#### Printing date 10/24/2023 Reviewed on 10/23/2023

# **Safety Data Sheet**

acc. to OSHA HCS

#### 1 Identification

- · Product identifier
- · Trade name: Vitamin A Palmitate 2.0 MIU/g
- · Article number: 102920
- · Application of the substance / the mixture Additive for cosmetic or pharmaceutic preparations
- · Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

Fagron Inc 2400 Pilot Knob Road St. Paul, MN 55120 www.fagron.us QA@fagron.us

· Information department:

Tel.: 800-423-6967 Fax: 800-339-1596

· Emergency telephone number:

Emergency Telephone: US: 1-800-535-5053

International: 1-352-323-3500

### 2 Hazard(s) identification

· Classification of the substance or mixture

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

Toxic to Reproduction 1B H360 May damage fertility or the unborn child.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS07 GHS08

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

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

· Hazard statements

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

· Precautionary statements

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Avoid breathing dust/fume/gas/mist/vapors/spray

Contaminated work clothing must not be allowed out of the workplace.

Fagron personalizing medicine

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

If on skin: Wash with plenty of water.

IF exposed or concerned: Get medical advice/attention.

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

Store locked up.

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

- Classification system:
- NFPA ratings (scale 0 4)



Health = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = \*1 Fire = 0

- Other hazards
- Results of PBT and vPvB assessment
- · PBT: Not applicable. · vPvB: Not applicable.

## 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 79-81-2	Retinyl palmitate Vitamini A Palmitate Vitaminum A densatum oleosum	10–≤25%
CAS: 10191-41-0	d,l- alpha tocopherol int-rac-alpha- tocopherolum	1%

#### 4 First-aid measures

- · 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.

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- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- Indication of any immediate medical attention and special treatment needed No further relevant information available.

#### 5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

Water spray

Foam

Fire-extinguishing powder

Carbon dioxide

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

#### 6 Accidental release measures

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

Dilute with plenty of water.

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

· 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.

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.

Protective Action Criteria for Chemicals

· PAC-1:

None of the ingredients is listed.

· PAC-2:

None of the ingredients is listed.

· PAC-3:

None of the ingredients is listed.

## 7 Handling and storage

- · Handling:
- · Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of aerosols.

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· Information about protection against explosions and fires:

Keep respiratory protective device available.

- · 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.

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

#### 8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see section 7.
- · Control parameters
- · Components 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 that were valid during the creation were used as basis.
- · Exposure controls
- · 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.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Protection of hands:



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 protection: Goggles recommended during refilling.

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· Body protection: Protective work clothing

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## 9 Physical and chemical properties

Information on basic physical and General Information	chemical properties
Appearance:	
Form:	Viscous
Color:	Beige
Odor:	Characteristic
Odor threshold:	Not determined.
pH-value at 20°C (68°F):	6.5–7.5
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not applicable.
Decomposition temperature:	Not determined.
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapor density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water at 20°C (68°F):	100 g/l
Partition coefficient (n-octanol/water): Not determined.	
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.

0.00 %

0.0 g/l / 0.00 lb/gal

No further relevant information available.

# 10 Stability and reactivity

**VOC** content:

· Other information

· Reactivity No further relevant information available.

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- · Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

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

### 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

· LD/LC5	0 value	es that are relevant for classification:
Oral	LD50	>2000 mg/kg (rat)

CAS: 79-81	<ul> <li>Retinyl palmitate</li> <li>Vitamini A Palmitate</li> <li>Vitaminum A densatum oleosum</li> </ul>

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

- · Primary irritant effect:
- · on the skin: No irritant effect.
- · **Sensitization**: Sensitization possible through skin contact.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

# 12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.

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- · 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 (Self-assessment): extremely hazardous for water Danger to drinking water if even extremely small quantities leak into the ground.

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · **vPvB:** Not applicable.
- · Other adverse effects No further relevant information available.

#### 13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

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

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

### 14 Transport information

· UN-Number · DOT, IMDG, IATA	not regulated
<ul><li>· UN proper shipping name</li><li>· DOT, IMDG, IATA</li></ul>	not regulated
· Transport hazard class(es)	
· DOT, ADN, IMDG, IATA · Class	not regulated
· Packing group · DOT, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
<ul> <li>Transport in bulk according to Annex II MARPOL73/78 and the IBC Code</li> </ul>	of Not applicable.
· UN "Model Regulation":	not regulated

## 15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · Sara
- · Section 355 (extremely hazardous substances):

None of the ingredients is listed.

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· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

TSCA (Toxic Substances Control Act):

All components have the value ACTIVE.

· Hazardous Air Pollutants

None of the ingredients is listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

TLV (Threshold Limit Value)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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

#### 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.

Department issuing SDS:

Fagron US

**Quality Assurance** 

- · Contact: QA@fagron.us
- Date of preparation / last revision 10/23/2023

Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)

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 NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health



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TLV: Threshold Limit Value PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit
Sensitization - Skin 1: Skin sensitisation - Category 1
Toxic to Reproduction 1B: Reproductive toxicity - Category 1B

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