

**1. Product and Company Identification**

Product name	KLONOPIN(R) Tablets (2 mg)	
Product code	CSE-1159	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone 001-973/235 50 00	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	
Roche Nutley Inventory Code	71801	
Characterization	final product	

2. Composition/Information on ingredients

Ingredients	Concentration
Microcrystalline cellulose CAS: 9004-34-6	~ 15 %
Corn starch CAS: 9005-25-8	~ 12 %
Clonazepam CAS: 1622-61-3	0.3 - 1.2 %

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3. Hazards identification

Emergency Overview

Form	solid
Color	white
Potential Health Effects	<ul style="list-style-type: none">- Exposure: Ingestion- Target Organs: mucous membranes, respiratory tract, gastrointestinal system, Central nervous system- Acute Effects: May cause drying and/or irritation of the mucous membrane., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite., May cause respiratory effects., Signs and symptoms may include difficulty in breathing, coughing, wheezing, irritation (inflammation) and respiratory arrest.- Chronic Effects: No adverse effects known- Carcinogenicity: formulation not listed by NTP, IARC or OSHA
Additional Health Information	<ul style="list-style-type: none">- 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.

4. First-aid measures

Eye contact	<ul style="list-style-type: none">- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	<ul style="list-style-type: none">- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	<ul style="list-style-type: none">- in case of inhalation remove to fresh air and seek medical aid
Ingestion	<ul style="list-style-type: none">- consult physician

5. Fire-fighting measures

Suitable extinguishing media	<ul style="list-style-type: none">- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	<ul style="list-style-type: none">- Toxic emissions may be given off in a fire
Protection of fire-fighters	<ul style="list-style-type: none">- use self-contained breathing apparatus
Special method of fire-fighting	<ul style="list-style-type: none">- cool endangered containers with water spray

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6. Accidental release measures

- | | |
|--------------------------|--|
| Personal precautions | - ensure adequate ventilation |
| Environmental protection | - avoid release to the environment |
| Methods for cleaning up | - Scoop or shovel spilled material into a suitable labeled open head drum
- Secure the drum cover and move the container to a safe holding area
- Clean spill area thoroughly
- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.
- Check area for residual material and repeat clean up if detected |

7. Handling and storage

Handling

- | | |
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| Technical measures | - local exhaust ventilation necessary
- avoid dust formation; consider dust explosion hazard |
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Storage

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| Storage conditions | - keep containers tightly closed
- room temperature
- store in a dry place |
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8. Exposure controls/Personal protection

Engineering Measures

- see 7.

- | | | |
|---------------------------|--|----|
| Threshold value (USA) air | - ACGIH-TLV: 10 mg/m ³ (not classifiable as a human carcinogen) | *1 |
| | - OSHA-PEL: 5 mg/m ³ (respirable fraction) | *1 |
| | - OSHA-PEL: 15 mg/m ³ (total dust) | *1 |
| | - NIOSH-REL: 5 mg/m ³ (respirable fraction) | *1 |
| | - NIOSH-REL: 10 mg/m ³ (total dust) | *1 |
| | - ACGIH-TLV: 10 mg/m ³ | *2 |
| | - OSHA-PEL: 5 mg/m ³ (respirable dust fraction) | *2 |
| | - OSHA-PEL: 15 mg/m ³ (total dust) | *2 |
| | - NIOSH-REL: 5 mg/m ³ (respirable dust fraction) | *2 |
| | - NIOSH-REL: 10 mg/m ³ (total dust) | *2 |

- | | | |
|-----------------------------|---|----|
| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m ³ | *3 |
|-----------------------------|---|----|

Personal protective equipment

- | | |
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| 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.
- respiratory protection not necessary |
|------------------------|---|

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Hand protection	- protective gloves
Eye protection	- safety glasses
Body protection	- protective clothing

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

9. Physical and chemical properties

Color	white
Form	solid

10. Stability and reactivity

Stability	- stable under normal conditions
Conditions to avoid	- None known
Materials to avoid	- None known

11. Toxicological information

Acute toxicity	- LD ₅₀ > 15'000 mg/kg (oral, rat)	*3
	- LD ₅₀ 2'000 mg/kg (oral, mouse)	*3
	- LD ₅₀ 16'500 mg/kg (i.p., mouse)	*3
Mutagenicity	- not mutagenic (various in vivo and in vitro test systems)	*3
Reproduction toxicity	- not teratogenic, not embryotoxic (≤ 40 mg/kg/d; oral, rat)	*3
Note	- maintenance dose: 2 to 4 mg/d (adults)	*3
	- initial therapeutic dose: 1 to 2 mg/d (adults)	*3
	- elimination half-life: 20 to 60 hours	*3
	- acts sedating caution: alcohol potentiates this effect!	*3
*3 referring to:	Clonazepam	

12. Ecological information

Inherent biodegradability	- not inherently biodegradable 0 %, 21 days	*3
	- inherently biodegradable	*2
Ecotoxicity	- moderately toxic for planktonic crustaceans (Daphnia magna) EC ₅₀ (48 h) 30.3 mg/l (FDA Technical Assistance Document No. 4.08)	*3
	- barely toxic for fish (as an emulsion) (rainbow trout) LC ₀ (96 h) 1000 mg/l	*3

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Air pollution - observe local/national regulations *3

*2 referring to: Microcrystalline cellulose

*3 referring to: Clonazepam

13. Disposal considerations

Waste from residues - incinerate in qualified installation with flue gas scrubbing
- observe local/national regulations regarding waste disposal

Contaminated packaging - Empty containers must be triple rinsed prior to disposal, recycling or reuse.

RCRA waste - not regulated under RCRA

14. Transport information

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

15. Regulatory information

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.

16. Other information

Use - Klonopin is an anticonvulsant agent.

Edition documentation - changes from previous version in sections 2, 3, 12

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.