Safety Data Sheet

according to WHS Regulations

Printing date 17.08.2023 Revision: 17.08.2023 Version number 1.0

1 Identification

· Product identifier

· Trade name: Cetylis palmitas

· Article number: 100282

• CAS Number: 95912-87-1 • EC number: 306-083-2

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

No further relevant information available.

· Application of the substance / the mixture

Plasticiser

Pharmaceutical intermediate

· Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Fagron Services B.V. Molenwerk 13, UITGEEST, 1911DB Netherlands

Phone: +31251361400

Supplier Azelis Australia Suite 217 117 Old Pittwater Road Brookvale NSW 2100 Australia

Phone: +61 0299392188 Fax: +61 0299392799 e-mail: info@azelis.com.au

· Further information obtainable from: info@fagron.com.au

· Emergency telephone number:

In case of emergency, please call your local poisons:

Emergency Australia: 13 11 26

Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE: +44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65 3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333 (English only)

2 Hazard(s) Identification

· Classification of the substance or mixture

The substance is not classified, according to the Globally Harmonised System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void

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

3 Composition and Information on Ingredients

· Chemical characterisation: Substances

· CAS No. Description

CAS: 95912-87-1 Cetylis palmitas

- · Identification number(s)
- · EC number: 306-083-2

4 First Aid Measures

- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Immediately rinse with water.

If skin irritation continues, consult a doctor.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing:

Rinse out mouth and then drink plenty of water.

Seek immediate medical advice.

- · 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

Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

Carbon dioxide

Foam

Fire-extinguishing powder

Water spray

· Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gases are produced.

· Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

6 Accidental Release Measures

 Personal precautions, protective equipment and emergency procedures Avoid formation of dust.

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Ensure adequate ventilation

- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up:

Pick up mechanically.

Dispose of the material collected according to regulations.

Dispose contaminated material as waste according to section 13.

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.

7 Handling and Storage

- · Handling:
- · Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of dust.

· Information about fire - and explosion protection:

Protect against electrostatic charges.

Protect from heat.

Keep ignition sources away - Do not smoke.

- · 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:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

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

8 Exposure controls and personal protection

- · Additional information about design of technical facilities: No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

- **Respiratory protection:** Not necessary if room is well-ventilated.
- 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.

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

Material of gloves

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.

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.2 mm

· 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:



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and Chemical Properties

General Information

· Appearance:

Form: Flakes
Colour: Whitish
Odour: Odourless
Odour threshold: Not determined.
pH-value: Not applicable.

· Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range:
 Undetermined.
 Flash point:
 239–241°C

• Flammability (solid, gas): Product is not flammable.

• Decomposition temperature: >300°C

· **Ignition temperature:** Not determined.

• **Explosive properties:** Product does not present an explosion hazard.

· Explosion limits:

Lower: Not determined.
 Upper: Not determined.
 Vapour pressure: Not applicable.
 Density at 80°C: 0.817–0.82 g/cm³
 Relative density Not determined.
 Vapour density Not applicable.
 Evaporation rate Not applicable.

· Solubility in / Miscibility with

water: Not determined.Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not applicable.Kinematic: Not applicable.

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Other information

No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- $\cdot \mbox{ Thermal decomposition / conditions to be avoided:} \\$

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: Poisonous gases/vapours

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

Oral	LD50	>2000 mg/kg (rat)
Dermal		>2000 mg/kg (rat)
Inhalative	LC50/4 h	>5.7 mg/l (rat)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · **Mobility in soil** No further relevant information available.
- Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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

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· Other adverse effects No further relevant information available.

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13 Disposal considerations

- · Waste treatment methods
- · Recommendation Smaller quantities can be disposed of with household waste.
- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

14 Transport information

4 Transport information		
· UN-Number · ADG, IMDG, IATA	not regulated	
· UN proper shipping name · ADG, IMDG, IATA	not regulated	
· Transport hazard class(es)		
· ADG, ADN, IMDG, IATA · Class	not regulated	
· Packing group · ADG, IMDG, IATA	not regulated	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not applicable.	
Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.		
· UN "Model Regulation":	not regulated	

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals Substance is listed.
- · Standard for the Uniform Scheduling of Medicines and Poisons Substance is not listed.
- · Australia: Priority Existing Chemicals Substance is not listed.
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)

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

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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: Product Safety Department
- · Contact:
- · 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

EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

AUS

