



Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : Clonazepam
Product code : 201600225

Synonyms : Clonazepam, salts, hydrates, isomers and impurities where applicable

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 - 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]

Reproductive toxicity, Category 2 H361d Specific target organ toxicity – Single exposure, Category 3, Narcosis H336

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) :





GHS08

GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H336 - May cause drowsiness or dizziness.

H361d - Suspected of damaging the unborn child.

Precautionary statements (CLP) : P261 - Avoid breathing dust, vapours.

P202 - Do not handle until all safety precautions have been read and understood.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Hazard pictograms (CLP)



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]
Clonazepam	-	Repr. 2, H361d STOT SE 3, H336

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

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.

03/04/2023 (Issue date) EN (English) 2/7

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

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

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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 Not available Colour Appearance : Powder. : Not available Odour Odour threshold : Not available : Not available Melting point : Not available Freezing point : Not available Boiling point Flammability : Not available **Explosive limits** : Not applicable Lower explosion limit : Not applicable Upper explosion limit : Not applicable Flash point : Not applicable Auto-ignition temperature : Not applicable Decomposition temperature : Not available рΗ : Not available pH solution : Not available Viscosity, kinematic : Not applicable Solubility : Water: < 0,1 g/l Partition coefficient n-octanol/water (Log Kow) : Not available : Not available Vapour pressure : Not available Vapour pressure at 50°C : Not available Density Relative density : Not available Relative vapour density at 20°C : Not applicable : Not available Particle size

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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.

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Lack of data)
Acute toxicity (dermal) : Not classified (Lack of data)
Acute toxicity (inhalation) : Not classified (Lack of data)

Clonazepam

LD50 oral rat > 2000

Skin corrosion/irritation : Not classified (Lack of data)
Serious eye damage/irritation : Not classified (Lack of data)

Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)

Reproductive toxicity : Suspected of damaging the unborn child. STOT-single exposure : May cause drowsiness or dizziness.

STOT-repeated exposure : Not classified (Further details: STOT-single exposure)

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Presents no specific risk for the environment.

Hazardous to the aquatic environment, short–term : Not of

(acute)

(chronic)

: Not classified

Hazardous to the aquatic environment, long-term : Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

03/04/2023 (Issue date) EN (English) 5/7

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

12.7. 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	
14.1. UN number or ID number			
Not applicable	Not applicable	Not applicable	
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	
14.4. Packing group			
Not applicable	Not applicable	Not applicable	
14.5. Environmental hazards			
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. Maritime transport in bulk according to IMO instruments

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

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:		
H336	May cause drowsiness or dizziness.	
H361d	Suspected of damaging the unborn child.	
Repr. 2	Reproductive toxicity, Category 2	
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis	

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.

03/04/2023 (Issue date) EN (English) 7/7