationsUN number:Not applicableUN proper shipping name:Not applicableTransport hazard class(es):Not applicablePacking group:Not applicableEnvironmental hazards:Not applicableSpecial precautions forNone known user

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	None known user	

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

Regulation:Not evaluatedShipment approved:Not evaluatedPollution name:Not evaluatedPollution category:Not evaluatedShip Type:Not evaluated

15. Regulatory Information

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. Other Information

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

Full text of classifications, hazard symbols and hazard statements, if mentioned in section 2 or 3: Repr. Reproductive toxicity

Skin Corr./Irrit.	Skin corrosion/irritation
Aquatic Acute	Hazardous to the aquatic environment - acute
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.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only regarding safety requirements. This safety data sheet is neither a Certificate of Analysis (CoA) nor technical data sheet and shall not be mistaken for a specification agreement. Identified uses in this safety data sheet do neither represent an agreement on the corresponding contractual quality of the substance/mixture nor a contractually designated use. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

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