

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

GLYCEROLUM

EN

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Glycerol
Glycerolum
Glycerine
Glycérol
Glycerin

N° CAS: 56-81-5

N° EC: 200-289-5

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FRAVER NV
Keizershoek 336
2550 Kontich
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Not classified.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.

Signal word(s): Not applicable.

Hazard statements: Not applicable.

Precautionary statements: Not applicable.

Additional applicable label elements: Not applicable.

2.3 Other hazards

Not available.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Glycerol
IUPAC name:	Propane-1,2,3-triol
Synonyms:	Glycerin Propanetriol Glycyl alcohol
N° CAS:	56-81-5
N° EC:	200-289-5
Molecular Formula:	C ₃ H ₈ O ₃
Content:	98.0 per cent <i>m/m</i> to 101.0 per cent <i>m/m</i> (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Immediately remove contaminated clothing.
After inhalation:	Supply fresh air. Consult a doctor in case of complaints.
After skin contact:	Wash with warm water. If the skin irritation remains, consult a doctor.
After eye contact:	Rinse eyes with open eyelid under running water for several minutes and consult a doctor.
After ingestion:	Rinse mouth and drink plenty of water. Seek expert medical treatment.

4.2 Most important symptoms and effects, both acute and delayed

Gastro-intestinal complaints, headache, nausea.
Hazards: Danger of cardiac arrhythmias.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray jet, water fog, alcohol resistant foam, extinguishing powder, carbon dioxide. Adapt fire-fighting measures to the environment.
Unsuitable extinguishing media:	Powerful water jet.

5.2 Special hazards arising from the substance/mixture

In case of heating or fire, toxic gases can be formed. In case of fire, the following can be released: Carbon monoxide (CO), Carbon dioxide (CO₂).

5.3 Advice for firefighters

Surrounding fires:	Cool endangered tanks with water spray jet. Fire residues and contaminated extinguishing water must be disposed of in accordance with government regulations. Collect contaminated fire extinguishing water separately, it must not enter the sewage system.
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Protection against fire:

Wear fully protective overalls. Wear a respiratory protection device that does not depend on the ambient air.

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear personal protective clothing.

For emergency responders

Wear personal protective clothing.

6.2 Environmental precautions

Dilute with plenty of water. Prevent the spread of the fire (e.g. by containment or stopping oil supplies). Do not allow to enter the ground/soil. Do not allow to enter sewers/surface water/ground water. The competent authority must be warned in case of penetration into the soil. Inform the competent authority in case of penetration into wastewater or sewerage. Stop and dispose of the contaminated washing water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, mountain meal, acid binder, universal binder, sawdust). Collect in special tanks for recovery or disposal. Dispose of contaminated material as waste according to item 13. Clean the accident site carefully; are suitable for this: warm water

6.4 Reference to other sections

Information on safe handling: See section 7.

Information on individual protection measures: See section 8.

Information on disposal: See section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Keep tanks tightly closed. Provide good ventilation/exhaustion at the workplace.

Personal protection:

Wear protective clothing.

Technical protective measures:

Information about fire and explosion hazard: Take precautions against static electricity discharge.

Handling:

Keep ignition sources away - no smoking. Protect from heat.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Suitable material for tanks and pipes: aluminum, ferrous alloys, glass. Store cool and dry in tightly closed, airtight containers. Product is hygroscopic. Storage class: VCI: 10-13

Conditions for safe storage, including any incompatibilities:

Keep only in the original packaging. Keep tank in a well-ventilated place. Maximum storage temperature: < 40°C. Recommended storage temperature: around 20 °C.

Storage – away from:

Store away from oxidizing agents. Do not store with acids. Do not store with alkalis (lyes). Store separately from water. Protect from heat and direct sunlight. Protect against humidity and water.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

Wear p

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

DNEL:

Oral, long term – systemic (consumer): 229 mg/kg bw/day

Inhalative, long term – local (worker): 56 mg/m³

Inhalative, long term – local (consumer): 33 mg/m³

PNEC:

Fresh water: 0.885 mg/L

Marine water: 0.0885 mg/L

Intermittent releases: 8.85 mg/L

Fresh water sediment: 3.3 mg/kg

Marine sediment: 0.33 mg/kg

Soil: 0.141 mg/kg

STP: 1 000 mg/L

8.2 Exposure controls

Appropriate engineering control

Do not eat, drink or smoke while handling. The usual precautions when handling chemicals should be taken.

Individual protection measures

Eye/face protection: Tight-fitting safety goggles (EN 166).

Skin protection: Wear suitable protective work clothing.

Hand protection: Safety 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.

Respiratory protection: Filter A/P2, filter P1, filter A, EN 143, EN 141. In case of insufficient ventilation: respiratory protection. Respiratory filter device for short or low exposure; with intensive resp. long-term exhibition one of the surrounding Use self-contained breathing apparatus.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Colourless or almost colourless syrupy liquid

Odour: Pleasant

Odour threshold: Not available.

pH: 6 – 8.5

Melting/freezing point: 18.2 °C

Initial boiling point: 290 °C

Boiling range: Not available.

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Flash point:	≥ 180 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	2.6 - 11.3 Vol %
Vapour pressure:	< 0.1 hPa (20 °C)
Vapour density:	3.1 – 3.17
Relative density:	1.258 to 1.268 g/cm ³
Solubility:	Miscible with ethanol (96 %), slightly soluble in acetone, practically insoluble in fatty oils and in essential oils.
Solubility in water:	Miscible with water.
Partition coefficient (n-octanol/water):	-1.75995 to -1.75007
Auto-ignition temperature:	≥ 370 °C
Decomposition temperature:	Not available.
Viscosity:	Dynamic (20 °C): 1.412 mPa·s
Explosive properties:	The product does not present an explosion hazard.
Oxidising properties:	Non oxidising.

9.2 Other information

Molecular mass: 92.1 g/mol.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable.

Thermal decomposition/conditions to be avoided: No degradation when used as directed. Stable at ambient temperature.

10.3 Possibility of hazardous reactions

Polymerization under heat development. Reactions with oxidizing agents. Reactions with acids. Heating above the decomposition point may release toxic fumes.

10.4 Conditions to avoid

Humidity, extremely high temperatures.

10.5 Incompatible materials

Strong oxidizing agents, strong bases, strong acids, water.

10.6 Hazardous decomposition products

Danger of forming toxic pyrolysis products.

Carbon monoxide and carbon dioxide.

Toxic gases/vapors.

Flammable gases/vapors.

Corrosive gases/vapors.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral, LD50: $\geq 11\,500$ mg/kg (rat) Dermal, LD50: $> 10\,000$ mg/kg (rabbit) $\geq 56\,750$ mg/kg (<i>Cavia porcellus</i>) Inhalative: LC50 (4 h) (Aerosol/Mist): > 2.75 mg/l (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/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.
Summary of evaluation of the CMR properties:	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.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:
EC 50 (24 h): $> 10\,000$ mg/l (<i>Daphnia magna</i>)
EC 50 (3 h): $> 1\,000$ mg/l (Activated Sludge) (OECD 209)
LC 50 (96 h): $> 1\,000$ mg/l (fish)
54 000 mg/l (<i>Oncorhynchus mykiss</i>)
885 mg/l (<i>Pimephales promelas</i>)
$> 1\,000$ mg/l (/) (other aquatic organisms)
54.000 mg/l (<i>Salmo gairdneri</i>)
LC 50 (48 h): 1.955 mg/l (<i>Daphnia magna</i>)

12.2 Persistence and degradability

Readily biodegradable. Elimination rate: OECD 301 D: 82 % (/) (20d)

12.3 Bioaccumulative potential

Due to the n-octanol/water partition coefficient, no significant accumulation in organisms is expected.

12.4 Mobility in soil

Not available.

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Further ecological information: COD value: 1.16 g O₂/g (ISO 15705), BOD5 value: 0.87 g O₂/g

General information:

Do not discharge undiluted or in large quantities into groundwater, surface water or sewers.

Danger to water class 1 (D) (List classification): danger to water small.

12.5 Results of PBT and vPvB assessment

Not applicable.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Must not be disposed of together with household waste or end up in the sewage system.

Recommendation: Packaging that can no longer be cleaned should be disposed of like the material itself.

Recommended cleaning agent: Water, possibly with the addition of cleaning agents.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FRAVER

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16.8 Department issuing MSDS

Quality Department

FRAVER NV

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