

# Prazepam

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 03/04/2023 Revision date: 26/11/2025 Supersedes version of: 03/04/2023 Version: 2.0

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Prazepam  
Chemical name : Prazepam  
EC-No. : 220-975-8  
CAS-No. : 2955-38-6  
Product code : 201600745

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

##### Relevant identified uses

Use of the substance/mixture : Scientific research and development  
Technical testing and analysis  
For professional use only  
Function or use category : Laboratory chemicals

##### Uses advised against

Restrictions on use : Not for food, drug or home use

#### 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]

Reproductive toxicity, Category 1B H360  
Reproductive toxicity, Additional category, Effects on or via lactation H362  
Specific target organ toxicity – single exposure, Category 1 H370  
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

May damage fertility or the unborn child. May cause harm to breast-fed children. Causes damage to organs. May cause drowsiness or dizziness.

#### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) : Danger

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- Hazard statements (CLP) : H336 - May cause drowsiness or dizziness.  
H360 - May damage fertility or the unborn child.  
H362 - May cause harm to breast-fed children.  
H370 - Causes damage to organs (central nervous system).
- Precautionary statements (CLP) : P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.  
P263 - Avoid contact during pregnancy and while nursing.  
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.  
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.  
P308+P313 - IF exposed or concerned: Get medical advice/attention.  
P312 - Call a POISON CENTRE or doctor if you feel unwell.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
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.

Hazard pictograms (CLP) :



GHS08

### 2.3. Other hazards

- Other information : Active substance (in pharmaceutical products) (Psychotropic substance).  
Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Prazepam	CAS-No.: 2955-38-6 EC-No.: 220-975-8	≤ 100	Repr. 1B, H360 Lact., H362 STOT SE 1, H370 STOT SE 3, H336

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.

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First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

### 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 : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.  
Unsuitable extinguishing media : Do not use a heavy water stream.

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

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

### 5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.  
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

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

General measures : Avoid contact with skin, eyes and clothing.

#### For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

#### For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

For containment : Absorb with an inert material and place in an appropriate waste disposal container.  
Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

### 6.4. Reference to other sections

See Section 13 for disposal information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed : Do not expose pregnant or breastfeeding women.  
Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.  
Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

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

Storage conditions	: Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials	: Keep in original containers.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### Personal protection equipment

##### Eye and face protection

###### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

##### Skin protection

###### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

###### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

##### Respiratory protection

###### Respiratory protection:

In case of dust formation use respirator with filter: P3

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: white. almost white.
Appearance	: Crystalline powder.
Molecular mass	: 324,8 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: ≈ 145 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 0,1 g/l

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Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

No additional information available

## SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

#### Prazepam (2955-38-6)

LD50 oral rat	> 4000 mg/kg (RTECS No DF2368000)
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Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)

#### Prazepam (2955-38-6)

IARC group	3 - Not classifiable
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Reproductive toxicity	: May damage fertility or the unborn child. May cause harm to breast-fed children.
STOT-single exposure	: Causes damage to organs (central nervous system). May cause drowsiness or dizziness.
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

### 11.2. Information on other hazards

No additional information available

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Lack of data)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Lack of data)

#### 12.2. Persistence and degradability

##### Prazepam (2955-38-6)

Persistence and degradability	Not rapidly degradable
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#### 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

#### 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
<b>14.1. UN number or ID number</b>		
Not regulated for transport		
<b>14.2. UN proper shipping name</b>		
Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>		
Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>		
Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>		
Not regulated	Not regulated	Not regulated
No supplementary information available		

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### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

### 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

#### 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)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### Ozone Regulation (1005/2009)

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

##### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

##### Explosives Precursors Regulation (EU 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 (EC 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)

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Indication of changes

Section	Changed item	Comments
	Supersedes version of	<b>Added</b>
	Revision date	<b>Added</b>
1.1	EC-No.	<b>Added</b>
1.1	CAS-No.	<b>Added</b>
1.1	Synonyms	<b>Removed</b>
1.2	Restrictions on use	<b>Modified</b>
1.2	Use of the substance/mixture	<b>Modified</b>

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Indication of changes		
Section	Changed item	Comments
1.2	Main use category	<b>Removed</b>
2.1	Adverse physicochemical, human health and environmental effects	<b>Modified</b>
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<b>Modified</b>
2.2	Signal word (CLP)	<b>Modified</b>
2.2	Hazard pictograms (CLP)	<b>Modified</b>
2.2	Precautionary statements (CLP)	<b>Modified</b>
2.2	Hazard statements (CLP)	<b>Modified</b>
2.3	Other information	<b>Added</b>
4.1	First-aid measures general	<b>Added</b>
4.1	First-aid measures after skin contact	<b>Modified</b>
4.1	First-aid measures after inhalation	<b>Added</b>
4.1	First-aid measures after ingestion	<b>Added</b>
4.1	First-aid measures after eye contact	<b>Modified</b>
5.1	Unsuitable extinguishing media	<b>Added</b>
5.1	Suitable extinguishing media	<b>Modified</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.2	Fire hazard	<b>Removed</b>
5.3	Protection during firefighting	<b>Added</b>
5.3	Firefighting instructions	<b>Modified</b>
6.1	Protective equipment	<b>Added</b>
6.1	Emergency procedures	<b>Modified</b>
6.1	General measures	<b>Added</b>
6.2	Environmental precautions	<b>Added</b>
6.3	For containment	<b>Added</b>
6.3	Methods for cleaning up	<b>Added</b>
6.4	Reference to other sections (8, 13)	<b>Added</b>
7.1	Additional hazards when processed	<b>Added</b>
7.1	Precautions for safe handling	<b>Added</b>
7.1	Hygiene measures	<b>Added</b>
7.2	Storage conditions	<b>Added</b>
7.2	Packaging materials	<b>Added</b>
7.3	Specific end uses	<b>Removed</b>
8.2	Respiratory protection	<b>Added</b>
8.2	Hand protection	<b>Modified</b>
8.2	Eye protection	<b>Added</b>
8.2	Appropriate engineering controls	<b>Modified</b>

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Indication of changes		
Section	Changed item	Comments
8.2	Skin and body protection	<b>Modified</b>
9	Solubility in water	<b>Added</b>
9	Molecular mass	<b>Added</b>
9	Melting point	<b>Added</b>
9	Colour	<b>Added</b>
9	Appearance	<b>Modified</b>
10.1	Reactivity	<b>Removed</b>
10.3	Possibility of hazardous reactions	<b>Removed</b>
10.5	Incompatible materials	<b>Removed</b>
10.6	Hazardous decomposition products	<b>Removed</b>
11.1	LD50 oral rat	<b>Modified</b>
12.1	Ecology - general	<b>Removed</b>

Full text of H- and EUH-statements:	
H336	May cause drowsiness or dizziness.
H360	May damage fertility or the unborn child.
H362	May cause harm to breast-fed children.
H370	Causes damage to organs (central nervous system).
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 1B	Reproductive toxicity, Category 1B
STOT SE 1	Specific target organ toxicity – single exposure, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis

Safety Data Sheet (SDS), EU

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