

# Material Safety Data Sheet

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

## BROMAZEPAMUM

EN

FORM-06-14-01 (V00)

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Revision: 23/08/2024

Version: 01



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

#### 1.1 Product identifier

Product name: Bromazepam  
Bromazepamum  
Bromazepam  
Bromazépam  
Bromazepam

N° CAS: 1812-30-2

N° EC: 217-322-4

#### 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: 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. 4	H302
Eye Irrit. 2	H319
Skin Irrit. 2	H315
STOT SE 3	H335

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

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H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray
P264	Wash hands 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.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/... if you feel unwell.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
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:	Bromazepam
IUPAC name:	7-bromo-5-pyridin-2-yl-1,3-dihydro-1,4-benzodiazepin-2-one
Synonyms:	Durazanil Lexotanil
N° CAS:	1812-30-2
N° EC:	217-322-4
Molecular Formula:	C <sub>14</sub> H <sub>10</sub> BrN <sub>3</sub> O
Content:	99.0 per cent to 101.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

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### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

General notes:	Consult a physician. Show this safety data sheet to the doctor in attendance. If breathed in, move person into fresh air. If not breathing, give artificial respiration.
After inhalation:	Consult a physician.
After skin contact:	Wash off with soap and plenty of water. Consult a physician.
After eye contact:	Flush eyes with water as a precaution. Consult a physician.
After ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician. If not breathing, give artificial respiration.

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

#### 5.2 Special hazards arising from the substance/mixture

Not available.

#### 5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Wear self-contained breathing apparatus for firefighting if necessary.
Hazardous combustion products:	Not available.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

##### For non-emergency personnel

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

##### For emergency responders

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

#### 6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

#### 6.3 Methods and material for containment and cleaning up

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Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

Not available.

## 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.
Personal protection:	For personal protective equipment, see section 8.
Technical protective measures:	Normal measures for preventive fire protection.
Handling:	Not available.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store below 30 °C.
Storage – away from:	Storage 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

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:	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:	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.

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Respiratory protection:	Where risk assessment shows air-purifying respirators are appropriate, use a full-face particle respirator type N99 (US) or type P2 (EN 143) 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 standards such as NIOSH (US) or CEN (EU).
Thermal hazards:	Not determined.
<b>Environmental exposure control</b>	
Not available.	

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance:	White or yellowish, crystalline powder
Odour:	Not available.
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:	Not available.
Solubility:	Slightly soluble or sparingly soluble in ethanol (96 %) and in methylene chloride.
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

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Not available.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Heat, flames and sparks.

### 10.5 Incompatible materials

Acids, oxidising agents, alkali metals, strong oxidising agents, acid chlorides, acid anhydrides, reducing agents.

### 10.6 Hazardous decomposition products

Formed under fire conditions: Carbon oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 1950 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 available.
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:	RTECS: DE9800000

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause eye irritation.
Skin contact:	May cause skin irritation.
Inhalation:	May be harmful if inhaled.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

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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

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 classified.

#### 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

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Not dangerous goods.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.

R38 Irritating to skin.

R36 Irritating to eyes.

Safety phrases:

S23 Do not breathe dust/fume/gas/mist/vapours/spray.

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

S51 Use only in well-ventilated areas.

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.

S28 After contact with skin, wash immediately with plenty of ...

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

S45 In case of accident or if you feel unwell, seek medical advice immediately

S27 Take off immediately all contaminated clothing.

S7/9 Keep container tightly closed and in a well-ventilated place.

#### 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



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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

Quality Department

FAC SECUNDUM ARTEM NV

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