

SAFETY DATA SHEET

Pharmaceutical glycerine 99,5%

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2015/830

Date of issue : 2022-11-29

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Version : 1

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

1.1. Product identifier

Product name	: Pharmaceutical glycerine 99,5%
Chemical name	: Propano-1,2,3-triol
EC number	: 200-289-5
CAS number	: 56-81-5
INCI Name	: Glycerin
REACH Registration number	: The substance does not require registration according to REACH.
Other means of identification	: Vegetable Glycerine Pharmaceutical Grade; Distilled Glycerin 99,5%; glycerine; glycerin; 1,2,3-Trioxypropane; 1,2,3-Trihydroxypropane; 1,2,3-Propanetriol
Chemical formula	: $C_3H_8O_3$

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture	: Glycerine is used (inter alia) in the food, pharmaceutical, cosmetic, crop protection and chemical industries, both as an ingredient of mixtures and as a raw material for further syntheses.
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1.3. Details of the supplier of the safety data sheet

Name	: GLI-THERM Sp. z o.o.
Address	: st. Rozwojowa 11, 44-338 Jastrzębie-Zdrój Poland
Regon	: 242850136
NIP/Tax No	: 6423178990
Telephone	: +48 733 525 533
E-mail	: sandra.stachowicz@gli-therm.eu
Website address	: www.glitherm.eu

1.4. Emergency telephone number

National advisory body/Poison Center:

Ireland	: National Poisons Information Centre Emergency number: +353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)
United Kingdom	: National Poisons Information Service (Newcastle Centre) Emergency number: 0844 892 0111 (UK only, 24/7, healthcare professionals only)

Poland	:	Szpital Praski p.w. Przemienienia Pańskiego Sp. z o.o. Emergency number: +48 22 619 66 54 +48 22 619 08 97
Germany	:	Vergiftungs-Informationen-Zentrale Freiburg Emergency number: +49 (0) 761 19240
24 Hour Emergency Telephone	:	+(44)-8708200418 CHEMTREC
Supplier		
Telephone number	:	+48 733 525 533

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Product definition : Mono-constituent substance

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

According to EC directives or the corresponding national regulations the product does not have to be labelled.

2.3. Other hazards

Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII : No experimental data available but good biodegradability expected based on conclusion by analogy.

Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII : No experimental data available but good biodegradability expected based on conclusion by analogy.

Other hazards which do not result in classification : Inhaling vapours and use in large quantities may cause nausea, sleepiness, vomiting and diarrhoea (see Sections 8 and 11 of the Safety Data Sheet).

SECTION 3: Composition/information on ingredients

3.1. Substance

Mono-constituent substance

Substance	Identifiers	%	Classification Regulation (EC) No. 1272/2008 [CLP/GHS]	Type
Glycerol (1,2,3-Propantriol)	CAS No.: 56-81-5 EC No.: 200-289-5	min. 99.5	The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	[A]

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

Type:

[A] Constituent

[B] Impurity

[C] Stabilizing additive

Occupational exposure limits, if available, are listed in Section 8.

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:	: Get medical advice/attention.
Eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Avoid a strong stream of water because of a risk of mechanical damage of the cornea. In case of irritation, contact an eye-doctor.
Inhalation	: Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration. If the victim feels bad, consult a doctor.
Skin contact	: After contact with skin, wash immediately with plenty of water and soap. IF ON CLOTHING: Immediately remove any contaminated clothing, shoes or stockings. In case of any irritation, contact a doctor.
Ingestion	: If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Never give anything by mouth to an unconscious person or a person with cramps.

4.2. Most important symptoms and effects, both acute and delayed

Longer stay in the atmosphere of glycerine vapours or use of larger quantities of glycerine may cause nausea, vomiting or diarrhoea. In case of occurrence of symptoms, contact a doctor.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to physician	: No special recommendations
Specific treatments	: No special recommendations

SECTION 5: Firefighting measures

Flammable substance. Flash point of pure product is ca. 177°C. Auto-ignition occurs in the temperature above 370°C. Containers not covered by a fire must be, if possible, transported into a safe place, Containers imposed to the activity of fire must be cooled with a spray jet.

5.1. Extinguishing media

Suitable extinguishing media : Water mist; alcohol resistant foam; Dry extinguishing powder; Carbon dioxide (CO₂)

Unsuitable extinguishing media : Strong stream of water; all extinguishing media are permitted

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Carbon monoxide; Carbon dioxide (CO₂); Acrolein

5.3 Advice for firefighters

Special precautions for fire-fighters : In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : Wear protective gloves/protective clothing and glasses.. Do not breathe vapour. Provide adequate ventilation.
In case of leak or unintended release eliminate potential sources of ignition and protect the place against access of unauthorised persons.

For emergency responders : Persons directly participating in the neutralisation of the leak should possess protective clothes in the form of leakproof gloves and glasses. Personal protection equipment: Refer to section 5.3 In case of contact with hot substance, use thermal protective clothes and protective equipment for the respiratory tract. Collect the leaked liquid with the use of available equipment (the product is not aggressive or caustic) or with the use of sorbent materials (mats, sawdust, etc.)

6.2. Environmental precautions

In case of leak, remove the sources of ignition and, if possible, eradicate the leak. Protect the surroundings against the product getting to watercourses. Do not empty into drains.

6.3. Methods and materials for containment and cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal. Rinse contaminated area with water. In case of large leaks, consider making a barrier in order to minimise the leak surface.

6.4. Reference to other sections

See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

6.5. Additional information

If appropriate sections 8 and 13 shall be referred to.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance.

7.1. Precautions for safe handling

Protective measures

Advices on safe handling : Use in well-ventilated rooms. Keep far from sources of high temperature and sources of ignition. It is recommended to use protective gloves and glasses, so as to avoid contact with the skin and eyes during work with the substance. Do not inhale vapours/aerosols. Do not consume, do not drink and do not smoke during work with the substance. After the end of work take off protective clothes and wash the hands.
Usual measures for fire prevention.

7.2. Conditions for safe storage, including any incompatibilities.

Hints on storage assembly : Store in a ventilated warehouse in tightly-closed packages or containers (possesses hygroscopic properties). Store far from sources of heat in the temperature above the freezing point (recommended temperature from 25 to 40°C). In case of solidification, heat the product to the recommended temperature of storage. Protect against the activity of light, contact with water or moisture. Do not store with substances that may get involved in a chemical reaction, such as strong oxidisers, phosphorus pentoxides, nitric acid and sulfuric acid.

7.3. Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance.

8.1. Control parameters

The highest permissible concentration in the work environment was established for the substance.

Ingredient : Glycerol (aerosols)

CAS-no : 56-81-5

Standard	:	NDS
Value	:	10
Unit	:	mg/m ³

8.2. Exposure controls

Technical means of control applied	:	Due to the NDS determined for the substance, it is recommended to carry out tests with regard to the content of glycerol vapours in the work environment.
Individual protection measures		
Hygiene measures	:	General provisions on industrial health and safety are applicable. Do not allow for exceeding permissible standard concentrations of hazardous ingredients in the work environment. Do not consume, do not drink and do not smoke during work. Wash hands and face before breaks and after work and take a shower if necessary.
Eye/face protection	:	Wear eye/face protection.
Hand protection	:	Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. Suitable material: PVC (polyvinyl chloride) NBR (Nitrile rubber) Thickness of the glove material: Breakthrough times and swelling properties of the material must be taken into consideration. Reference: NBR 0.11 mm, > 480 min (EN 374) In case of contact with hot substance, use thermal protective clothes.
Body protection	:	Protective clothing: Check leak tightness/impermeability prior to use.
Respiratory protection	:	In case of exceeding permissible concentrations of vapours of the substance or in case of insufficient ventilation, use protective equipment for the respiratory tract with properly selected filter.
Environmental exposure controls	:	No data available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Appearance:	:	transparent, thick liquid
Odor	:	odourless
Odor threshold	:	Not applicable
pH	:	within the range of 5-8,
Initial boiling point and boiling range	:	290°C (1013hPa),
Melting point/freezing point	:	18°C,
Flash point	:	ca. 177°C (1013hPa),
Upper/lower flammability or explosive limits	:	No data available.

Vapor pressure	:	in the temperature of 50°C : 0.03 0.26 hPa
Density	:	1.261 g/cm ³ in the temperature of 20°C.
Solubility	:	The substance dissolves in water very well. The substance also dissolves in other organic and non-organic solvents. It mixes well with such organic liquids as ethanol, methanol and phenol.
Partition coefficient: n-octanol/water	:	(log Pow): 2.66.
Auto-ignition temperature	:	>370°C.
Decomposition temperature	:	
Viscosity	:	1410 mPas. in the temperature of 20°C
Surface tension	:	63.4 mN/m.

9.2. Other information

The substance possesses hygroscopic properties, in high temperature (fire) it may be subject to thermal decomposition and emit poisonous acrolein.

SECTION 10: Stability and reactivity

10.1. Reactivity

The substance may react with strong oxidisers, phosphorus pentoxide, nitric acid, sulfuric acid and their derivatives.

10.2 Chemical stability

The substance is chemically stable in normal conditions of storage (temperature 25-40°C). Access of water or moisture may cause deterioration of the quality of the product due to hygroscopic properties of glycerine.

10.3. Possibility of hazardous reactions

The substance is stable in normal conditions of use and storage. Decomposition of the substance and side reactions occur above the temperature of 180°C. Decomposition of the substance may cause emission of harmful acrolein. The substance may react with strong oxidisers, phosphorus pentoxide, nitric acid, sulfuric acid and their derivatives; strong acid, alkali (lye), concentrated.

10.4. Conditions to avoid

Avoid heating the product to a high temperature and exposing it to the light, protect the product from sources of ignition.

10.5. Incompatible materials

Avoid contact of the product with compounds listed in pt. 10.3

10.6 Hazardous decomposition products

During thermal decomposition poisonous acrolein may be emitted. During incomplete combustion carbon monoxide may be emitted.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

The substance is not toxic for people. Use of the product in large quantities may cause stomachache, nausea, sleepiness and diarrhoea.

Severe toxicity:

Oral	:	LD50 12'600 mg/kg (Rat) OECD
Skin	:	LD50 18'700 mg/kg (Rabbit) OECD

Caustic/irritating activity on the skin : none or slightly irritating.

Severe damage to eyes/irritating activity on the eyes	:	slightly irritating.
Allergising activity on the respiratory tract or the skin	:	No allergising activity was found.
Mutagenic activity on reproductive cells	:	No cases of mutagenic activity are known.
Carcinogenicity	:	No carcinogenicity activity was found.
Harmful activity on reproduction	:	No reprotoxic activity is known.
Toxic activity on target organs - one-time exposure	:	No toxic activity on the human system was found.
Toxic activity on target organs - repeated exposure	:	No toxic activity on the human system was found.
Hazard caused by aspiration	:	Inhaling vapours/aerosols may be harmful to health (see pt. 8 of the Safety Data Sheet).

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity:

Leuciscus idus	:	LC50	> 10'000 mg/l
Carassius auratus	:	LC50	> 5'000 mg/l/24h
Daphnia magna	:	UE50	> 10'000 mg/l/24h

Toxic concentration limits:

algae	:	IC5	> 10'000 mg/l/7 days
bacteria	:	UE5	> 10'000 mg/l/16 h
protozoa	:	UE5	3'200 mg/l/72h

When used properly, the substance is not hazardous to the environment.

12.2 Persistence and degradability

Prevent the substance from getting into the sewage system, the soil, watercourses and water tanks. The product is easily biodegradable, (log Pow = -2.66).

CHZT - 1160 mgO₂/g,

BZT5 - 700 mgO₂/g,

12.3 Bioaccumulative potential

The product does not reveal bioaccumulative potential in the environment.

12.4 Mobility in soil

No data available on product mobility in the soil.

12.5 Results of PBT and vPvB assessment

PBT : No experimental data available but good biodegradability expected based on conclusion by analogy.

vPvB : No experimental data available but good biodegradability expected based on conclusion by analogy.

12.6. Endocrine disrupting properties

No data available

12.7 Other adverse effects

The product does not contain substances with endocrine disrupting properties.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not remove the substance with municipal waste. Do not remove to the sewage system. Do not contaminate ground or surface waters. Give excesses of the product to companies specialising in waste collection. Consult the appropriate local waste disposal expert about waste disposal.

Product

Methods of disposal : It must undergo special treatment in accordance with official regulations. Incineration is recommended.

Waste code proposed by the manufacturer

European waste catalogue (EWC)

Waste code	:	Waste designation
07 01 99	:	Other waste not listed.

Packaging

Methods of disposal : It must undergo special treatment in accordance with official regulations.
Handle contaminated packages in the same way as the substance itself.
Wash with plenty of water. .

Type of packaging	:	European waste catalogue (EWC)
Can	:	15 01 10* - packaging containing residues of or contaminated by hazardous substances
Barel	:	15 01 10* - packaging containing residues of or contaminated by hazardous substances
Container	:	15 01 10* - packaging containing residues of or contaminated by hazardous substances
Can	:	15 01 10* - packaging containing residues of or contaminated by hazardous substances

SECTION 14: Transport information

	ADR/RID	ADNR/ADN	IMDG	IATA
14.1. UN Number	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.2. UN Proper Shipping Name	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport Hazard Class(es)	Not relevant	Not relevant	Not relevant	Not relevant
14.4. Packing Group	Not relevant	Not relevant	Not relevant	Not relevant
14.5. Environmental Hazards	The substance is not classified as hazardous to the environment pursuant to applicable legal provisions.			
14.6. Special Precautions for users	The product does not require use of any special precautions apart from basic OHS provisions and recommendations of Sections 6, 7, 8 and 10.			

14.7 Maritime transport in bulk according to IMO instruments

N/A

SECTION 15: Regulatory information

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

Road Carriage of Hazardous Goods Act of 28 October 2002 (Journal of Laws Dz. U. No. 199, item 1671, 2002).

The Government's Statement on coming into effect of amendments to Annexes A and B to the European Agreement regarding international carriage of hazardous goods by road (ADR) prepared in Geveva as of 30 September 1957 of 26 July 2005 (Journal of Laws Dz. U. No. 178, item 1481, 2005 as amended).

The Minister of Health Regulation on marking of hazardous substances and preparations and some chemical preparations of 5 March 2009 (Journal of Laws Dz. U. No. 53 item 439, 2009).

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a 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 Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (published in the Official Journal of the European Union series L No. 396 of 30 December 2006, as amended).

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

The Waste Act of 27 April 2001 (Journal of Laws Dz. U. No. 62, item 628, 2001, as amended).

The Package and Package Waste Act of 11 May 2001 (Journal of Laws Dz. U. No. 63, item 638, 2001).

The Minister of Environment Regulation on the catalogue of waste of 27 September 2001 (Journal of Laws Dz. U. No. 112, item 1206, 2001).

The Act on Amendment to the Waste Act and Some Other Acts of 29 July 2005 (Journal of Laws Dz. U. No. 175, item 1458, 2005).

The Minister of Labour and Social Policy Regulation on the highest permissible concentrations and intensities of factors harmful to health in the work environment of 29 November 2002 (Journal of Laws Dz. U. No. 217, item 1833, 2002 as amended).

15.2 Chemical Safety Assessment:

No chemical safety assessment was required or performed.

SECTION 16: Other information

The data is confirmed based on the state of our knowledge, but does not determine how the production properties and cannot be used to justify legally binding contracts.

Abbreviations; acronyms and full text of H-Statements

H290	:	May be corrosive to metals.
H301	:	Toxic if swallowed.
H302	:	Harmful if swallowed.
H312	:	Harmful in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H315	:	Causes skin irritation.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H331	:	Toxic if inhaled.
H334	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	:	May cause respiratory irritation.
H341	:	Suspected of causing genetic defects.
H350i	:	May cause cancer by inhalation.
H360D	:	May damage the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
REACH	:	Registration, Evaluation, Authorisation and Restriction of Chemical
MARPOL	:	(from Marine Pollutant) International Convention for the Prevention of Marine Pollution from Ships
N/A	:	Not applicable
N/D	:	Not determined
NE	:	Not established
VOC	:	Volatile Organic Compound
AICS	:	Australian Inventory of Chemical Substances
AIHA WEEL	:	American Industrial Hygiene Association Workplace Environmental

Exposure Limits

DSL	:	Domestic Substance List (Canada)
ELINCS	:	European List of Notified Chemical Substances
ENCS	:	Existing and new Chemical Substances (Japanese inventory)
IECSC	:	Inventory of Existing Chemical Substances in China
KECI	:	Korean Existing Chemicals Inventory
NDSL	:	Non-Domestic Substances List (Canada)
NZIoC	:	New Zealand Inventory of Chemicals
PICCS	:	Philippine Inventory of Chemicals and Chemical Substances
TLV	:	Threshold Limit Value (American Conference of Governmental Industrial Hygienists)
TSCA	:	Toxic Substances Control Act (U.S. inventory)
UVCB	:	Substances of Unknown or Variable composition, Complex reaction products or Biological materials
IBC Code	:	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
UN	:	United Nations (also UNO: United Nations Organization)
NOEC	:	No Observed Effect Concentration
NOELR	:	No Observable Effect Loading Rate
OECD	:	Organization for Economic Co-operation and Development
ASTM	:	American Society for Testing and Materials
WAF	:	Water Accommodated Fraction
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 Labeling of Chemicals
EINECS	:	European Inventory of Existing Commercial Chemical Substances
CAS	:	Chemical Abstracts Service (division of the American Chemical Society)
DNEL	:	Derived No-Effect Level (REACH)
PNEC	:	Predicted No-Effect Concentration (REACH)
LC	:	Lethal Concentration
LD	:	Lethal Dose
LL	:	Lethal Loading
EC	:	Effective Concentration
EL	:	Effective Loading
LC50	:	Lethal concentration, 50 percent
LD50	:	Lethal dose, 50 percent
PBT	:	Persistent, Bioaccumulative and Toxic
vPvB	:	very Persistent and very Bioaccumulative
Acute Tox, 4	:	Acute toxicity - Category 4

Notice to reader

: The information contained herein is accurate to the latest knowledge and describes the product from the point of view of help and environmental protection as well as safe handling. The information presented in this SDS refers to the technical product only and will not apply to any processed product. Final determination of the suitability of any materials for the chosen application(s) is the sole responsibility of the user"