

Safety Data Sheet

VALIUM(R) Tablets (5 mg)

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

1.1. Product identifier

Product name VALIUM(R) Tablets (5 mg)

Product code SAP-10018402

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

Use - pharmaceutical active substance (anxiolytic) *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: Diazepam

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: Diazepam

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SECTION 3: Composition/information on ingredients

Ingredients	Concentration	GHS-Classification (pure ingredient)
Diazepam 439-14-5	2.9 %	- Combustible dust (No category), USH003 - Acute toxicity (Category 3), H301
Corn starch 9005-25-8	37.7 %	

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

Note to physician	- treat symptomatically	*1
	- preserve blood and urine samples	*1
	- in severe cases of intoxication: Anexate i.V. (Caution: must possibly be repeated, because the half-life of elimination of Anexate is shorter than the one of Valium)	*1

*1 referring to: Diazepam

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
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Flash point (liquid) not applicable

5.2. Special hazards arising from the substance or mixture

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

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
- Packaging materials
- polyethylene bag in metal drum
 - blister packages
 - glass vials, brown

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air	- ACGIH-TLV: 10 mg/m ³ (not classifiable as a human carcinogen)	*2
	- OSHA-PEL: 5 mg/m ³ (respirable fraction)	*2
	- OSHA-PEL: 15 mg/m ³ (total dust)	*2
	- NIOSH-REL: 5 mg/m ³ (respirable fraction)	*2
	- NIOSH-REL: 10 mg/m ³ (total dust)	*2
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.02 mg/m ³ (defined as 8-hour time-weighted average)	*1

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	
Analytics	- sampling on glass fibre filter and gravimetric or chemical determination	*1
*1 referring to:	Diazepam	
*2 referring to:	Corn starch	

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	pale yellow	
Form	cylindrical biplane tablet	
Solubility	50 mg/l, water (20 °C)	*1
	49'000 mg/l, methanol (20 °C)	*1
	125'000 mg/l, acetone (20 °C)	*1
	18'000 mg/l, ether (20 °C)	*1
	161 g/l, water (20 °C)	*3
	50 g/l, water (90 °C)	*2
pH value (20 °C)	4 to 6.6 (100 g/l)	*3
(25 °C)	4 to 7 (20 g/l)	*2

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9.2. Other information

Note - no information available

*1 referring to: Diazepam
*2 referring to: Corn starch
*3 referring to: Lactose

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

Materials to avoid - oxidizing agents, strong bases, mineral acids *1

10.6. Hazardous decomposition products

Note - no information available

*1 referring to: Diazepam

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - LD₅₀ 249 mg/kg (oral, rat) *1
- LD₅₀ > 2'000 mg/kg (oral, rat) *4

Chronic toxicity - liver enzyme induction after high doses *1

Mutagenicity - not mutagenic (various test systems) *1

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Carcinogenicity	- rat; no evidence of carcinogenicity	*1
Reproductive toxicity	- not teratogenic	*1
Note	- Diazepam has anxiety relaxant, sedative, muscle relaxant and anti-convulsive effects	*1
	- therapeutic dose: 5 to 20 mg/d (adults)	*1
	- elimination half-life: 3 to 48 hours	*1
	- may lead to psychological and physical dependence	*1
	- Caution: alcohol potentiates the 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. Respiratory system conditions.	
	- This material may cause impairment of mental and/or physical abilities which are required to perform hazardous tasks, such as operating machinery or driving a motor vehicle.	
	- Reproductive Toxicity: An increased risk of congenital malformations associated with the use of minor tranquilizers, such as diazepam and chlordiazepoxide, during the first trimester of pregnancy has been suggested.	
	- The placental transfer of this material in humans has been documented.	
	- Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure.	
	- It is also advisable for nursing mothers to exercise caution regarding exposure.	
*1 referring to:	Diazepam	
*4 referring to:	Magnesium stearate	

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- strongly toxic for algae (<i>Scenedesmus (=Desmodesmus) subspicatus</i>) ErC ₅₀ (72 h) 3.11 mg/l (average measured concentration) ErC ₅₀ (72 h) 22.8 mg/l (nominal concentration) NOEC (72 h) < 2.56 mg/l (nominal concentration) (OECD No. 201)	*1
	- <i>Daphnia magna</i> NOEC (21 d) 0.8 mg/l (average measured concentration) (OECD No. 211 (semi-static))	*1
	- zebrafish NOEC (35 d) 0.273 mg/l (average measured concentration) (OECD No. 210)	*1

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12.2. Persistence and degradability

Inherent biodegradability	- not inherently biodegradable partial primary degradation evidenced by HPLC < 5 % BOD/ThOD, 28 d < 5 % BOD/ThOD, 84 d (MITI Test II, OECD No. 302 C)	*1
	- well inherently biodegradable ≥ 82 %, 24 h (batch-wise test similar to SCAS with adaptation phase)	*2
Abiotic degradation	- notable degradation, photodegradation, no hydrolysis 36.3 mg/l, water; HPLC 100 %, 0 h, ~ 22 °C, start of test 98 %, 120 h, ~ 22 °C, dark 75 %, 120 h, ~ 22 °C, under illumination	*1

12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Mobility	- medium adsorption (, 72 h)	*1
	- strong adsorption (water-activated sludge, 24 h, ~22 °C) $K_d = 52000$ to 57000 l/kg (activated sludge)	*1

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Diazepam
*2 referring to: Corn starch

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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

Full text of H-Statements referred to under section 3

H301 Toxic if swallowed.

USH003 May form combustible dust concentrations in the air

- 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

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.