

Safety Data Sheet

# KLONOPIN(R) Tablets (0.5 mg)

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

### 1.1. Product identifier

Product name KLONOPIN(R) Tablets (0.5 mg)

Product code SAP-10018326

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

Use - pharmaceutical active substance (anti-epileptic drug) \*1

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

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America	Local representation:
	Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	

### 1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

\*1 referring to: Clonazepam

## SECTION 2: Hazards identification

### Classification of the substance or mixture / Label elements

GHS Classification no classification and labelling according to GHS

### Other hazards

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. \*1

\*1 referring to: Clonazepam

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### SECTION 3: Composition/information on ingredients

Characterization mixture of 0.3% Clonazepam with excipients

<b>Ingredients</b>	<b>Concentration</b>	<b>GHS-Classification (pure ingredient)</b>
Clonazepam 1622-61-3	0.3 %	- Combustible dust (No category), USH003
Corn starch 9005-25-8	11.8 %	
Microcrystalline cellulose 9004-34-6	14.7 %	

*For the full text of the H-phrases mentioned in this Section, see Section 16.*

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for 10 minutes - open eyelids forcibly
Skin contact	- drench affected skin with plenty of water
Inhalation	- remove the casualty to fresh air - in the event of symptoms get medical treatment

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

Note - no information available

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

Note to physician - treat symptomatically  
- 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

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions - water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable

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

- Specific hazards
- formation of toxic and corrosive combustion gases (nitrous oxide, hydrogen chloride) possible
  - consider dust explosion hazard

### 5.3. Advice for firefighters

- Protection of fire-fighters
- precipitate gases/vapours/mists with water spray

## SECTION 6: Accidental release measures

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

- Personal precautions
- avoid exposure

### 6.2. Environmental precautions

- Environmental protection
- do not allow to enter drains or waterways

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

- Methods for cleaning up
- collect solids (avoid dust formation) and hand over to waste removal

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

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

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

- Storage conditions
- protected from light and humidity
  - below 30 °C
- Validity
- 60 months, < 30 °C, see "best use before" date stated on the label
  - 24 months, < 30 °C, Holding Time (Bulk)
- Packaging materials
- polyethylene bag in metal drum
  - high density polyethylene (HDPE) bottles with a child-resistant polypropylene screw cap

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Threshold value (USA) air	- ACGIH-TLV: 10 mg/m <sup>3</sup>	*2
	- OSHA-PEL: 5 mg/m <sup>3</sup> (respirable dust fraction)	*2
	- OSHA-PEL: 15 mg/m <sup>3</sup> (total dust)	*2
	- NIOSH-REL: 5 mg/m <sup>3</sup> (respirable dust fraction)	*2
	- NIOSH-REL: 10 mg/m <sup>3</sup> (total dust)	*2
	- ACGIH-TLV: 10 mg/m <sup>3</sup> (not classifiable as a human carcinogen)	*3
	- OSHA-PEL: 5 mg/m <sup>3</sup> (respirable fraction)	*3
	- OSHA-PEL: 15 mg/m <sup>3</sup> (total dust)	*3
	- NIOSH-REL: 5 mg/m <sup>3</sup> (respirable fraction)	*3
	- NIOSH-REL: 10 mg/m <sup>3</sup> (total dust)	*3

Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.01 mg/m <sup>3</sup>	*1
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#### 8.2. Exposure controls

General protective and hygiene measures	- instruction of employees recommended
Respiratory protection	- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. - 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

*1 referring to:	Clonazepam
*2 referring to:	Microcrystalline cellulose
*3 referring to:	Corn starch

### SECTION 9: Physical and chemical properties

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

Color	orange	
Form	round, biplanar tablet	
Solubility	27'800 mg/l, acetone (20 °C)	*1
	18'500 mg/l, chloroform (20 °C)	*1
	7'600 mg/l, methanol (20 °C)	*1
	< 100 mg/l, hexane (20 °C)	*1
	< 100 mg/l, water (20 °C)	*1
Partition coefficient	log P <sub>ow</sub> 2.41 (n-octanol/buffer 25 °C) pH 7.4	*1
pH value	5.0 to 7.0 (1 % suspension in water)	*1

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Melting temperature 236.5 to 238.5 °C \*1

### 9.2. Other information

Dissociation constant pK<sub>1</sub> 1.5  
pK<sub>2</sub> 10.5 \*1

\*1 referring to: Clonazepam

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Note - no information available

### 10.2. Chemical stability

Note - no information available

### 10.3. Possibility of hazardous reactions

Note - no information available

### 10.4. Conditions to avoid

Conditions to avoid - warming  
- light  
- humidity

### 10.5. Incompatible materials

Note - no information available

### 10.6. Hazardous decomposition products

Note - no information available

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity - LD<sub>50</sub> > 15'000 mg/kg (oral, rat) \*1  
- LD<sub>50</sub> 2'000 mg/kg (oral, mouse) \*1

Mutagenicity - not mutagenic (various in vivo and in vitro test systems) \*1

Reproductive toxicity - not teratogenic, not embryotoxic (≤ 40 mg/kg/d; oral, rat) \*1

Note - maintenance dose: 2 to 4 mg/d (adults) \*1

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	- initial therapeutic dose: 1 to 2 mg/d (adults)	*1
	- elimination half-life: 20 to 60 hours	*1
	- acts sedating caution: alcohol potentiates this effect!	*1
Potential Health Effects	- Exposure: Ingestion	
	- Carcinogenicity: not listed by NTP, IARC or OSHA	
Additional Health Information	- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class. Acute narrow angle glaucoma. Liver conditions and/or impaired liver function. Respiratory system conditions.	
*1 referring to:	Clonazepam	
<b>SECTION 12: Ecological information</b>		
<b>12.1. Toxicity</b>		
Ecotoxicity	- barely toxic for algae (nominal concentration > 100 mg/l), test performed with water accommodated fractions (Scenedesmus (=Desmodesmus) subspicatus) ErC <sub>50</sub> (72 h) > 240 mg/l (nominal concentration) ErC <sub>10</sub> (72 h) 3.9 mg/l (nominal concentration) NOEC (72 h) ≤ 2.46 mg/l (nominal concentration) (OECD No. 201)	*1
	- moderately toxic for planktonic crustaceans (Daphnia magna) EC <sub>50</sub> (48 h) 30.3 mg/l (FDA Technical Assistance Document No. 4.08)	*1
	- barely toxic for fish (as an emulsion) (rainbow trout) LC <sub>0</sub> (96 h) 1000 mg/l	*1
<b>12.2. Persistence and degradability</b>		
Inherent biodegradability	- not inherently biodegradable 0 %, 21 days	*1
<b>12.3. Bioaccumulative potential</b>		
Note	- no information available	
<b>12.4. Mobility in soil</b>		
Note	- no information available	
<b>12.5. Results of PBT and vPvB assessment</b>		
Note	- no information available	

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### 12.6. Other adverse effects

Air pollution - observe local/national regulations

\*1 referring to: Clonazepam

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste from residues - return to supplier or hand over to authorized disposal company  
- observe local/national regulations regarding waste disposal  
- incinerate in qualified installation with flue gas scrubbing  
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

## SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

## SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.  
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.  
- State and local regulations vary and may impose additional reporting requirements.

## SECTION 16: Other information

Safety-lab number - BS-2427

\*1

Full text of H-Statements referred to under section 3  
USH003 May form combustible dust concentrations in the air

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- Note
- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.
- Edition documentation
- changes from previous version in sections 2, 3, 16
- \*1 referring to: Clonazepam

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.