

# Bromazepam

## Safety Data Sheet

Safety Data Sheet in accordance with regulation (EC) No 1907/2006, as amended.  
Issue date: 31/05/2017 Revision date: 28/07/2021 Supersedes version of: 31/05/2017 Version: 2.0

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Substance  
Substance name : Bromazepam  
Product code : 201600115  
Synonyms : Bromazepam, salts, hydrates, isomers and impurities where applicable  
Other means of identification : Ph.Eur. 0879

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.  
Use of the substance/mixture : For professional use only  
Function or use category : Laboratory chemicals

##### 1.2.2. Uses advised against

Restrictions on use : Do not use : Ingestion, Inhalation, Dermal

#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe 7, Allée Kastner, CS30026  
F- 67081 Strasbourg  
France  
T +33(0)388412035 - F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu) - [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

Emergency number : +33(0)390215608

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4 H302  
Skin corrosion/irritation, Category 2 H315  
Serious eye damage/eye irritation, Category 2 H319  
Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation H335

Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning  
Hazard statements (CLP) : H302 - Harmful if swallowed.  
H315 - Causes skin irritation.

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### Precautionary statements (CLP)

H319 - Causes serious eye irritation.  
H335 - May cause respiratory irritation.  
: P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.  
P264 - Wash hands, forearms and face 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/hearing protection.  
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.  
P302+P352 - IF ON SKIN: Wash with plenty of water.  
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 CENTRE or doctor if you feel unwell.  
P321 - Specific treatment (see supplemental first aid instruction 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+P364 - Take off contaminated clothing and wash it before reuse.  
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

No labelling required

### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Bromazepam	-	≤ 100	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H- and EUH-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after skin contact : Wipe off as much as possible (using a clean, soft, absorbent material).  
First-aid measures after eye contact : Rinse eyes with water as a precaution.

### 4.2. Most important symptoms and effects, both acute and delayed

No additional information available

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Extinguishing blanket.

#### 5.2. Special hazards arising from the substance or mixture

Fire hazard : See Heading 2.2.

#### 5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

### SECTION 6: Accidental release measures

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

##### 6.1.1. For non-emergency personnel

Emergency procedures : Avoid all unnecessary exposure.

##### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

No additional information available

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

No additional information available

#### 6.4. Reference to other sections

No additional information available

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

No additional information available

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

No additional information available

#### 7.3. Specific end use(s)

See Heading 1.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

No additional information available

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### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

No additional information available

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Lab coat

##### Hand protection:

Protective gloves

#### 8.2.2.3. Respiratory protection

No additional information available

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

No additional information available

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Appearance	: Powder.
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Stable under normal conditions.

#### 10.2. Chemical stability

No additional information available

#### 10.3. Possibility of hazardous reactions

None known.

#### 10.4. Conditions to avoid

No additional information available

#### 10.5. Incompatible materials

None under normal use. See Heading 7.

#### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

Acute toxicity (oral) : Harmful if swallowed.  
Acute toxicity (dermal) : Not classified  
Acute toxicity (inhalation) : Not classified

#### Bromazepam

LD50 oral rat	300 – 2000 mg/kg
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Skin corrosion/irritation : Causes skin irritation.  
Serious eye damage/irritation : Causes serious eye irritation.  
Respiratory or skin sensitisation : Not classified  
Germ cell mutagenicity : Not classified  
Carcinogenicity : Not classified  
Reproductive toxicity : Not classified  
STOT-single exposure : May cause respiratory irritation.  
STOT-repeated exposure : Not classified  
Aspiration hazard : Not classified

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : Presents no specific risk for the environment.  
Hazardous to the aquatic environment, short-term (acute) : Not classified  
Hazardous to the aquatic environment, long-term (chronic) : Not classified

#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

No additional information available

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### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

No additional information available

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number</b>		
Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>		
Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>		
Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>		
Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>		
Not applicable	Not applicable	Not applicable
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

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Bromazepam is not on the REACH Candidate List

Bromazepam is not on the REACH Annex XIV List

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Indication of changes:

Classification of the substance or mixture.

Indication of changes			
Section	Changed item	Change	Comments
2	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Added	H315, H319, H335
2	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Removed	H336

### Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

**DISCLAIMER OF LIABILITY** The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.