

## 1. Identification of the substance/preparation and of the company/undertaking

Product name	Clonazepam	
Product code	04 3967 3	
Use	- pharmaceutical active substance (anti-epileptic drug)	
Company information	Enquiries: F. Hoffmann-La Roche AG Postfach CH-4070 Basel Switzerland	Local representation:
	Phone	+41-61/688 54 80
	Fax	+41-61/681 72 76
	E-Mail	info.sds@roche.com

## 2. Hazards identification

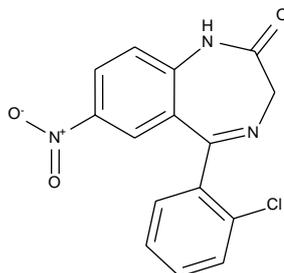
Most important hazards	- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Note	- Benzodiazepines induce central nervous system depression and drowsiness. In addition, longer use may be habit forming. Hence, these compounds are also misused by addicts.

## 3. Composition/Information on ingredients

Characterization	pharmaceutical active substance in the class of benzodiazepines
Chemical name	- 5-(2-Chlorophenyl)-1,3-dihydro-7-nitro-2H-1,4-benzodiazepin-2-one
Synonyms	- Clonopin - Rivotril - Klonopin
CAS number	1622-61-3
EINECS number	216 596 2
Roche number	Ro0054023-000
Empirical formula	C <sub>15</sub> H <sub>10</sub> ClN <sub>3</sub> O <sub>3</sub>

# Clonazepam

Molecular mass 315.7 g/mol



## 4. First-aid measures

- |                   |  |
|-------------------|--|
| Eye contact       | - rinse immediately with tap water for 10 minutes - open eyelids forcibly  |
| Skin contact      | - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents  |
| Inhalation        | - remove the casualty to fresh air and keep him/her calm   |
| Note to physician | - treat symptomatically<br>- in cases of severe poisoning: Anexate i.V. has possibly to be repeated, because of the half-life of elimination of Clonazepam is much higher than this of Anexate |

## 5. Fire-fighting measures

- |                              |   |
|------------------------------|---|
| Suitable extinguishing media | - water spray jet, dry powder, foam, carbon dioxide<br>- adapt extinguishing media to surrounding fire conditions   |
| Specific hazards             | - consider dust explosion hazard<br>- formation of toxic and corrosive combustion gases (nitrous oxide, hydrogen chloride) possible<br>- substance is hazardous for water: contain fire-fighting wastewater |
| Protection of fire-fighters  | - precipitate gases/vapours/mists with water spray  |

## 6. Accidental release measures

- |                          |  |
|--------------------------|--|
| Environmental protection | - do not allow to enter drains or waterways<br>- if the substance reaches waters or the sewer system, inform the competent authority |
| Methods for cleaning up  | - collect solids (avoid dust formation) and hand over to waste removal   |

# Clonazepam

## 7. Handling and storage

### Handling

- Technical measures
- avoid dust formation; very high dust explosion hazard
  - processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
  - take precautionary measures against electrostatic charging
  - local exhaust ventilation necessary

- Suitable materials
- glass, enamel, plastic

### Storage

- Storage conditions
- room temperature
  - protected from light
  - keep container tightly closed

- Validity
- 36 months, at room temperature

- Packaging materials
- tightly closing; material: glass, plastic, steel (lined with polyethylene bag)

## 8. Exposure controls/Personal protection

- Engineering Measures**
- see 7.

### Monitoring

- Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m<sup>3</sup>

- Analytcs
- sampling on glass fibre filter and gravimetric or chemical determination

### Personal protective equipment

- Respiratory protection
- in case of open handling or accidental release: particle mask or respirator with independent air supply

- Hand protection
- protective gloves (neoprene, nitrile or butyl rubber)

- Eye protection
- safety glasses

- Body protection
- protective clothing

- General protective and hygiene measures
- instruction of employees recommended

# Clonazepam

## 9. Physical and chemical properties

Colour	white to yellow-white
Form	fine powder
Odour	odourless
Solubility	27'800 mg/l, acetone (20 °C) 18'500 mg/l, chloroform (20 °C) 7'600 mg/l, methanol (20 °C) < 100 mg/l, hexane (20 °C) < 100 mg/l, water (20 °C) ~ 15 mg/l, aquatic ecotoxicity media (~ 20 °C)
Partition coefficient	log P <sub>ow</sub> 2.41 (n-octanol/buffer 25 °C) pH 7.4
pH value	5.0 to 7.0 (1 % suspension in water)
Dissociation constant	pK <sub>1</sub> = 1.5 pK <sub>2</sub> = 10.5
Melting temperature	236.5 to 238.5 °C

## 10. Stability and reactivity

Conditions to avoid	- light
Materials to avoid	- atmospheric oxygen

## 11. Toxicological information

Acute toxicity	- LD <sub>50</sub> > 15'000 mg/kg (oral, rat) - LD <sub>50</sub> 2'000 mg/kg (oral, mouse) - LD <sub>50</sub> 16'500 mg/kg (i.p., mouse)
Mutagenicity	- not mutagenic (various in vivo and in vitro test systems)
Reproduction toxicity	- not teratogenic, not embryotoxic (≤ 40 mg/kg/d; oral, rat)
Note	- maintenance dose: 2 to 4 mg/d (adults) - initial therapeutic dose: 1 to 2 mg/d (adults) - elimination half-life: 20 to 60 hours - sedating effects caution: alcohol potentiates this effect!

# Clonazepam

## 12. Ecological information

- |                           |   |
|---------------------------|---|
| Inherent biodegradability | - not inherently biodegradable<br>0 %, 21 days  |
| Ecotoxicity               | - barely toxic for algae (nominal concentration > 100 mg/l), test performed with water accommodated fractions (Scenedesmus (=Desmodesmus) subspicatus)<br>ErC <sub>50</sub> (72 h) > 240 mg/l (nominal concentration)<br>ErC <sub>10</sub> (72 h) 3.9 mg/l (nominal concentration)<br>NOEC (72 h) ≤ 2.46 mg/l (nominal concentration) (OECD No. 201)<br>- moderately toxic for planktonic crustaceans (Daphnia magna)<br>EC <sub>50</sub> (48 h) 30.3 mg/l (FDA Technical Assistance Document No. 4.08)<br>- barely toxic for fish (as an emulsion) (rainbow trout)<br>LC <sub>0</sub> (96 h) 1000 mg/l |
| Air pollution             | - observe local/national regulations  |

## 13. Disposal considerations

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|---------------------|--|
| Waste from residues | - observe local/national regulations regarding waste disposal<br>- large amounts: incinerate in qualified installation with flue gas scrubbing |
|---------------------|--|

## 14. Transport information

- |      |   |
|------|---|
| Note | - not classified by transport regulations |
|------|---|

## 15. Regulatory information

Classification and labelling according to EU directives

- |        |   |
|--------|---|
| R52/53 | Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. |
| S61    | Avoid release to the environment. Refer to special instructions/Safety data sheets.           |

- |                              |   |
|------------------------------|---|
| Water hazard class (Germany) | 1: weakly hazardous for water (own classification according to directive VwVwS of 17.05.1999) |
|------------------------------|---|

## 16. Other information

- |                       |  |
|-----------------------|--|
| Safety-lab number     | - BS-2427  |
| Edition documentation | - changes from previous version in sections 1, 3, 5, 7 |

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.