


## 1 Identification

- **Product identifier**
- **Trade name:** AMIFARM® CUM OLEO OLIVAE 10%
- **Article number:** 611027
- **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
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Services B.V.  
Molenwerk 13, UITGEEEST, 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**  
Serious eye damage/irritation – Category 2A H319 Causes serious eye irritation.
- **Label elements**
- **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**  
  
GHS07
- **Signal word** Warning

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- **Hazard statements**  
Causes serious eye irritation.
- **Precautionary statements**  
Wash thoroughly after handling.  
Wear eye protection / face protection.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
If eye irritation persists: Get medical advice/attention.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

• <b>Dangerous components:</b>		
CAS: 8002-74-2	Vaselinum Album Paraffinum solidum Paraffin, white soft	10–≤25%
CAS: 8042-47-5	White mineral oil, petroleum Asp. Tox. 1, H304	5–≤10%
CAS: 57-55-6	Propylene glycol	3–≤5%
CAS: 68439-50-9	Alcohols, C12-14, ethoxylated Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Irrit. 2, H315	≥1–<3%

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

### 4 First Aid Measures

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **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. If symptoms persist, consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **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.

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- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** Wear self-contained respiratory protective device.

## 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **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 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:**

CAS: 8002-74-2 Vaselineum Album  
Paraffinum solidum  
Paraffin, white soft

WES Long-term value: 2 mg/m<sup>3</sup>

CAS: 57-55-6 Propylene glycol

WES Long-term value: 474\* 10\*\* mg/m<sup>3</sup>, 150\* ppm  
\*vapour&particulates;\*\*particulates only

- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:**  
Suitable respiratory protective device recommended.  
Filter P1
- **Protection of hands:**



Protective gloves

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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**

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:**



Tightly sealed goggles

• **Body protection:** Protective work clothing

## 9 Physical and Chemical Properties

• **General Information**

• **Appearance:**

- **Form:** Solid
- **Colour:** Yellowish
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.

• **Change in condition**

- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**
- **water:** Soluble.
- **Partition coefficient: n-octanol/water:** Not determined.

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- **Viscosity:**
- **Dynamic:** Not applicable.
- **Kinematic:** Not applicable.
- **Solvent content:**
- **Organic solvents:** 4.9 %
- **Water:** 62.9 %
- **Other information** No further relevant information available.

## 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **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:** No dangerous decomposition products known.

## 11 Toxicological Information

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

### · LD/LC50 values relevant for classification:

#### ATE (Acute Toxicity Estimates)

Oral	LD50	27784 mg/kg
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#### CAS: 57-55-6 Propylene glycol

Oral	LD50	>10400 mg/kg (rat)
Dermal	LD50	20800 mg/kg (rabbit)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **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.

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- **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.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **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.

### 14 Transport information

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

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Australian Inventory of Industrial Chemicals**  
All ingredients are listed.

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• **Standard for the Uniform Scheduling of Medicines and Poisons**

CAS: 8042-47-5	White mineral oil, petroleum	S5
CAS: 102-71-6	Triethanolamine	S4, S5

• **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

• **Directive 2012/18/EU**

• **Named dangerous substances - ANNEX I** None of the ingredients is 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.

## 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**

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H318 Causes serious eye damage.

• **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

ELINCS: European List of Notified 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

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Asp. Tox. 1: Aspiration hazard – Category 1

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