

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

- **1.1 Product identifier**
- **Trade name:** Glyceroli unguentum
- **Article number:** 610768
- **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**
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **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.

(Contd. on page 2)

GB

Trade name: Glyceroli unguentum

(Contd. of page 1)

· Dangerous components:		
CAS: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	50–≤100%
CAS: 9005-25-8 EINECS: 232-679-6	Starch Amylum Potato starch Solani amyllum Mazize starch Maydis amyllum Rice starch Oryzae amyllum Wheat starch Tritici amyllum substance with a Community workplace exposure limit	5–≤10%
CAS: 99-76-3 EINECS: 202-785-7	Methyl 4-hydroxybenzoate Methyl Parahydroxybenzoate Methylis parahydroxybenzoas Aquatic Chronic 2, H411	≥0.1–<0.25%

· 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:** No special measures required.
- After inhalation:** Supply fresh air; consult doctor in case of complaints.
- After skin contact:**
Generally the product does not irritate the skin.
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:** 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.
Wear fully protective suit.

GB

(Contd. on page 3)

Trade name: Glyceroli unguentum

(Contd. of page 2)

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **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 of the material collected according to regulations.
- **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.
- **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:** Keep container tightly sealed.
- **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:

CAS: 56-81-5 glycerol

WEL Long-term value: 10 mg/m³

CAS: 9005-25-8 Starch

Amylum
Potato starch
Solani amyllum
Mazize starch
Maydis amyllum
Rice starch
Oryzae amyllum
Wheat starch
Tritici amyllum

WEL Long-term value: 10* 4** mg/m³
*total inhalable **respirable

• DNELs

CAS: 56-81-5 glycerol

Inhalative DNEL 56 mg/m³ (hum)

(Contd. on page 4)

GB

Trade name: Glyceroli unguentum

(Contd. of page 3)

- **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:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **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.
- **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 state** Fluid
- **Colour:** White
- **Odour:** Light
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** 100°C (CAS: 7732-18-5 Water, distilled, conductivity or of similar purity)
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** 177–199°C

(Contd. on page 5)

GB

Trade name: Glyceroli unguentum

(Contd. of page 4)

· Auto-ignition temperature:	400°C (CAS: 56-81-5 glycerol)
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20°C:	23 hPa (CAS: 7732-18-5 Water, distilled, conductivity or of similar purity)
· Vapour pressure at 50°C:	~0 hPa
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.

· 9.2 Other information	
· Appearance:	
· Form:	Highly viscous
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Organic solvents:	66.4 %
· Water:	24.9 %
· VOC (EC)	0.84 %
· Solids content:	8.7 %
· Change in condition	
· Evaporation rate	Not determined.

· 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

(Contd. on page 6)

GB

Trade name: Glyceroli unguentum

(Contd. of page 5)

- | | |
|---------------------------|------|
| • 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: 56-81-5 glycerol

Oral LD50 12600 mg/kg (rat)

CAS: 9005-25-8 Starch

Amylum
Potato starch
Solani amyllum
Mazize starch
Maydis amyllum
Rice starch
Oryzae amyllum
Wheat starch
Tritici amyllum

Oral LD50 >50000 mg/kg (rat)

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.

(Contd. on page 7)

GB

Trade name: Glyceroli unguentum

(Contd. of page 6)

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

CAS: 99-76-3	Methyl 4-hydroxybenzoate Methyl Parahydroxybenzoate Methylis parahydroxybenzoas	List II
--------------	---	---------

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 be specially treated adhering to official regulations.

· **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

(Contd. on page 8)

GB

Trade name: Glyceroli unguentum

(Contd. of page 7)

- | | |
|--|-----------------|
| · 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.
- 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**
H411 Toxic to aquatic life with long lasting effects.
- **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)
DNEL: Derived No-Effect Level (UK REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
- *** Data compared to the previous version altered.**

GB