

Safety Data Sheet

acc. to OSHA HCS

Page 1/9

Printing date 04/09/2024

Reviewed on 04/09/2024

1 Identification

- **Product identifier**
- **Trade name:** Glyceroli unguentum
- **Article number:** 610768
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
Carcinogenicity 1A H350 May cause cancer.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS08

- **Signal word** Danger
- **Hazard-determining components of labeling:**
Ethanol / Alcohol 99,5% v/v (absolute)
- **Hazard statements**
May cause cancer.
- **Precautionary statements**
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/protective clothing/eye protection/face protection.
IF exposed or concerned: Get medical advice/attention.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)

USA

Safety Data Sheet

acc. to OSHA HCS

Page 2/9

Printing date 04/09/2024
Reviewed on 04/09/2024

Trade name: Glyceroli unguentum

(Contd. of page 1)

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 1
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = *0
Fire = 1
Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

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

· **Dangerous components:**

CAS: 56-81-5	glycerol	50–≤100%
CAS: 9005-25-8	Starch Amylum Potato starch Solani amyllum Mazize starch Maydis amyllum Rice starch Oryzae amyllum Wheat starch Tritici amyllum	5–≤10%
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	0.1–≤1%

4 First-aid measures

- **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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

(Contd. on page 3)

USA

Trade name: Glyceroli unguentum

(Contd. of page 2)

- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **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.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose of the collected material 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.
- **Protective Action Criteria for Chemicals**

· PAC-1:

CAS: 56-81-5	glycerol	45 mg/m ³
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	1,800 ppm

· PAC-2:

CAS: 56-81-5	glycerol	180 mg/m ³
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	3300* ppm

· PAC-3:

CAS: 56-81-5	glycerol	1,100 mg/m ³
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	15000* ppm

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:** No special measures required.
- **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 receptacle tightly sealed.

(Contd. on page 4)

Trade name: Glyceroli unguentum

(Contd. of page 3)

- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**

· Components with limit values that require monitoring at the workplace:

CAS: 56-81-5 glycerol

PEL Long-term value: 15* 5** mg/m³
mist; *total dust **respirable fraction

TLV TLV withdrawn-insufficient data human occup. exp.

CAS: 9005-25-8 Starch

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

PEL Long-term value: 15* 5** mg/m³
*total dust **respirable fraction

REL Long-term value: 10* 5** mg/m³
*total dust **respirable fraction

TLV Long-term value: 10 mg/m³
A4

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

PEL Long-term value: 1900 mg/m³, 1000 ppm

REL Long-term value: 1900 mg/m³, 1000 ppm

TLV Short-term value: 1000 ppm
A3

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.

- **Breathing equipment:**

Suitable respiratory protective device recommended.

Filter P1

- **Protection of hands:**



Protective gloves

(Contd. on page 5)

USA

Trade name: Glyceroli unguentum

(Contd. of page 4)

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

• **Information on basic physical and chemical properties**

• **General Information**

• **Appearance:**

Form: Highly viscous

Color: White

• **Odor:** Light

• **Odor threshold:** Not determined.

• **pH-value:** Not determined.

• **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: 100°C (212°F)

• **Flash point:** 177–199°C (350.6–390.2°F)

• **Flammability (solid, gaseous):** Not applicable.

• **Auto igniting:** 400°C (752°F)

• **Decomposition temperature:** Not determined.

• **Ignition temperature:** Product is not selfigniting.

• **Danger of explosion:** Product does not present an explosion hazard.

• **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

• **Vapor pressure at 20°C (68°F):** 23 hPa (17.3 mm Hg)

• **Vapor pressure at 50°C (122°F):** ~0 hPa

• **Density:** Not determined.

• **Relative density** Not determined.

• **Vapor density** Not determined.

(Contd. on page 6)

USA

Safety Data Sheet

acc. to OSHA HCS

Page 6/9

Printing date 04/09/2024
Reviewed on 04/09/2024

Trade name: Glyceroli unguentum

(Contd. of page 5)

· Evaporation rate	Not determined.
· 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 content:	0.84 %
	8.4 g/l / 0.07 lb/gal
Solids content:	8.7 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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:**

- **LD/LC50 values that are relevant for classification:**

CAS: 56-81-5 glycerol

Oral	LD50	12600 mg/kg (rat)
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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)
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(Contd. on page 7)

USA

Trade name: Glyceroli unguentum

(Contd. of page 6)

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

Oral	LD50	7060 mg/kg (rat)
Inhalative	LC50/4 h	51 mg/l (rat)

• **Primary irritant effect:**

- **on the skin:** No irritant effect.
- **Sensitization:** No sensitizing effects known.

• **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

• **Carcinogenic categories**

• **IARC (International Agency for Research on Cancer)**

CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute)	1
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• **NTP (National Toxicology Program)**

None of the ingredients is listed.

• **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

• **Toxicity**

- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.

• **Behavior 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 (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 packagings:**

- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

USA

(Contd. on page 8)

Trade name: Glyceroli unguentum

(Contd. of page 7)

14 Transport information

· UN-Number	
· DOT, IMDG, IATA	not regulated
· UN proper shipping name	
· DOT, IMDG, IATA	not regulated
· Transport hazard class(es)	
· DOT, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· DOT, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 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**

No further relevant information available.

- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

- **Hazardous Air Pollutants**

None of the ingredients is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

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

(Contd. on page 9)

USA

Safety Data Sheet

acc. to OSHA HCS

Page 9/9

Printing date 04/09/2024
Reviewed on 04/09/2024

Trade name: Glyceroli unguentum

(Contd. of page 8)

• **Carcinogenic categories**

• **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

• **TLV (Threshold Limit Value)**

CAS: 9005-25-8	Starch Amylum Potato starch Solani amyllum Mazize starch Maydis amyllum Rice starch Oryzae amyllum Wheat starch Tritici amyllum	A4
CAS: 64-17-5	Ethanol / Alcohol 99,5% v/v (absolute	A3

• **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

• **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:**

Fagron US
Quality Assurance

• **Contact:** QA@fagron.us

• **Date of preparation / last revision** 04/09/2024

• **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

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Carcinogenicity 1A: Carcinogenicity – Category 1A

• *** Data compared to the previous version altered.**

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