

[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).

<u>Uses advised against:</u> other than listed above.

1.3. Details of the supplier of the safety data sheet

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

Address: Ludwika Spiessa 9, 20-270 Lublin, POLAND

Phone: +48 814754442;

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 1272/2008/EC

This mixture is not classified for its health hazards under CLP.

This mixture is not classified for its physical hazards under CLP.

This mixture is not classified for its environmental hazards under CLP

## 2.2. Label elements

Hazard symbols and signal words

Not applicable.

**Hazard statements** 

Not applicable.

**Precautionary statements** 

Not applicable.

### 2.3. Other hazards

This mixture does not meet criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation. Product does not have endocrine disrupting properties. No other hazards to determine. This mixture does not contain "Substances of Very High Concern" on the list published by the European Chemicals Agency (ECHA) pursuant to Art. 57 of the REACH regulation.



# 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<sub>3</sub>H<sub>8</sub>O<sub>3</sub>

**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

As a general rule, in case of doubt, or when symptoms persist, always call a physician. NEVER make an unconscious person vomit.

<u>Skin contact:</u> 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.

<u>Eye contact</u>: 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

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

<u>Ingestion:</u> 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

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

Skin contact: Slight irritation

<u>Ingestion</u>: 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

<u>For non-emergency personnel</u>: 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.

<u>For persons providing assistance</u>: 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

Appropriate conduct with waste product - see section 13. Personal protective equipment - see section 8.

### 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 information about the applications other than those listed in subsection 1.2.



# Section 8: Exposure control/personal protection

#### 8.1. Control parameters

Maximum acceptable concentrations:

glycerol (aerosols) - NDS 10 mg/m<sup>3</sup>

<u>Note:</u> 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

<u>Technical protective measures</u>: 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:**

<u>Inhalation</u>: 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.

<u>Protection of hands and skin</u>: 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.

<u>Occupational hygiene</u>: 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) Physical state: liquid
b) Colour: colourless

c) Odour: odorless or almost odorless

d) Melting point/freezing point: 18,17 °C at 1.013 hPa

e) Boiling point or initial boiling point and boiling range: 290 °C at 101.325 kPa non flammable

g) Lower and upper explosion limit [% V/V]: no data available

h) Flash point: 177 – 199 °C at 101.3 kPa

i) Auto-ignition temperature: > 370 °C j) Decomposition temperature: > 130 °C

k) pH: 6,5-7,5 (50 %)
l) Kinematic viscosity: no data available

m) Solubility: soluble in water (1000 g/l at 25 °C)

n) Partition coefficient n-octanol/water (log value): 2.66

o) Vapour pressure: 0.333 – 573.286 Pa at 50 – 150 °C

p) Vapour density: 2.60 (20 °C).

q) Density and/or relative density: 1.261 g/cm³ at 20 °C r) Relative vapour density: no data available



#### 9.2. Other information

Surface tension: 63.4 mN/m at 1000 g/L and 20 °C

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

Particle characteristics: no data available Viscosity: 1412 mPa s at 20 °C

# 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/m³/1h (rat)

b) Skin corrosion/irritation

Does not cause irritation or slightly irritating.

c) Serious eye damage/irritation

Does not cause irritation or slightly irritating

d) Respiratory or skin sensitization

No sensitizing effects found

e) Germ cell mutagenicity

No data available.

f) Carcinogenicity

No carcinogenic effects.



#### g) Reproductive toxicity

No cases of reprotoxic effects are known.

#### h) STOT-single exposure

No toxic effects on the human body were found.

#### i) STOT-repeated exposure

No toxic effects on the human body were found.

#### j) Aspiration hazard

Inhalation of vapors / aerosols may be harmful to health (see section 8)

#### 11.2. Information on other hazards

No data available.

## 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. Endocrine disrupting properties

Product does not have endocrine disrupting properties.

#### 12.7. Other adverse effects

This product has no influence on the global warming or the ozone layer depletion. Consider other harmful effects of the individual components of the mixture on the environment (eg impact on the growth of global warming).

## **Section 13: Disposal considerations**

### 13.1. Waste treatment methods

<u>Disposal methods for the product</u>: disposal in accordance with the local legislation. Store remainings in <u>original containers</u>. Do not empty into drains. Submit to neutralization by a licensed waste processing company.

<u>Disposal methods for used packing:</u> reuse/recycling/liquidation of empty containers, dispose in accordance with the local legislation. Do not dispose empty packing with regular household waste. Do not mix with other waste. Submit to neutralization by a licensed waste processing company. Proper waste management of the mixture and / or container should be determined in accordance with the provisions of Directive 2008/98 / EC.



## **Section 14: Transport Information**

#### 14.1. UN number or ID 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 IMO instruments

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 (EC) 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) 2020/878** of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

#### 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.

Version 3.0 - New MSDS format update and company address update.

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

EC50 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

H300 Fatal if swallowed

H310 Fatal in contact with skin

H330 Fatal if inhaled

H411 Toxic to aquatic life with long lasting effects

#### 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.