

Material Safety Data Sheet

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

EN

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BROMHEXINI HYDROCHLORIDUM

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

1.1 Product identifier

Product name: Bromhexine hydrochloride
Bromhexini hydrochloridum
Broomhexine hydrochloride
Bromhexine (chlorhydrate de)
Bromhexinhydrochlorid

N° CAS: 611-75-6

N° EC: 210-280-8

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

Acute Tox. 4 H312+H332

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H312+H332 Harmful in contact with skin or if inhaled.

Precautionary statements:

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P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P321	Specific treatment (see on this label).
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTER/doctor if you feel unwell.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation .
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Bromhexine hydrochloride
IUPAC name:	2,4-Dibromo-6-[[cyclohexyl(methyl)amino]methyl]aniline;hydrochloride
Synonyms:	Auxit Bromhexine chloride
N° CAS:	611-75-6
N° EC:	210-280-8
Molecular Formula:	C ₁₄ H ₂₁ Br ₂ ClN ₂
Content:	98.0 per cent to 102.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Take off immediately all contaminated clothing. Symptoms of poisoning may not appear until after many hours. For this reason, medical monitoring is necessary for at least 48 hours after an accident.
After inhalation:	Supply fresh air, respiratory if necessary, warmth. If the symptoms persist, consult a doctor. In case of unconsciousness position and transport in recovery position.
After skin contact:	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.
After eye contact:	In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.
After ingestion:	Rinse mouth hand drink plenty of water.

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4.2 Most important symptoms and effects, both acute and delayed

Not available.

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: Water spray. Carbon dioxide, dry chemical powder, or appropriate foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

In case of heating or fire, toxic gases can be formed.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Put on protective clothing. Keep unprotected persons away. Provide adequate ventilation.

For emergency responders

Put on protective clothing. Keep unprotected persons away. Provide adequate ventilation.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Dispose of contaminated material as waste according to section 13. Provide adequate ventilation.

6.4 Reference to other sections

Information on safe handling, see section 7.

Information on personal protection 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 tanks tightly closed.

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Personal protection:	For personal protective equipment, see section 8.
Technical protective measures:	Provide good ventilation/exhaustion at the workplace.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store cool and dry in tightly closed containers.
Conditions for safe storage, including any incompatibilities:	Store cool and dry in tightly closed containers.
Storage – away from:	Store protected from light.

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

Take off immediately all contaminated clothing. Avoid contact with eyes and skin. Mechanical exhaust required.

Individual protection measures

Eye/face protection:	Safety goggles.
Skin protection:	Wear suitable protective work clothing.
Hand protection:	Chemical-resistant gloves. The glove material has to be impermeable and resistant to the product/the substance/the preparation. Due to missing tests no recommendation to the glove material can be given for the product / the preparation / the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
Respiratory protection:	Respiratory protection recommended. Respiratory filter device for short or low exposure; with intensive resp. long exposure use a self contained breathing apparatus.
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, crystalline powder
Odour:	Odourless
Odour threshold:	Not available.

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pH:	Not available.
Melting/freezing point:	> 230 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	The substance is not flammable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Slightly soluble in ethanol (96 %) and in methylene chloride.
Solubility in water:	Very slightly soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	The product does not present an explosion hazard.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Thermal decomposition/conditions to be avoided: No decomposition if used as directed.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide, nitrogen oxide (NO_x), hydrogen chloride (HCl).

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 6 000 mg/kg Intraperitoneal LD50 (rat): 1 680 mg/kg Subcutaneous LD50 (rat): > 14 gm/kg Oral LD50 (mouse): 3 000 mg/kg Intraperitoneal LD50 (mouse): 2 210 mg/kg Subcutaneous LD50 (mouse): > 14 gm/kg Intravenous LD50 (mouse): 44 mg/kg Intravenous LD50 (rabbit): 10 000 mg/kg
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:	Based on available data; the classification criteria are not met.
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:	Not available.
Skin contact:	Harmful in contact with skin.
Inhalation:	Harmful if inhaled.
Ingestion:	May cause gastro-intestinal upset and transient rise in aminotransferase.
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.

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12.4 Mobility in soil

Not available.

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

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations. Must not be disposed of together with household waste or end up in the sewage system.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not classified.
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

No hazard in accordance with the above regulations.

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SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Risk phrases:

R20/21 Harmful by inhalation and in contact with skin.

Safety phrases:

S22 Do not breathe dust.

S24/25 Avoid contact with skin and eyes.

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 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

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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

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