according to 1907/2006/EC, Article 31

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

- · 1.1 Product identifier
- · Trade name: Vitamin A Palmitate 2.0 MIU/g
- · Article number: 102920
- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Additive for cosmetic or pharmaceutic preparations
- · 1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

Fagron UK Ltd 4B Coquet St Newcastle upon Tyne England NE1 2QB Tel. 0845 6522525

· Further information obtainable from:

Emergency response telephone number:

+44 (0) 845 652 2525

· 1.4 Emergency telephone number:

Emergency response telephone number:

+44 (0) 845 652 2525

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

Repr. 1B H360 May damage fertility or the unborn child.

- · 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

Hazard pictograms





GHS07 GHS08

- · Signal word Danger
- · Hazard-determining components of labelling:

Retinyl palmitate Vitamini A Palmitate Vitaminum A densatum oleosum d,l- alpha tocopherol int-rac-alpha- tocopherolum

· Hazard statements

H317 May cause an allergic skin reaction. H360 May damage fertility or the unborn child.

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· Precautionary statements

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P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313 IF exposed or concerned: Get medical advice/attention. P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

PBT: Not applicable.vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous components:				
CAS: 79-81-2	Retinyl palmitate	≥10–<25%		
EINECS: 201-228-5	8-5 Vitamini A Palmitate			
	Vitaminum A densatum oleosum			
	Repr. 1B, H360; Aquatic Chronic 4, H413			
CAS: 10191-41-0	S: 10191-41-0 d,l- alpha tocopherol			
EINECS: 233-466-0	S: 233-466-0 int-rac-alpha- tocopherolum			
	Skin Sens. 1B, H317			

· Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: Immediately remove any clothing soiled by the product.
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

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

No further relevant information available.

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SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

Water spray

Foam

Fire-extinguishing powder

Carbon dioxide

- · 5.2 Special hazards arising from the substance or mixture Carbon monoxide (CO)
- 5.3 Advice for firefighters
- · **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of aerosols.

- · Information about fire and explosion protection: Keep respiratory protective device available.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Store in cool, dry conditions in well sealed receptacles.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· Additional information: The lists valid during the making were used as basis.

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- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Hand protection



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

Nitrile rubber, NBR

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · Eye/face protection Goggles recommended during refilling
- · Body protection: Protective work clothing

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information

Physical stateColour:FluidBeige

Odour: Characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: Undetermined.

· Boiling point or initial boiling point and boiling

range Undetermined. • Flammability Not applicable.

· Lower and upper explosion limit

· Lower: Not determined.

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Upper:	Not determined.
Flash point:	Not applicable.
Decomposition temperature:	Not determined.
pH at 20°C	6.5–7.5
· Viscosity:	
Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
Solubility	
· water at 20°C:	100 g/l
· Partition coefficient n-octanol/water (log	•
value)	Not determined.
· Vapour pressure:	Not determined.
Density and/or relative density	
· Density:	Not determined.
Relative density	Not determined.
· Vapour density	Not determined.
9.2 Other information	
· Appearance:	Manage
· Form:	Viscous
Important information on protection of health	
and environment, and on safety.	Decided to the control of the control
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	
· VOC (EC)	0.00 %
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard	
Information with regard to physical hazard classes	
classes	Void
classes Explosives	Void Void
classes	
classes Explosives Flammable gases Aerosols	Void Void
classes Explosives Flammable gases Aerosols Oxidising gases	Void Void Void
classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure	Void Void Void Void
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classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water Oxidising liquids	Void Void Void Void Void Void Void Void

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· Desensitised explosives

Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:				
Oral	LD50	>2000 mg/kg (rat)		
CAS:	79-81-2	Retinyl palmitate		

Vitamini A Palmitate
Vitamini A Palmitate
Vitaminum A densatum oleosum

Oral | LD50 | >2000 mg/kg (rat)

CAS: 10191-41-0 d,l- alpha tocopherol

int-rac-alpha- tocopherolum

Oral	LD50	>4000 mg/kg (mouse)
		>4000 mg/kg (rat)
Dermal	LD50	>3000 mg/kg (rat)

- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- Reproductive toxicity May damage fertility or the unborn child.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

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· 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Do not allow product to reach ground water, water course or sewage system, even in small quantities. Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water Danger to drinking water if even extremely small quantities leak into the ground.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

not regulated
not regulated
not regulated
not regulated
Not applicable.
Not applicable.
ing to Not applicable.
not regulated
i

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

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• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H317 May cause an allergic skin reaction.

H360 May damage fertility or the unborn child.

H413 May cause long lasting harmful effects to aquatic life.

· Department issuing SDS:

Fagron UK

Quality Assurance

Contact: quality@fagron.co.uk

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1: Skin sensitisation - Category 1

Skin Sens. 1B: Skin sensitisation - Category 1B

Repr. 1B: Reproductive toxicity - Category 1B

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard - Category 4

· * Data compared to the previous version altered.

