

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

- **1.1 Product identifier**
- **Trade name:** **AMIFARM® CUM OLEO OLIVAE 10%**
- **Article number:** 611027
- **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 a.s.
Holická 1098/31m
779 00 Olomouc
Česká republika
- **Further information obtainable from:**
Tel.: +420 585 222 590
info@fagron.cz
- **1.4 Emergency telephone number:**
Toxikologické informační středisko,
Na Bojišti 1,
128 08 Praha 2
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),
e-mail:tis.cuni@cesnet.cz

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

• **Determination of endocrine-disrupting properties**

CAS: 99-76-3	Methyl 4-hydroxybenzoate Methyl Parahydroxybenzoate Methylis parahydroxybenzoas	List II
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SECTION 3: Composition/information on ingredients

3.2 Mixtures

• **Description:** Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 8042-47-5 EINECS: 232-455-8	White mineral oil, petroleum Asp. Tox. 1, H304	5–≤10%
CAS: 67762-27-0 EINECS: 267-008-6	Cetostearyl Alcohol Aquatic Chronic 3, H412	≥1–<2,5%
CAS: 68439-50-9	Alcohols, C12-14, ethoxylated Aquatic Acute 1, H400; Aquatic Chronic 3, H412	≥1–<2,5%
CAS: 99-76-3 EINECS: 202-785-7	Methyl 4-hydroxybenzoate Methyl Parahydroxybenzoate Methylis parahydroxybenzoas Aquatic Chronic 3, H412	0,1–≤1%

• **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

• **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.

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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

• **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

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

• **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.

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· **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** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **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.
- **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:** Wash hands before breaks and at the end of work.
- **Respiratory protection:**
Suitable respiratory protective device recommended.
Filter P1
- **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**

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.

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- **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**



Tightly sealed goggles

- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** Yellowish
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not determined.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH** Not applicable.
- **Viscosity:**
- **Kinematic viscosity** Not applicable.
- **Dynamic:** Not applicable.
- **Solubility**
- **water:** Soluble.
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not applicable.
- **Density and/or relative density**
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Particle characteristics**
See section 3.

- **9.2 Other information**
- **Appearance:**
- **Form:** Solid
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Product is not selfigniting.

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· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Organic solvents:	4,9 %
· Water:	62,9 %
· Change in condition	
· Evaporation rate	Not applicable.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· 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:** No dangerous decomposition products known.

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:**

CAS: 67762-27-0 Cetostearyl Alcohol

Oral	LD50	>5000 mg/kg (rat)
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Dermal	LD50	>8000 mg/kg (rabbit)
CAS: 99-76-3 Methyl 4-hydroxybenzoate Methyl Parahydroxybenzoate Methylis parahydroxybenzoas		
Oral	LD50	2100 mg/kg (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.
- **11.2 Information on other hazards**

• Endocrine disrupting properties		
CAS: 99-76-3	Methyl 4-hydroxybenzoate Methyl Parahydroxybenzoate Methylis parahydroxybenzoas	List II
CAS: 94-13-3	Propyl Parahydroxybenzoate	List II; III

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.
- **12.6 Endocrine disrupting properties**
For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **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.

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.

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- **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

• 14.1 UN number or ID number	
• ADR, IMDG, IATA	not regulated
• 14.2 UN proper shipping name	
• ADR, IMDG, IATA	not regulated
• 14.3 Transport hazard class(es)	
• ADR, ADN, IMDG, IATA	
• Class	not regulated
• 14.4 Packing group	
• ADR, IMDG, IATA	not regulated
• 14.5 Environmental hazards:	Not applicable.
• 14.6 Special precautions for user	Not applicable.
• 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
• UN "Model Regulation":	not regulated

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.

- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

- REGULATION (EU) 2019/1148

- Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

- Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

- Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

- Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

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**

H304 May be fatal if swallowed and enters airways.
H400 Very toxic to aquatic life.
H412 Harmful to aquatic life with long lasting effects.

- **Department issuing SDS:** Fagron Česká republika

- **Contact:** msds@fagron.cz

- **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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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