# Safety Data Sheet

**VALIUM(R) Tablets (10 mg)**

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

### 1.1. Product identifier

| Use | pharmaceutical active substance (anxiolytic) |

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

- pharmaceutical active substance (anxiolytic)

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

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone</td>
<td>001-(650) 225-1000</td>
</tr>
<tr>
<td>E-Mail</td>
<td><a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
<tr>
<td>US Chemtrec phone:</td>
<td>(800)-424-9300</td>
</tr>
</tbody>
</table>

### 1.4. Emergency telephone number

- **Diazepam**

## SECTION 2: Hazards identification

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

- **no classification and labelling according to GHS**

### Other hazards

- **Diazepam**

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*Diazepam* referring to:

- Benzodiazepines induce central nervous system depression and drowsiness. In addition, longer use may be habit forming. Hence, these compounds are also misused by addicts.

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*1 referring to:  Diazepam
SECTION 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazepam</td>
<td>5.9 %</td>
<td>- Combustible dust (No category), USH003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Acute toxicity (Category 3), H301</td>
</tr>
<tr>
<td>Corn starch</td>
<td>34.8 %</td>
<td></td>
</tr>
</tbody>
</table>

For the full text of the 'Hazard statements' 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 at least 20 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
                        - preserve blood and urine samples
                        - 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 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
Flash point (liquid)               - not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards          - consider dust explosion hazard
- 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
SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (USA) air  
- ACGIH-TLV: 10 mg/m³ (not classifiable as a human carcinogen)  
- OSHA-PEL: 5 mg/m³ (respirable fraction)  
- OSHA-PEL: 15 mg/m³ (total dust)  
- NIOSH-REL: 5 mg/m³ (respirable fraction)  
- NIOSH-REL: 10 mg/m³ (total dust)

Threshold value (Roche) air  
- IOEL (Internal Occupational Exposure Limit): 0.02 mg/m³ (defined as 8-hour time-weighted average)

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 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 blue

Form  
cylindrical biplane tablet

Solubility  
50 mg/l, water (20 °C)  
49‘000 mg/l, methanol (20 °C)  
125‘000 mg/l, acetone (20 °C)  
18‘000 mg/l, ether (20 °C)  
161 g/l, water (20 °C)  
50 g/l, water (90 °C)

pH value  
(20 °C) 4 to 6.6 (100 g/l)  
(25 °C) 4 to 7 (20 g/l)
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

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
- \( \text{LD}_{50} \) 249 mg/kg (oral, rat) *1
- \( \text{LD}_{50} \) > 2'000 mg/kg (oral, rat) *4

Chronic toxicity
- liver enzyme induction after high doses *1

Local effects
- no information available
VALIUM(R) Tablets (10 mg)

Sensitization - no information available

Mutagenicity - not mutagenic (various test systems)

Carcinogenicity - rat; no evidence of carcinogenicity

Reproductive toxicity - not teratogenic

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

Note - Diazepam has anxiety relaxant, sedative, muscle relaxant and anti-convulsive effects
- therapeutic dose: 5 to 20 mg/d (adults)
- elimination half-life: 3 to 48 hours
- may lead to psychical and physical dependence
- Caution: alcohol potentiates the effect!

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
VALIUM(R) Tablets (10 mg)

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity
- strongly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  ErC₅₀ (72 h) 3.11 mg/l (average measured concentration)
  ErC₅₀ (72 h) 22.8 mg/l (nominal concentration)
  NOEC (72 h) < 2.56 mg/l (nominal concentration)
  (OECD No. 201) *1
  - Daphnia magna
    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

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)
    Kᵣ = 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

### 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 as Dangerous Good according to the Dangerous Goods 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 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 3, 15

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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.