Material Safety Data Sheet

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

PROPYLENGLYCOLUM

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Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Propylene glycol Propylenglycolum Propyleenglycol Propylèneglycol Propylenglycol
N° CAS:	57-55-6
N° EC:	200-338-0

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

The substance is not classified according to the CLP regulation.

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

Results of PBT and vPvB assessment: PBT: Not applicable. vPvB: Not applicable.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Propylene glycol
IUPAC name:	Propane-1,2-diol
Synonyms:	Methylethyl glycol Isopropylene glycol
N° CAS:	57-55-6
N° EC:	200-338-0
Molecular Formula:	$C_3H_8O_2$
Content:	100%

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove contaminated clothing immediately.
After inhalation:	Supply fresh air; consult doctor in case of symptoms.
After skin contact:	If skin irritation continues, consult a doctor. Immediately wash with water and soap and rinse thoroughly.
After eye contact:	Rinse eyes for several minutes under running water, keeping the eye socket open. Consult a doctor if symptoms persist.
After ingestion:	Rinse mouth with water

4.2 Most important symptoms and effects, both acute and delayed

Dizziness, headache, cough, nausea, cramps.

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:	Alcohol-resistant foam, carbon dioxide, water spray, extinguishing powder, BC powder. Adapt fire-fighting measures to the surrounding area.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

In case of heating or fire, toxic gases may be formed. In case of fire, gases may be released: Carbon monoxide (CO), carbon dioxide (CO_2).

5.3 Advice for firefighters

Surrounding fires:	Cool the exposed containers with water spray. Collect the contaminated fire fighting water separately; it may not be discharged into the sewer system. The fire debris and contaminated

	extinguishing water must be disposed of in accordance with official regulations.
Protection against fire:	Wear respiratory protection equipment that is not dependent 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 equipment. Use breathing protection against the effects of fumes/dust/aerosol. Ensure adequate ventilation. Keep away from ignition sources. Keep people at a distance and stay upwind.

For emergency responders

Wear personal protective equipment. Use breathing protection against the effects of fumes/dust/aerosol. Ensure adequate ventilation. Keep away from ignition sources. Keep people at a distance and stay upwind.

6.2 Environmental precautions

Do not allow to penetrate into the ground/soil.

Dilute with plenty of water.

Do not allow to enter drains/surface water/groundwater.

6.3 Methods and material for containment and cleaning up

Collect in special tanks for recovery or salvage. Carefully clean the accident site; are suitable for this purpose: Dilute with plenty of water. Absorb with liquid-binding material (sand, mountain flour, acid binders, universal binders, sawdust).

6.4 Reference to other sections

Information on safe handling - see section 7.

Information on personal protective equipment - 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 container tightly sealed. Information about fire and explosion protection: Use explosion-proof appliances/fittings and spark-proof tools.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in an airtight container.
Conditions for safe storage, including any incompatibilities:	Store only in the original packaging. Suitable material for tanks and pipes: aluminium, copper. Store separately from oxidising agents.

	Product is hygroscopic. Store tank in a well-ventilated place. Maximum storage temperature: 40 °C. Minimum storage temperature: 0 °C. Recommended storage temperature: ~ 20 °C.
Storage – away from:	Protect from humidity and water. Protect from light. Protect from air/oxygen exposure.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

DNELs

Inhalation DNEL Long-term - Systemic (worker): 168 mg/m^3 (/)

Inhalation DNEL Long-term - Local (worker): 10 mg/m^3 (/)

Inhalation DNEL Long-term - Systemic (consumer): 50 mg/m^3 (/)

Inhalation DNEL Long-term - Local (consumer): 10 mg/m^3 (/)

PNECs

PNEC Fresh water: 260 mg/l (/)

PNEC Marine water: 26 mg/l (/)

PNEC Intermittent releases: 183 mg/l (/)

PNEC Fresh water sediment: 572 mg/kg (/)

PNEC Marine sediment: 57.2 mg/kg (/)

PNEC Soil: 50 mg/kg (/)

PNEC STP: 20 000 mg/l (/)

Additional data: Lists valid at the time of compilation were used as basis.

8.2 Exposure controls

Appropriate engineering control

Clean the skin thoroughly after work and before breaks. The usual precautionary measures for handling chemicals should be observed.

Individual protection measures

Eye/face protection:	Close-fitting safety goggles. EN 166.
Skin protection:	Wear suitable protective work clothing.
Hand protection:	The glove material must be impermeable and resistant to the product/substance/preparation. No recommendation for the glove material for the product/preparation/chemical mixture can be made on the basis of failed tests. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation Material of gloves: Nitrile rubber. The selection of a suitable glove is not only dependent on the material, but also on other quality characteristics and varies from manufacturer to manufacturer. Penetration time of glove material: The exact penetration time can be found out from the glove manufacturer; please keep this in mind.

Respiratory protection:	Filter A.
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:	A viscous, clear, colourless, hygroscopic liquid.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	6,5 – 7,5
Melting/freezing point:	-60 °C
Initial boiling point:	102 °C
Boiling range:	Not available.
Flash point:	102 °C
Evaporation rate:	< 0,1
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Lower explosion limit: 2.6 Vol %. Upper explosion limit: 12.6 Vol %
Vapour pressure:	20 hPa (25 °C)
Vapour density:	2.60 (20 °C)
Relative density:	Not available.
Solubility:	Miscible with ethanol (96 per cent).
Solubility in water:	Miscible with water. 1000 g/l (20 °C)
Partition coefficient (n-octanol/water):	-0,92082
Auto-ignition temperature:	> 400 °C
Decomposition temperature:	Not available.
Viscosity:	Dynamic at 20 °C: 43.43 mPas
Explosive properties:	The product is not explosive.
Oxidising properties:	Non-oxidising.

9.2 Other information

Density: 1,03 - 1,04 g/cm3 (20 °C)
Molar mass: 76.10 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable.

Thermal degradation/ conditions to be avoided: No degradation if stored and handled as directed.

10.3 Possibility of hazardous reactions

Reacts with strong acids.

Reactions with strong alkalis.

Reactions with strong oxidizing agents.

10.4 Conditions to avoid

Extremely high temperatures.

10.5 Incompatible materials

Strong oxidising agents, strong acids, strong bases, zinc.

10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide, aldehydes, toxic gases/vapours.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Based on available data, the classification criteria are not met. Oral LD_{50} (rat): > 10 400 mg/kg Dermal LD_{50} (rabbit): 20 800 mg/kg Inhalation LC_{50} (rabbit): > 317.042 mg/l (2h)
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:	Not available.
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:	Based on available data, the classification criteria are not met.
Skin contact:	Based on available data, the classification criteria are not met.
Inhalation:	Based on available data, the classification criteria are not met.
Ingestion:	Based on available data, the classification criteria are not met.
Aspiration:	Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:

EC50 (72 h): 24 200 mg/l (*Selenastrum capricornutum*)

LC/EC/IC 50: > 100 mg/l (fish)

LC/EC/IC 50: > 100 mg/l (algae)

LC/EC/IC 50: > 100 mg/l (TISBE marine copepod)

LC/EC/IC 50: > 100 mg/l (activated sludge)

NOEC: > 100 mg/l (fish)

NOEC: 13 020 mg/l (daphnia) (*Ceriodaphnia sp.*, 7d)

LC 50 (96 h): 51 600 mg/l (*Oncorhynchus mykiss*)

LC 50 (96 h): 46 500 mg/l (*Pimephales promelas*)

EC 50 (48 h): 43 500 mg/l (*Daphnia magna*)

12.2 Persistence and degradability

Readily biodegradable.

Degree of elimination: OECD 301 F: 81 % (/) (28d); OECD 301 A: 90-100 % (/) (8d)

12.3 Bioaccumulative potential

Due to the n-octanol/water partition coefficient, enrichment in organisms is not to be expected.

BCF: < 100 (/)

12.4 Mobility in soil

No further relevant information available.

Behaviour in waste water treatment plants: When a small quantity is added correctly to a biological wastewater treatment plant, disturbances of the activated sludge are not to be expected.

COD value: 1.63 g/g

General information Water hazard class 1 (D) (Listed classification): slightly hazardous for water.

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 rubbish.

European waste catalogue:

07 00 00: WASTES FROM ORGANIC CHEMICAL PROCESSES

07 01 00: wastes from the manufacture, formulation, supply and use (MFSU) of basic organic chemicals

07 01 99: wastes not otherwise specified

Contaminated packaging: Recommendation: Non-contaminated packaging may be re-used. Packagings that cannot be cleaned are to be disposed of like the substance itself.

Recommended cleaning agent: Water, if necessary with cleaning agents added.

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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 applicable.

14.6 Special precautions for user

Not applicable.

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

Not applicable.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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 Bioaccumalative

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.

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16.8 Department issuing MSDS

Quality Department
FRAVER NV
info@magis-pharma.be