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 PROPYLENE GLYCOL

Other name: 1,2-Propylene Glycol, Mono Propylene Glycol, Propane-1,2-diol, 1,2-Dihydroxypropane, E1520

INCI name: Propylene Glycol

Identifier (CAS no.): 57-55-6

EC no.: 200-338-0

REACH Registration no.: 01-2119456809-23-XXXX

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

Relevant identified uses: Substance production, industrial applications, Applications in coatings, in cleaning agents, as binders and in release agents, production of polymers: rubber production and processing, water treatment chemicals, mining chemicals, use as binders and release agents, in coatings, professional special fluids , for thawing and anti-icing, use in agrochemicals. Consumer applications in cosmetics, e-liquids, food industry, medicine and pharmacy as well as in the tobacco industry.

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 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 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: product not classified as posing a hazard pursuant to valid regulations.
- Phrases determining conditions of safe use: not applicable

2.3. Other hazards

The product does not meet the criteria for PBT or vPvB in accordance with the criteria in Annex XIII of Regulation 1907/2006.

Section 3: Composition/information on ingredients

3.1. Substance

Composition according to Regulation 1272/2008.

- **> 99,9 % Propane-1,2-diol**
- **CAS no.:** 57-55-6
- **Index No.:** not applicable
- **EC no.:** 200-338-0
- **Chemical formula:** $C_3H_8O_2$
- **Reach registration number:** 01-2119456809-23-XXXX

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

Skin contact: Wash the skin after contact with the substance with soap and plenty of water as a precaution.

Eye contact: Flush eyes with water at least 15 minutes as a precaution. Get medical attention if eye irritation develops or persists.

Inhalation: Move victim into fresh air as a precaution. If not breathing, give artificial respiration.

Ingestion: Rinse mouth with water as a precaution. Never give anything by mouth to an unconscious person.

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

No additional symptoms or effects are expected.

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

No special antidote. Supporting treatment, based on assessment made by a doctor on the basis of the patient's response.

Section 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: adjust the extinguishing agent to the material collected in the environment. Water spray, alcohol-resistant foam, dry chemical, carbon dioxide (CO_2)

Unsuitable extinguishing media: no data available.

5.2. Special hazards arising from the substance or mixture

Under the influence of a high temperature (fire), flammable vapours are developed, that form explosive mixtures with air. Incomplete combustion products may contain carbon monoxide and dioxide. As a result of fire the container may burst and cause a gas leak. Direct addition of water to hot liquid may result in rapid generation of steam or even its eruption.

5.3. Advice for firefighters

Personal protection typical in case of fire. Wear suitable respiratory equipment. Cool down containers with water from safe distance to prevent bursting. Evacuate personnel to safe areas. Evacuate personnel and keep upwind of fire.

Section 6: Accidental release measures

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

6.1. Personal precautions, protective equipment and emergency procedures

Limit the access for the outsiders into the breakdown area, until the suitable cleaning operations are completed. In case of large spills, isolate the exposed area. Ensure adequate ventilation. Avoid contact with skin and eyes. Avoid contact with spilled material. Danger of slipping, do not passed through spilled material. Wear adequate personal protective equipment. Do not allow the product to get into mouth. Avoid breathing vapours, mist or gas.

6.2. Environmental precautions

In case of release of large amounts of the product, it is necessary to take appropriate steps to prevent it from spreading into the environment.

6.3. Methods and material for containment and cleaning up

Stop the leakage, if possible. Soak up with liquid-binding material (e.g. sand, universal binding agent, diatomaceous earth). Collect spilled material in containers for disposal. Disposal in accordance with the local legislation. Clean the contamination place.

6.4. Reference 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

No special precautions are needed in handling this material. Remove contaminated clothing immediately. Clean contaminated clothing. Thoroughly clean/dry the installation before use. Use earthed equipment. Keep away from naked flames/heat. At temperature > flashpoint: use spark-/explosion proof appliances. Finely divided: spark- and explosion proof appliances. Finely divided: keep away from ignition sources/sparks. Observe normal hygiene standards. Keep container tightly closed. Measure the concentration in the air regularly. Carry operations in the open/under local exhaust/ventilation or with respiratory protection.

7.2. Conditions of safe storage, including any incompatibilities

Keep in properly labeled, original containers in ventilated warehouse. Eliminate all sources of combustion. Do not store near heat sources or expose to direct sunlight, to preserve the quality of the product. Keep away from food, feed and beverages. Keep away from moisture (hygroscopic). Suggested storage temperature: 10-25 °C, not higher than < +40 °C. Incompatible substances: No data available.

7.3. Specific end use(s)

No data available

Section 8: Exposure controls/personal protection

8.1. Control parameters

DNEL value for employees under the conditions of long-term exposure by inhalation (system effect): 50 mg/m^3
DNEL value for employees under the conditions of long-term exposure by inhalation (local effect): 10 mg/m^3
DNEL value for consumers under the conditions of long-term exposure by inhalation (system effect): 168 mg/m^3
DNEL value for consumers under the conditions of long-term exposure by inhalation (local effect): 10 mg/m^3
PNEC value for the environment of fresh waters: 260 mg/l PNEC value for the environment of marine waters: 26 mg/l
PNEC value (temporary release): 183 mg/l PNEC value (sewage treatment plant): 20000 mg/l
PNEC value for the environment of sediment (fresh waters): 572 mg/kg
PNEC value for the environment of sediment (marine waters): 57,2 mg/kg
PNEC value for the environment of soil: 50 mg/kg
Maximum acceptable concentrations:
The Mallinckrodt Baker, Inc. MSDS P6928 for propylene glycol lists the AIHA Workplace Environmental Exposure Limit (WEEL) of 10 mg/m^3 TWA. This limit is also posted in the 2010 WEEL Values from AIHA. ACGIH does not have a TLV for propylene glycol. The lesser of the AIHA limits for propylene glycol exposure will be used by COUPP.
● WEL TWA: 474 mg/m^3 (UK)

● WEL TWA 150 ppm (UK)

Propylene Glycol is listed under Paragraph 9, the Ontario (Canada) Table, of Regulation 833 with

1. a TWA of 50 ppm or 155 mg/m^3 of vapour or aerosol,
2. or a TWA of 10 mg/m^3 of aerosol for assessing the visibility in a work environment where 1,2-propylene glycol aerosol is present.

As no aerosol is being formed the first limit is legally applicable.

Respiratory protection: A respiratory protection program that meets country requirements should be followed whenever workplace conditions warrant respirator use. Consult the respirator manufacturer to determine the appropriate type of equipment for a given application. Observe respirator use limitations specified by the manufacturer.

Eye protection: Wear safety glasses with side shields.

Skin and body protection: Where there is potential for skin contact have available and wear as appropriate impervious gloves, apron, pants, and jacket.

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

Protection of the respiratory system: not required under normal conditions, in the case of formation of a mist/aerosol, use a mask with an organic vapour absorber.

Eye Protection: safety goggles / sealed safety glasses according to EN 166

Protection of hands: handle with gloves according to EN 374. Avoid skin contact with this product.

Technical protective measures: local exhaust ventilation

Other protection equipment: impervious working clothes

General recommendations: Comply with good personal hygiene.

Do not consume, nor store food at the workplace. Before smoking tobacco or eating, wash hands.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance:	colorless liquid
b) Smell:	odorless or almost odorless
c) Smell threshold:	not applicable
d) pH:	6,5-7,5 (50 %)
e) Melting/freezing point, [°C]:	-20 at 1.013 hPa
f) Initial boiling point and range of boiling points, [°C]:	184 at 100.32 kPa
g) Flash point, [°C]:	104 at 100.01 kPa
h) Evaporation rate:	<0.1 (butyl acetate=1)
i) Flammability (of solid body, gas):	not applicable
j) Upper explosiveness limit, [% V/V]:	Upper: 12.6 vol %
Lower explosiveness limit, [% V/V]:	Lower: 2.6 vol %.
k) Vapour Pressure [hPa]:	20 at 25 °C
l) Density pressure:	2.60 (20 °C).
m) Density, [g/cm^3]:	1,03 at 20 °C
n) Solubility in water:	100 % at 20 °C and pH 7.1 - 7.8
o) partition coefficient n-octanol / water:	log Pow = -1.07 at 20.5 ˚C and pH = 6.2-6.4

p) auto-ignition temperature, [°C]:	400 at 100.01 – 101.44 kPa
r) decomposition temperature:	not determined
s) explosive properties:	non-explosive
t) oxidising properties:	no
u) Viscosity, [mPa s]:	43.4 at 25 ˚C

9.2. Other information

No data available

Section 10: Stability and reactivity

10.1. Reactivity

Hazardous reactions under conditions of normal use are not known.

10.2. Chemical stability

Stable at normal temperatures and storage conditions.

10.3. Possibility of hazardous reactions

Reacts violently with (strong) oxidants (increased) risk of fire. Violent and explosive reaction with (strong) acids.

10.4. Conditions to avoid

Keep away from open flames / heat. If a higher temperature than the flash point is possible: use explosion-proof, anti-static devices. Hygroscopic product, avoid moisture.

10.5. Incompatible materials

Strong acids and oxidizing and reducing agents, water (moisture).

10.6. Hazardous decomposition products

Substance does not decompose by itself. Carbon oxides formed under fire conditions.

Section 11: Toxicological information

11.1 Information on toxicological effects

a) Acute toxicity:
Acute toxicity - alimentary tract: LD50 22000 mg/kg bw (rat). It is believed that oral toxicity of a single dose is extremely low. No hazard is expected after consumption of small amounts, which happens during normal manipulation operations.
Acute toxicity - after application on skin: LD50 2000 mg/kg bw (rabbit). Absorption through the skin, in one-time, long-term exposure, of harmful amounts of this material, is not possible
Acute toxicity - inhalation: At room temperature concentration of vapours is very low due to physical properties. Mists may cause irritation of the upper respiratory tract (nose and throat). At this concentration, no cases of death were recorded.
b) Caustic/irritating effect on the skin: Long-term contact is generally not irritating for the skin. Repeated exposure may cause the skin to flake and soften.
c) Serious damage to eyes/ irritating effect on eyes: It may cause very weak, temporary irritation to eyes. Damage to the cornea is improbable. Mists may cause irritation to the eyes
d) Allergenic effect on the respiratory tract or skin: in the tests it did not induce allergic reactions of skin.
e) Mutagenic effect on reproductive cells: In vitro mutagenicity studies were negative. Tests of genetic toxicity on animals rendered negative results.
f) Carcinogenicity: it did not cause occurrence of malignant tumours in laboratory animals.
g) Reproductive toxicity: in tests on animals it did not show an effect on reproduction capacity. In tests on animals it did not affect fertility. Development toxicity: No cases of defects in new-borns or other harmful effects on the foetus in laboratory animals were observed.
h) Substance toxic for organs or systems - One-time exposure: no data available

i) Substance toxic for organs or systems - Repeated exposure: in rare cases, repeated exposure to glycol may cause effects related to the impact on the central nervous system.
j) Hazard caused by aspiration: no data available.

Section 12: Ecological information

12.1. Toxicity

Aquatic Toxicity

Toxicity to fish: LC50: 40.613 g/l/96 h (Oncorhynchus mykiss)
Toxicity to aquatic invertebrates: LC50: 18.34 g/l/48 h (Ceriodaphnia dubia), LC50: 18.8 g/l/96 h (Mysidopsis bahia)
Toxicity to algae: EC50: 19 g/l/96 h, (Selenastrum capricornutum) inhibiting the growth rate, EC50: 19.1 g/l/96h, (Skeletonema costatum) inhibiting the growth rate.

Toxicity to microorganisms: NOEC 20 g/l/18 h (Pseudomonas putida)
Value of chronic toxicity for water invertebrates: NOEC: 13020 mg/l/7 d (Ceriodaphnia), static regeneration, reproduction.

12.2. Persistence and degradability

Readily biodegradable. Photodegradation in water is slow. Biodegradable in soil under anaerobic conditions.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

Low potential for absorption in soil.

12.5. Results of PBT and vPvB assessment

The product does not meet the criteria for PBT or vPvB in accordance with the criteria in Annex XIII of Regulation 1907/2006.

12.6. Other adverse effects

This substance is not included in Annex I to Regulation (EC) 2037/2000 on substances that deplete the ozone layer.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal methods for the product: disposal in accordance with the local legislation. Disposal methods for used packing: reuse/recycling/liquidation of empty containers dispose in accordance with the local legislation. Do not dispose empty packing with regular household waste.

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. Chemical safety assessment

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 concentration, the point where 50% of test subjects exposed would die

half maximal effective concentration

UN number is four-digit number that identify hazardous substances

ATE mix 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.