

LORMETAZEPAMUM

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

1.1 Product identifier

Product name:	Lormetazepam
	Lormetazepamum
	Lormetazepam
	Lormétazépam
	Lormetazepam
N° CAS:	848-75-9
N° EC:	212-700-5

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 toxicity (category 4)	H302
Eye Irritation 2A	H319
Toxic to Reproduction 1B	H360-H362

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

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H360	May damage fertility or the unborn child.
H361	Suspected of damaging fertility or the unborn child.
H362	May cause harm to breast-fed children.
Precautionary statements:	
P203	Obtain, read and follow all safety instructions before use.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P263	Avoid contact during pregnancy/while nursing.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P312	If swallowed: Call a poison center/doctor if you feel unwell.
P304+P340	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P305+P351+P338	If inhaled: Remove person to fresh air and keep comfortable for breathing.
P318	If exposed or concerned, get medical advice.
P319	Get medical help if you feel unwell.
P330	Rinse mouth.
P337+P317	If eye irritation persists: Get emergency medical help.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to local/regional/national/international regulations.

Additional applicable label elements: Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Lormetazepam
IUPAC name:	7-chloro-5-(2-chlorophenyl)-3-hydroxy-1-methyl-3H-1,4-benzodiazepin-2-one
Synonyms:	Lormetazepam Methyllorazepam N-Methyllorazepam Noctamid Loramet
N° CAS:	848-75-9
N° EC:	212-700-5
Molecular Formula:	C ₁₆ H ₁₂ Cl ₂ N ₂ O ₂

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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 doctor. Show this safety data sheet to the doctor in attendance.
After inhalation:	Supply fresh air; consult doctor in case of complaints.
After skin contact:	Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
After eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
After ingestion:	Seek immediate medical advice. Immediately call a doctor.
Self-protection of the first aider:	Not applicable.

4.2 Most important symptoms and effects, both acute and delayed

Central nervous system depression, drowsiness, confusion, headache, ataxia, vertigo, urinary retention, jaundice, blood dyscrasias, hypotension, altered libido.

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:	Use water spray, appropriate foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Carbon oxides, nitrogen oxides (NO_x), hydrogen chloride gas.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Wear self-contained respiratory protective device. Wear fully protective suit. Mouth respiratory protective device.
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. Keep unprotected persons away. Avoid formation of dust. Use respiratory protective device against the effects of fumes/dust/aerosol.



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For emergency responders

Wear protective equipment. Keep unprotected persons away. Avoid formation of dust. Use respiratory protective device against the effects of fumes/dust/aerosol.

6.2 Environmental precautions

Do not allow to enter sewers/ surface or ground water. Inform respective authorities in case of seepage into water course or sewage system.

6.3 Methods and material for containment and cleaning up

Dispose of the collected material according to regulations. Dispose contaminated material as waste according to section 13.

6.4 Reference to other sections

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep receptacle tightly sealed. Protect from exposure to the light. Store in cool, dry conditions in well sealed receptacles. Store receptacle in a well ventilated area.
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

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Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Individual protection measures

Eye/face protection:	Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).
Skin protection:	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Complete suit protecting against chemicals, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Hand protection:	Not determined.
Respiratory protection:	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standers such as NIOSH (US) 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, crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	206 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Product is not flammable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.

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Relative density:	Not available.
Solubility:	Practically insoluble in water, soluble in ethanol (96 %) and in methanol.
Solubility in water:	Practically insoluble 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

Not available.

10.2 Chemical stability

Stable under recommended storage condition.

10.3 Possibility of hazardous reactions

Reacts with strong oxidizing agents.

10.4 Conditions to avoid

Materials to avoid: strong oxidizing agents.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Poisonous gases/vapors.
Carbon monoxide and carbon dioxide.
Nitrogen oxides (NO_x).
Hydrogen chloride (HCl).
Chlorine compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	LD ₅₀ Oral – rat – 4.500 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.

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Carcinogenicity:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	May cause congenital malformation in the fetus. Suspected human reproductive toxicant Reproductive toxicity – mouse – subcutaneous Effects on Newborn: biochemical and metabolic. Effects on Newborn: Behavioral. Overexposure may cause reproductive disorders(s) based on tests with laboratory animals. Developmental toxicity – rat – oral Specific Developmental Abnormalities: Musculoskeletal system. Developmental toxicity – mouse – intraperitoneal Specific developmental abnormalities: craniofacial (including nose and tongue). Specific developmental abnormalities: skin and skin appendages.
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:	May be harmful if absorbed through skin. May cause skin irritation.
Inhalation:	May be harmful if inhaled. May cause respiratory irritation.
Ingestion:	May be 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.

12.6 Other adverse effects

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Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. 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.

Contaminated packaging: Dispose of 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),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

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

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 classified.

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.

Safety phrases: Not applicable.

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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-



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16.8 Department issuing MSDS

Magis-Pharma NV

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