

BUPIVACAINI HYDROCHLORIDUM

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

1.1 Product identifier

Product name:	Bupivacaine hydrochloride Bupivacaini hydrochloridum Bupivacaïne hydrochloride Bupivacaïne (chlorhydrate de) Bupivacainhydrochlorid
N° CAS:	73360-54-0
N° EC:	241-917-8

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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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 Tox. 2	H300
Eye Irrit. 2	H319
Aquatic Chronic 3	H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

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H300	Fatal if swallowed.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.
Precautionary statements:	
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P337+P313	If eye irritation persists: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of contents/container in accordance with all federal, state and local regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Bupivacaine hydrochloride
IUPAC name:	(2RS)-1-Butyl-N-(2,6-dimethylphenyl)piperidine-2-carboxamide hydrochloride monohydrate
Synonyms:	Bupivacaine hydrochloride monohydrate Bupivacaine hydrochloride hydrate
N° CAS:	73360-54-0
N° EC:	642-205-3
Molecular Formula:	C ₁₈ H ₂₉ ClN ₂ O ₂ ·H ₂ O
Content:	98.5 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

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After inhalation:	Move to fresh air. Assure fresh air breathing.
After skin contact:	Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of soap and water.
After eye contact:	Rinse with water while holding the eyes wide open.
After ingestion:	Rinse mouth. Immediately call a POISON CENTER or doctor/physician. Specific medical surveillance.

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

Recommendation for immediate medical care: Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active agent. Pharmaceutical.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Carbon dioxide, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Following can be released: Carbon monoxide, carbon dioxide, nitrogen oxide, hydrogen chloride.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Wear self-contained respirator. Wear fully protective impervious suit.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear protective equipment as mentioned in section 5. Keep unprotected persons away. Ensure adequate ventilation.

For emergency responders

Wear protective equipment as mentioned in section 5. Keep unprotected persons away. Ensure adequate ventilation.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Dispose of contaminated material as waste according to national regulations to ensure proper disposal.

6.4 Reference to other sections

Not available.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Keep container tightly sealed.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Do not store in direct sunlight. Store at below 40 °C in a dry, well-ventilated place.
Storage – away from:	Protected from light. Store away from incompatible substances. Keep away from water.

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

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.

Individual protection measures

Eye/face protection:	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations or European standard.
Skin protection:	Wear appropriate protective clothing to prevent skin exposure.
Hand protection:	Wear appropriate protective gloves to prevent skin exposure.
Respiratory protection:	Follow the OSHA respirator regulations or European standard. Always use a NIOSH or European standard approved respirator when necessary.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

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Appearance:	White or almost white, crystalline powder or colourless crystals.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	About 248 °C
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:	Not available.
Solubility:	Freely soluble in ethanol (96%).
Solubility in water:	Soluble in water.
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 available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable at normal temperature and pressure.
May decompose on exposure to moist air or water.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

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High temperatures, light, dust generation, moisture, excess heat.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Carbon monoxide, oxides of nitrogen, irritating and toxic fumes and gases, carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Feeling of numbness. Nervous system disorders. Oral LD ₅₀ (rat): 18 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	May cause drowsiness or dizziness.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Under proper conditions and consideration of the normal hygienic measures it can be handled without risk of health.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Fatal if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology – general: Hazardous waste. Use suitable disposal containers.
Ecotoxicological information: Harmful to aquatic organisms.

12.2 Persistence and degradability

Not available.

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12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

General notes: As no further relevant information available for aquatic toxicity, persistence & degradability etc., do not allow product to reach ground water, water course or sewage system. Avoid transfer into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Use proper landfill disposal or incineration.

Dispose of in accordance with all federal, state and local regulations.

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), TOXIC SOLID, ORGANIC, N.O.S. (Bupivacaine hydrochloride)
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), II
IATA/ICAO (Air) :

14.5 Environmental hazards

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

14.6 Special precautions for user

Classification of the Substance: GHS06 Skull & Crossbones
Signal Word: Danger

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

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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:



Risk phrases:

R28 Very toxic if swallowed.

R36 Irritating to eyes.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

S1 Keep locked up.

S20/21 When using do not eat, drink or smoke.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S46 If swallowed, seek medical advice immediately and show this container or label.

S61 Avoid release to the environment. Refer to special instructions/safety data sheet.

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

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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.

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16.8 Department issuing MSDS

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