Material Safety Data Sheet

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

TROMETAMOLUM

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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:	Trometamol Trometamolum Trometamol Trométamol Trometamol
N° CAS:	77-86-1
N° EC:	201-064-4

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:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts 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

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

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

This substance is not considered to be persistent, bioaccumulative and toxic (PBT).
This substance is not considered to be very persistent and very bioaccumulating (vPvB).

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Trometamol
IUPAC name:	2-amino-2-(hydroxymethyl)propane-1,3-diol
Synonyms:	Tris(hydroxymethyl)aminomethane Tromethamine Tris Tris base Trisamine Trizma Tham
N° CAS:	77-86-1
N° EC:	201-064-4
Molecular Formula:	$C_4H_{11}NO_3$
Content:	Trometamol contains not less than 99.0 per cent and not more than the equivalent of 100.5 per cent of aminomethylidynetri(methanol), calculated with reference to the dried substance.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Take to fresh air. In case of symptoms of illness, consult a doctor.
After skin contact:	Wash off with plenty of water.
After eye contact:	Rinse eyes thoroughly with water for several minutes. Remove contact lenses after the first 1-2 minutes and continue rinsing for several minutes. Consult a doctor if any side effects occur, preferably an ophthalmologist.
After ingestion:	No urgent medical treatment required.
Self-protection of the first aider:	If there is a risk of exposure, consult section 8 for specific personal protective equipment.

4.2 Most important symptoms and effects, both acute and delayed

Remarks for the physician: Treatment of exposure should take into account the symptoms and the clinical condition of the patient. No specific antidote.

4.3 Indication of any immediate medical attention and special treatment needed

Nothing known.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water, CO_2 fire extinguishers, extinguishing powder.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Specific hazards in case of firefighting: Pneumatic transport and other mechanical actions can generate combustible dust. To reduce the risk of dust explosion, avoid dust accumulation. During a fire, gas development can cause the container to rupture.

Hazardous combustion products: In case of fire, the smoke may contain the original product as well as combustion products of varying composition which may be toxic and/or irritating. Hazardous combustion by-products include: Carbon dioxide, carbon monoxide, nitrogen oxides.

5.3 Advice for firefighters

Surrounding fires:	Hand-held fire extinguishers filled with carbon dioxide or dry chemicals can be used in the event of a small fire. Soak thoroughly with water to cool and prevent re-ignition. Keep people away. Isolate the area where the fire is burning and do not allow unnecessary access. Fight the fire from a protected place or at a safe distance. Consider the use of unmanned water cannons. Evacuate personnel immediately if the ventilation system starts to sound or if the container becomes discoloured. Remove container from fire area if this can be done without risk. Use water spray to cool containers exposed to fire and the area involved in the fire until the fire is extinguished and the danger of re-ignition eliminated.
Protection against fire:	Wear self-contained breathing apparatus (positive pressure type) and protective firefighting clothing including a helmet, jacket, trousers, boots, and gloves. Fight the fire at a safe distance if protective equipment is not available or not used.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Only allow necessary and sufficiently protected personnel into the area. Use appropriate protective equipment. For additional information, see section 8: Exposure controls/personal protection.

For emergency responders

Only allow necessary and sufficiently protected personnel into the area. Use appropriate protective equipment. For additional information, see section 8: Exposure controls/personal protection.

6.2 Environmental precautions

Avoid any discharge of the product into soil, ditches, sewers, waterways and/or groundwater. See section 12, Ecological Information.

6.3 Methods and material for containment and cleaning up

Contain spillage if possible.

Collect in suitable containers, properly labelled.

Ensure that dust formation in the air is prevented as far as possible.

For additional information, see section 13, Disposal instructions.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid generation and inhalation of dust. Keep container tightly closed.
Personal protection:	See section 8: Exposure controls/Personal protection.
Technical protective measures:	Avoid generation and inhalation of dust. Proper care and control of dust are necessary for safe handling of the product.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store in a dry place. Do not store in: Zinc, galvanised containers, aluminium, copper, copper alloys.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any components for which MAC values have been established.

8.2 Exposure controls

Appropriate engineering control

Local exhaust ventilation may be required for some operations. Provide local exhaust ventilation, or other technical measures, to keep the concentrations in the atmosphere below the limit values. If no limit values exist, general ventilation should be sufficient for most work activities.

Individual protection measures

Eye/face protection:	Use safety goggles with side-shields. The safety goggles with side-shields must comply with EN 166 or a comparable standard.
Skin protection:	Wear clean, long-sleeved body-covering clothes.
Hand protection:	When prolonged or frequently repeated contact may occur, gloves are recommended to avoid contact with the solid. For this substance, use non-penetrable gloves, if prolonged or frequently repeated contact may occur. Use chemical-resistant gloves, classified under EN374: gloves for protection against chemicals and micro-organisms. Examples of preferred glove materials that provide a barrier: Neoprene. Polyvinyl chloride ("PVC" or "vinyl"). Nitrile/butadiene rubber ('nitrile' or 'NBR').

	ATTENTION: The selection of specific gloves for a particular application and time of use in a workplace should also take into account all other relevant factors at the workplace such as (but not limited to): other chemicals that may be handled, physical requirements (cut/puncture protection, dexterity, thermal protection), possible physical reactions to the glove material, and the glove supplier's instructions/specifications.
Respiratory protection:	Respiratory protection should be worn if the MAC value is exceeded. If no MAC values exist, wear respiratory protection if adverse effects (such as respiratory irritation) or discomfort occur, or when indicated by your risk assessment process. In dusty or misty environments, use an approved dust filter. The following air-purifying respirators should be effective: Particle filter.
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 white or almost white, crystalline powder, or colourless crystals.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	10.4 (Method: Literature) (1% aqueous solution)
Melting/freezing point:	171 - 172 °C (Method: Literature)
Initial boiling point:	Not applicable.
Boiling range:	Not applicable.
Flash point:	Test type: closed cup Not applicable
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Zero (Method: Literature)
Vapour density:	Not available.
Relative density:	Not applicable.
Solubility:	Sparingly soluble in alcohol, very slightly soluble in ethyl acetate.
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Log Pow: -2.31 (Method: Measured) Bioconcentration potential is low (BCF < 100 or log Pow < 3).
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Kinematic: Not applicable.

Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular weight: 121 g/mol (Method: Calculated)

Hygroscopic: yes

NOTE: The physical and chemical data presented in section 9 are typical values for this product and are not intended as product specifications.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reactions have been observed under normal conditions of use.

10.2 Chemical stability

Hygroscopic.

Stable under recommended storage conditions. See section 7, Storage.

10.3 Possibility of hazardous reactions

Polymerisation will not occur.

10.4 Conditions to avoid

Exposure to high temperatures may cause this product to decompose.

Gas formation during decomposition may lead to pressure build-up in closed systems.

Avoid moisture.

10.5 Incompatible materials

Avoid contact with: Strong acids. Strong oxidising agents.

Avoid contact with metals such as: Zinc. Galvanised metals. Aluminium. Copper. Copper alloys.

Prevent accidental contact with: Halogenated hydrocarbons.

10.6 Hazardous decomposition products

The decomposition products depend on temperature, air supply and the presence of other substances.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not classified based on available information.	
	Acute oral toxicity:	Remarks: Very low toxicity if swallowed. Swallowing small amounts is unlikely to cause harm. LD_{50} (Rat): > 5 000 mg/kg Symptoms: No deaths have been observed at this concentration.
	Acute toxicity by inhalation:	Remarks: Dust may cause irritation of the upper respiratory organs (nose and throat). Vapour formation is unlikely due to physical properties. Remarks: The LC_{50} was not determined.

	Acute dermal toxicity:	Notes: Prolonged skin contact is unlikely to result in absorption of harmful amounts. LD_{50} (Rat, male and female): > 5 000 mg/kg Method: OECD 402 or equivalent Symptoms: No deaths have been observed at this concentration.
Skin corrosion/irritation:	Not classified based on available information. Remarks: Prolonged contact is essentially non-irritating to the skin. Short-term contact with the skin is essentially non-irritating.	
Serious eye damage/irritation:	Not classified based on available information. Notes: May cause transient slight eye irritation. Corneal damage is unlikely.	
Respiratory/skin sensitisation:	Skin sensitisation: Not classified based on available information. Respiratory sensitisation: Not classified based on available information. Notes: In case of hypersensitivity of the skin: Did not cause allergic skin reactions when tested with guinea pigs. Notes: Respiratory sensitisation: No relevant data found.	
Germ cell mutagenicity:	Not classified based on available information. Mutagenicity: Results of genetic toxicity studies in vitro were negative.	
Carcinogenicity:	Not classified based on available information.	
Reproductive toxicity:	Not classified based on available information. In animal studies, the product had no effects on reproduction. Teratogenicity: For similar substance(s): Did not cause birth defects or other foetal effects in laboratory animals.	
Summary of evaluation of the CMR properties:	Not available.	
STOT-single exposure:	Not classified based on available information. Assessment: Evaluation of available data suggests this material is not a STOT-SE toxicant.	
STOT-repeated exposure:	Not classified based on available information.	
Aspiration Hazard:	Not classified based on available information. Based on its physical properties, it is not likely to be a respiratory hazard.	
Other:	Repeated dose toxicity: Remarks: Based on available data, repeated exposures are not expected to cause significant adverse effects.	

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Fish toxicity:	Comments: Material is not classified as dangerous to aquatic organisms (LC_{50}/EC_{50}/LL_{50}/EL_{50} are greater than 100 mg/L for the most sensitive species). LC_{50} (zebrafish (*Brachydanio rerio*)): 460 mg/l Exposure time: 96.0 h Remarks: For similar substance(s)
Toxicity to daphnia and other aquatic invertebrates aquatic invertebrates:	EC_{50} (*Daphnia magna* (large water flea)): 980.00 mg/l Exposure time: 48.0 h
Toxicity to algae:	ErC_{50} (*Pseudokirchneriella subcapitata* (green algae)): 397 mg/l Endpoint: Growth rate Exposure time: 72 h
Toxicity to daphnia and other aquatic invertebrates (chronic toxicity):	NOEC: 3.99 mg/l Exposure time: 21 d Endpoint: number of offspring Species: Water flea *Daphnia magna* Remarks: For similar substance(s)

12.2 Persistence and degradability

Biodegradability:	Result: Readily biodegradable. Remarks: The material readily biodegrades. Passes OECD rapid biodegradation test(s). Biodegradation: 100 % Exposure time: 28 d Method: OECD Directive 301F or equivalent Remarks: Time interval per 10 days: Passed
Photodegradation:	Test type: Half-life (indirect photolysis) Sensitizer: OH-radicals Rate constant: 3.35E-11 cm^3/s Method: estimated

12.3 Bioaccumulative potential

Partition coefficient n- octanol/water:	Log Pow: -2,31 Method: Measured Remarks: Bioconcentration potential is low (BCF < 100 or log Pow < 3).

No data available.

12.4 Mobility in soil

Distribution within and between environmental compartments:	Koc: 75 Method: estimated Remarks: Potential for spread to soil is high (Koc between 50 and 150).

12.5 Results of PBT and vPvB assessment

Assessment:	This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very Persistent and very Bioaccumulative (vPvB).

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: This product, when disposed of in its unused and uncontaminated state, must be treated as hazardous waste according to EC Directive 2008/98/EC. Disposal practices should comply with all national and provincial laws and any municipal or local bylaws on hazardous waste. Additional assessments may be required for used, contaminated and residual materials. Do not discharge into drains, onto soil or onto surface water.

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 regulated as dangerous substance.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not regulated as dangerous substance.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not regulated as dangerous substance.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not regulated as dangerous substance.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not regulated as dangerous substance.

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 for product as supplied.

14.8 Additional transport information

Not available.

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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 is not required for this substance.

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

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