Safety Data Sheet

according to WHS Regulations

Printing date 27.02.2024 Revision: 27.02.2024 Version number 1.0

1 Identification

- · Product identifier
- · Trade name: Glyceroli unguentum
- · Article number: 610768
- 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, 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 product 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
- · Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

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3 Composition and Information on Ingredients

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

· Dangerous components:		
CAS: 56-81-5	glycerol	50–≤100%
	Starch Amylum Potato starch Solani amylum Mazize starch Maydis amylum Rice starch Oryzae amylum Wheat starch Tritici amylum	5–≤10%

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

4 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.
- · 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.
- · Special hazards arising from the substance or mixture No further relevant information available.
- Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.

Environmental precautions:

Dilute with plenty of water.

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

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· 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.

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.
- · 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: Keep container tightly sealed.
- · 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: 56-81-5 glycerol

WES Long-term value: 10 mg/m³

inhalable dust

CAS: 9005-25-8 Starch

Amylum

Potato starch

Solani amylum

Mazize starch

Maydis amylum

Rice starch

Oryzae amylum

Wheat starch

Tritici amylum

WES Long-term value: 10 mg/m³

inhalable dust

· DNELs

CAS: 56-81-5 glycerol

Inhalative DNEL 56 mg/m3 (hum)

- · 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.

Respiratory protection:

Suitable respiratory protective device recommended.

Filter P1

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· Protection of hands:

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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 protection: Goggles recommended during refilling
- · Body protection: Protective work clothing

9 Physical and Chemical Properties

· General Information

· Appearance:

· Form: Highly viscous

· Colour: White · Odour: Light

· Odour threshold: Not determined. • pH-value: Not determined.

· Change in condition

• Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: 100°C
 Flash point: 177–199°C
 Flammability (solid, gas): Not applicable.

• Auto-ignition temperature: 400°C

· **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 at 20°C: 23 hPa · Vapour pressure at 50°C: ~0 hPa

Density: Not determined.
Relative density Not determined.
Vapour density Not determined.
Evaporation rate Not determined.

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· Solubility in / Miscibility with

· water: Fully miscible. · Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

· Dynamic: Not determined. · Kinematic: Not determined.

· Solvent content:

· Organic solvents: 66.4 % · Water: 24.9 % · VOC (EC) 0.84 % · Solids content: 8.7 %

· 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:

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)

- · 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.

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

13 Disposal considerations

- · 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 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.

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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

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

CAS: 64-17-5 Ethanol / Alcohol 99,5% v/v (absolute

Not scheduled

· 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.

- · 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)

VOC: Volatile Organic Compounds (USA, EU) DNEL: Derived No-Effect Level (REACH) LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

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