

TETRACAINI HYDROCHLORIDUM

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

1.1 Product identifier

Product name:	Tetracaine hydrochloride Tetracaini hydrochloridum Tetracaïne hydrochloride Tétracaïne (chlorhydrate de) Tetracainhydrochlorid
N° CAS:	136-47-0
N° EC:	205-248-5

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient.
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1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk 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

Acute toxicity (category 3)	H301
Skin sensitization (category 1)	H317
Eye irritation (category 2)	H319
Organ toxicity (category 1)	H370

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

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H301	Toxic if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H370	Causes damage to organs.
Precautionary statements:	
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P264	Wash hands [and ...] thoroughly after handling.
P264+P265	Wash hands [and ...] thoroughly after handling. Do not touch eyes.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...
P301+P316	IF SWALLOWED: Get emergency medical help immediately.
P302+P352	IF ON SKIN: wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P308+P316	IF exposed or concerned: Get emergency medical help immediately.
P321	Specific treatment (see section 4 on this label).
P330	Rinse mouth.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P333+P317	If skin irritation or rash occurs: Get medical help.
P337+P317	If eye irritation persists: Get medical help.
P362+P364	Take off contaminated clothing and wash it before reuse.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional applicable label elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Tetracaine hydrochloride
IUPAC name:	2-(dimethylamino)ethyl 4-(butylamino)benzoate;hydrochloride
Synonyms:	Butethanol Curtacain Menonasal

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	Pantocaine
	Anethaine
	Amethocaine hydrochloride
N° CAS:	136-47-0
N° EC:	205-248-5
Molecular Formula:	C ₁₅ H ₂₅ ClN ₂ O ₂
Content:	99.0 % to 101.0 % (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a physician. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, also under eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.
Self-protection of the first aider:	Not applicable.

4.2 Most important symptoms and effects, both acute and delayed

Ingestion of even a small amount of this product can produce a serious health hazard.

4.3 Indication of any immediate medical attention and special treatment needed

In cases of doubt, or when symptoms of discomfort persist, seek medical attention. Never administer anything by mouth to unconscious persons.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist.

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Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

Emits toxic fumes in case of fire.

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to avoid product decomposition and the development of health hazards. Always use complete fire protection. Collect water that should not enter sewage system. Dispose of contaminated water used to extinguish and the remains of the second in accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and pants with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or the car (self-protector) in the case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For exposure control and personal protective measures, see section 8. In general, evacuate the area of unnecessary personnel. Wear self-contained breathing apparatus, boots and heavy rubber gloves.

For emergency responders

Not available.

6.2 Environmental precautions

Product not classified as hazardous to the environment, avoid as far as possible any spillage.

6.3 Methods and material for containment and cleaning up

Collect dry, place in a bag and keep for later disposal as waste according to local and/or national authorities' legislation. Avoid raising dust. Ventilate the room and wash the place where the product has been spilled, once it has been completely removed.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.
For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: For personal protection, see section 8. Wash thoroughly after handling. Do not eat, drink or smoke while handling this product. Ask for special instructions before use. Avoid contact during pregnancy and lactation. Do not breathe dust, fumes, gas, mist, vapors or spray. Use only outdoors or in a well-ventilated area.

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Personal protection: Not available.

Technical protective measures: Not available.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: The product does not require special storage measures. Keep containers tightly closed, in a cool and dry place.

Conditions for safe storage, including any incompatibilities: Not available.

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

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must bear the CE marking attesting to compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Individual protection measures

Eye/face protection: Protective face shields and safety glasses according to EN166.

Skin protection: Choose body protection according to the amount and concentration of the hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Respiratory protection: Where risk assessment shows that air purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (USA) or CEN (EU).

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: White or almost white, slightly hygroscopic, crystalline powder.

Odour: Characteristic.

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Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	(25 °C): 0.290 g/mL
Solubility:	Freely soluble in water, soluble in ethanol (96 %)
Solubility in water:	Not available.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not applicable.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions. Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Decomposition by heat may produce toxic fumes of CO, CO₂ and NO_x.

The product has no possibility of hazardous polymerization.

10.4 Conditions to avoid

Avoid any type of incorrect handling: high pressures and/or temperatures.

10.5 Incompatible materials

Strong bases. Strong acids. Sources of ignition. Direct sunlight.

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10.6 Hazardous decomposition products

Carbon oxides (COx).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity: toxic if swallowed.
Skin corrosion/irritation:	Causes skin irritation.
Serious eye damage/irritation:	Causes serious eye irritation.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	No component of this product is identified as a probable, possible or confirmed human carcinogen at levels greater than or equal to 0.1%.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause eye irritation.
Skin contact:	Harmful if absorbed through the skin. May cause skin irritation.
Inhalation:	Harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

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12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 2811
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Not classified.
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 6.1
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), It is not dangerous for the environment.
IATA/ICAO (Air) :

14.6 Special precautions for user

Not available.

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

Not available.

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.

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Safety phrases: Not applicable.

15.2 Chemical safety assessment

Not available.

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 Bioaccumulative

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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the Magis-Pharma



MATERIAL SAFETY DATA SHEET

EN

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

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16.8 Department issuing MSDS

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