according to 1907/2006/EC, Article 31

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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.

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· Dangerous compor	nents:	
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 amylum Mazize starch Maydis amylum Rice starch Oryzae amylum Wheat starch Tritici amylum 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%

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

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

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- \cdot 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.

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SECTION 6: Accidental release measures

 \cdot 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 amylum

Mazize starch

Maydis amylum

Rice starch

Oryzae amylum

Wheat starch

Tritici amylum

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

· DNELs

CAS: 56-81-5 glycerol

Inhalative DNEL 56 mg/m3 (hum)

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- · 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 stateColour: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

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· 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	

personalizing medicine

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Organic peroxides
 Corrosive to metals
 Desensitised explosives

Void
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 amylum
Mazize starch
Maydis amylum
Rice starch
Oryzae amylum

Wheat starch Tritici amylum

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.

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Trade name: Glyceroli unguentum				
	· 11.2 Information on other hazards	(Contd. of page 6)		
	· 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.

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	



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· 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.

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