SAFETY DATA SHEET

[In accordance with the criteria of Regulation No 1907/2006 (REACH) with further changes]

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

1.1. Product identifier

Commercial name: PHARMACEUTICAL VEGETABLE GLYCERINE

Other name: 1,2,3-Propanetriol, 1,2,3-Trihydroxypropane, Glycerol, Glycerin, E422

INCI name: Glycerin

Identifier (CAS no.): 56-81-5

EC no.: 200-289-5

REACH Registration no.: glycerine is exempted from REACH registration obligation

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

Relevant identified uses: pharmacy, food industry, feed industry, cosmetic industry, plant protection industry, chemical industry (both as a component of mixtures and as a raw material for further syntheses).

Uses advised against: other than listed above.

1.3. Details of the supplier of the safety data sheet

Supplier: **CHEMNOVATIC Sp. z o.o. Sp. k.**

Address: Dobrzańskiego 3/BS002, 20-262 Lublin, POLAND

Phone: +48 81 475 44 42

E-mail address of the person responsible for the information card: office@chemnovatic.com

1.4. Emergency telephone number.

112 (general emergency phone number)

Section 2: Hazards Identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 of 16 December 2008 on classification, labeling and packaging (CLP)

- General Hazard: The product is not classified as hazardous under current legislation
- Health Hazards: Not applicable
- Hazardous properties: not applicable
- Environmental hazard: not applicable

2.2. Label elements

- Pictograms determining the type of hazards: not applicable
- Warning: not applicable
- Phrases indicating type of hazard: not applicable
- Phrases determining conditions of safe use: not applicable

2.3. Other hazards

Not applicable

Section 3: Composition/Information on ingredients

3.1 Substances

Composition according to Regulation 1272/2008.

- **Glycerol 99,5 %**
- **CAS no.:** 56-81-5
- **Index No.:** not applicable
- **EC no.:** 200-289-5
- **Chemical formula:** $C_3H_8O_3$
- **REACH Registration no**.: glycerin is exempted from REACH registration obligation

Provided that hazardous components are stated, meaning of H-phrases is specified in item 16 of the material safety data sheet.

Section 4: First Aid measures

4.1. Description of first aid measures

Inhalation: In the event of exposure through the respiratory system, provide access of fresh air. If the victim feels unwell, contact a doctor.

Skin contact: The product does not cause irritation, however, it is recommended to remove contaminated clothing and wash the skin with water. If any irritation occurs, contact a physician.

Eye contact: The product does not cause eye irritation, however it is recommended to flush eyes with plenty of lukewarm water, preferably running water. Remove contact lenses. Avoid strong water stream due to the risk of mechanical damage to the cornea. If irritation occurs, consult an ophthalmologist.

Ingestion: If swallowed, do not induce vomiting. It is recommended to rinse the mouth. In case of any complaints, please contact your doctor.

4.2. Most import ant symptoms and effects, both acute and delayed

Inhalation: Prolonged exposure to glycerin vapors may cause malaise, nausea, vomiting or diarrhea. If symptoms worsen, contact your doctor.

Skin contact: Slight irritation

Ingestion: Ingestion of more may cause malaise, nausea, vomiting or diarrhea. If symptoms worsen, contact your doctor.

No additional symptoms or effects are expected.

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

No data available.

Section 5: Firefighting measures

Flammable substance. The flash point of the pure product is approximately 177 °C. Auto-ignition occurs at temperatures above 370 °C. Containers not covered by fire should be transported to a safe place, if possible. Cool exposed containers with water spray.

5.1. Extinguishing media

Extinguishing agents: fire extinguishing powders, snow extinguishers, fire-fighting foams, water.

Unsuitable extinguishing agents: all extinguishing media are allowed.

5.2. Specific hazards associated with substance or mixture

At incomplete combustion, carbon monoxide may be generated, acrolein may be emitted. Wear gas-tight and gas-tight clothing, instead of respiratory protective equipment. Hot glycerin adheres strongly to the skin, causing severe burns.

5.3. Advice for firefighters

Containers exposed to fire or high temperatures are to be cooled down by spraying water from a safe distance. Use protective measures of the respiratory system and protective clothing.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: In the event of leakage or unintentional release, eliminate potential sources of ignition and secure the place from unauthorized persons. It is recommended to use basic protection in the form of protective gloves (e.g. rubber) and glasses.

For persons providing assistance: Persons directly involved in the neutralization of leakage should wear protective clothing in the form of tight gloves and glasses. In case of contact with hot substance, use heat-protective clothing and respiratory protection equipment. Collect the spilled liquid with the available equipment (the product is not aggressive or corrosive) or with the use of sorbents (mats, sawdust, etc.).

6.2. Environmental precautions

In the event of a leak, remove all sources of ignition and eliminate the leak if possible. Protect the surroundings against the product entering watercourses.

6.3. Methods and material for containment and cleaning up

Absorb the substance in a chemically inert binding material (sand, diatomaceous earth, sorbent), transfer to tightly closed containers and transfer for recycling. Rinse contaminated surface with water. For large leaks, consider creating a dam to minimize the leakage area.

6.4. References to other sections

Information on relevant personal protection equipment are specified in section 8. Information on additional waste treatment are specified in section 13.

Section 7: Handling and storage

7.1. Precautions for safe handling

Use in well ventilated rooms. Keep away from heat and sources of ignition. It is advisable to use gloves and goggles to avoid contact with skin and eyes when working with the substance. Do not breathe vapors / aerosols. Do not eat, drink or smoke when working with the substance. After work, remove protective clothing and wash your hands.

7.2. Conditions of safe storage, including any incompatibilities

Store in a ventilated storage room in tightly closed containers or containers (it has hygroscopic properties). Store away from heat sources at temperatures above freezing point (recommended from 10-25 °C, but not higher than 40 °C). In case of solidification, the product should be heated to the recommended storage temperature. Protect against light, contact with water or moisture. Do not store with substances that may enter a chemical reaction such as strong oxidants, phosphorus oxides, nitric and sulfuric acid.

7.3. Specific end use(s)

No data available

Section 8: Exposure control/personal protection

8.1. Control parameters

Maximum acceptable concentrations:

- glycerol (aerosols) - NDS 10 mg/m^3

Note: When the concentration of substance is determined and known, personal protection equipment should be selected, taking account of the concentration of substances present at a given working post, exposure time and activities

performed by the employee. In case of emergency, if the concentration of substances at the work post is unknown, use personal protection equipment with the highest recommended protection class.

The employer is obliged to ensure that any personal protection equipment used, as well as working clothes and footwear have protective and utility properties and provide their appropriate laundering, maintenance, repair and disinfection.

8.2. Exposure controls

Technical protective measures: general ventilation; due to the NDS established for the substance, it is recommended to carry out tests for the content of glycerol vapors in the work environment.

Individual protection measures:

Inhalation: If the permissible vapor concentration of the substance is exceeded or in case of insufficient ventilation, use road protection equipment with a properly selected filter.

Eye Protection: Wear eye protection, e.g. glasses, visors.

Protection of hands and skin: Use protective clothing made of natural materials or synthetic fibers, protective gloves e.g. made of nitrile rubber. In case of contact with hot substance, use heat-protective clothing.

Occupational hygiene: General industrial hygiene regulations apply. Do not eat and drink, do not smoke while working with the product. Avoid contamination of skin and eyes. Wash hands after work and before each breaks. Do not allow permissible normative concentrations of hazardous ingredients in the workplace.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance:	colourless
b) Smell:	odourless or almost odorless
c) Smell threshold:	not applicable
d) pH:	5-8
e) Melting/freezing point, [°C]:	18,17 at 101.3 kPa
f) Initial boiling point and range of boiling points, [°C]:	290 at 101.325 kPa
g) Flash point, [°C]:	177 – 199 at 101.3 kPa
h) Evaporation rate:	no data available
i) Flammability:	non flammable
j) Upper explosiveness limit, [% V/V]:	no data available
Lower explosiveness limit, [% V/V]:	no data available
k) Vapour Pressure [Pa]:	0.333 – 573.286 Pa at 50 – 150 °C
l) Density pressure:	no data available
m) Relative density [g/cm^3]:	1.261 at 20 °C
n) Solubility in water [g/l]:	1000 at 25 °C
o) Partition coefficient n-octanol / water:	2.66
p) Autoignition temperature, [°C]:	> 370
r) decomposition temperature:	> 130
s) Explosive properties:	no data available
t) Oxidising properties:	no data available
u) Viscosity [mPa s]:	1412 at 20 °C

9.2. Other information

Vapour density:	no data available
Surface tension [mN/m]:	63.4 at 1000 g/L and 20 °C

The substance has hygroscopic properties, at high temperature (fire) it may undergo thermal decomposition emitting poisonous acrolein.

Section 10: Stability and reactivity

10.1. Reactivity

The substance may react with strong oxidants, phosphorus oxide, nitric and sulfuric acids and derivatives.

10.2. Chemical stability

Stable under normal conditions. Access to water or moisture can cause deterioration product due to the hygroscopic properties of glycerin.

10.3. Possibility of hazardous reactions

The substance is stable under normal conditions of use and storage. Decomposition and side reactions occur above 290 °C. The breakdown of the substance may release harmful acrolein. The substance may react with strong oxidants, phosphorus oxide, nitric and sulfuric acids and derivatives.

10.4. Conditions to avoid

Avoid heating the product to high temperatures and light exposure and protect from sources of ignition.

10.5. Incompatible materials

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

10.6. Hazardous decomposition products

Carbon oxides at combustion, acrolein. During thermal decomposition, poisonous acrolein may be released. Carbon monoxide may be evolved during incomplete combustion.

Section 11: Toxicological information

11.1. Information on toxicological effects

The substance is not toxic to humans. Ingestion of the product in large quantities may cause abdominal pain, nausea, drowsiness and diarrhea.

a) Acute toxicity:

Acute toxicity - orally: LD50 12600 mg/kg (rat)

Acute toxicity - skin: LD50 18700 mg/kg (rabbit)

Acute toxicity - inhalation: LC50 > 570 mg/m^3/1h (rat)

b) Caustic/irritating effect on the skin:

- skin: does not cause irritation or slightly irritating

c) Caustic/irritating effect on the eyes:

- eyes: does not cause irritation or slightly irritating

d) Sensitisation:

- skin: no sensitizing effects found
- inhalation: no data available

e) Mutagenic effect: no data available

f) Carcinogenic effect: no carcinogenic effects

g) Harmful impact on reproduction capacity: no cases of reprotoxic effects are known

h) Toxic effect on target organs - single exposure: no toxic effects on the human body were found.

i) Toxic effect on target organs - repeatable exposure: no toxic effects on the human body were found.

j) Hazard caused by aspiration: inhalation of vapors / aerosols may be harmful to health (see section 8)

Section 12: Ecological Information

12.1. Toxicity

Toxicity to fish: LC50 > 10000 mg/l (Leuciscus idus); LC50 > 5000 mg/l/24 h (Carassius auratus)

Toxicity to daphnia: EC50> 10000 mg/l/24 h (Daphnia magna)

Toxicity to freshwater algae: EC50 2,9 g/L

Toxicity to bacteria: EC50 > 10000 mg/l/16 h (Pseudomonas putida)

If used correctly, the substance is not dangerous for the environment.

12.2. Persistence and degradability

Biodegradation: > 60% after 28 days, closed bottle test.

Prevent the substance from entering drains, soil, watercourses and water reservoirs. The product is easily biodegradable (log Pow = -2.66).

12.3. Bioaccumulative potential

The product has no capacity to accumulate in the environment

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

Not applicable.

12.6. Other adverse effects

No data available

Section 13: Disposal considerations

13.1. Waste treatment methods

Do not dispose of the substance as municipal waste. Do not empty into drains. Avoid contamination of ground and surface water. Transfer surplus product to companies specialized in waste collection.

Section 14: Transport Information

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5 Environmental hazards

The mixture is not classified as dangerous for the environment.

14.6 Special precautions for user

Use protective measures according to section 8

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

Not applicable

Section 15: Regulatory Information

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

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization 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.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
Commission Regulation (EU) No 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).

15.2. Assessment of chemical safety.

The manufacturer did not made a Chemical Safety Assessment.

Section 16: Other Information

a) revised safety data sheet – changes

All sections - current changes based on available data

b) legend to abbreviations and acronyms used in the safety data sheet

TWA Time Weighted Average

PEL Permissible exposure limit

TLV-C Threshold limit value- Ceiling Limit

STEL Short-term exposure limit

PBT Persistent, Bioaccumulative and Toxic substance

vPvB very Persistent, very Bioaccumulative substance

CAS Chemical Abstract Service

EC No. is a unique seven-digit identifier that is assigned to chemical substances for regulatory purposes within the European Union by the regulatory authorities.

LD50 lethal dose, the point where 50% of test subjects exposed would die

LC50 lethal concentraction, the point where 50% of test subjects exposed would die

half maximal effective concentration

UN number is four-digit number that identify hazardous substances

ATEmix Acute Toxicity Estimates for mixture

PEB permitted exposure for a biological material

c) list of relevant H phrases, hazard statements, safety phrases and/or precautionary statements- full text

not applicable

d) trainings

Before commencing working with the product, the user should learn the Health & Safety regulations, regarding handling chemicals, and in particular, undergo a proper workplace training.

e) other data

Classification was made on the basis of data on hazardous substances calculation method based on the guidelines of Regulation 1272/2008/EC (CLP).

The above information is prepared on the basis of current state of knowledge and relates to the product in the form in which it is used. Data relating to the product are presented in order to include safety requirements, and not to guarantee their particular properties.

In the event when conditions of application of the product are beyond control of the manufacturer, responsibility for safe use of the product is borne by the user.

The Employer is obligated to inform all employees who have contact with the product, about hazards and personal protection equipment specified in this material safety data sheet.

This material safety data sheet has been prepared on the basis of MSDS provided by the manufacturer and/or web databases and the binding regulations regarding hazardous substances and chemical agents.

The product is classified as hazardous. EXPOSURE SCENARIOS are not required.