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

1.1. Product identifier

Product name: VALIUM 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:
F. Hoffmann-La Roche AG
Postfach
CH-4070 Basel
Switzerland

Phone: +41-61/688 54 80
Fax: +41-61/681 72 76
E-Mail: info.sds@roche.com

Local representation: Company information

1.4. Emergency telephone number

Emergency telephone number: Phone: +41-61/688 54 80

*1 referring to: Diazepam

SECTION 2: Hazards identification

2.1. / 2.2. Classification of the substance or mixture / Label elements

GHS Classification: Environmental Hazards:
4.1 Hazardous to the aquatic environment (Category 3)
   H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:
- P273 Avoid release to the environment.
2.3. 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

SECTION 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazepam 439-14-5</td>
<td>2.9 %</td>
<td>- Acute toxicity (Category 3), H301</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Hazardous to the aquatic environment (Category 2), H411</td>
</tr>
<tr>
<td>Lactose monohydrate 10039-26-6</td>
<td>58.8 %</td>
<td></td>
</tr>
<tr>
<td>Corn starch 9005-25-8</td>
<td>37.7 %</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate 557-04-0</td>
<td>0.4 %</td>
<td></td>
</tr>
<tr>
<td>Iron (III) oxide monohydrate, yellow 51274-00-1</td>
<td>0.1 %</td>
<td></td>
</tr>
</tbody>
</table>

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
- 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

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 (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.02 mg/m³ (defined as 8-hour time-weighted average) *1

8.2. Exposure controls

General protective and hygiene measures
- instruction of employees recommended

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

Analytics
- sampling on glass fibre filter and gravimetric or chemical determination *1

*1 Diazepam referring to:

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour
- pale yellow

Form
- cylindrical biplane tablet

Date: 8.6.15/LS (SEISMO)  Replacing edition of: 28.11.13  Page: 4/8
### Solubility

<table>
<thead>
<tr>
<th>Solubility</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mg/l, water (20 °C)</td>
<td>*1</td>
</tr>
<tr>
<td>49'000 mg/l, methanol (20 °C)</td>
<td>*1</td>
</tr>
<tr>
<td>125'000 mg/l, acetone (20 °C)</td>
<td>*1</td>
</tr>
<tr>
<td>18'000 mg/l, ether (20 °C)</td>
<td>*1</td>
</tr>
<tr>
<td>161 g/l, water (20 °C)</td>
<td>*2</td>
</tr>
<tr>
<td>50 g/l, water (90 °C)</td>
<td>*3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>pH value</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>(20 °C)</td>
<td>4 to 6.6 (100 g/l)</td>
</tr>
<tr>
<td>(25 °C)</td>
<td>4 to 7 (20 g/l)</td>
</tr>
</tbody>
</table>

### 9.2. Other information

Note - no information available

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

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

Chronic toxicity
- liver enzyme induction after high doses *1

Mutagenicity
- not mutagenic (various test systems) *1

Carcinogenicity
- rat; no evidence for 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 psychical and physical dependence *1
- Caution: alcohol potentiates the effect! *1

*1 referring to: Diazepam
*4 referring to: Magnesium stearate

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity
- strongly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  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
- 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) *3
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)
  \( K_d = 52000 \text{ to } 57000 \text{ l/kg (activated sludge)} \) *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
*3 referring to: Corn starch

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**
Waste from residues - return to supplier or hand over to authorised disposal company
- observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing
- medicines should not be disposed of via wastewater

**SECTION 14: Transport information**

**Note** - not classified by transport regulations

**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**
Water hazard class (Germany) 1: weakly hazardous for water (own classification according to directive VwVwS of 27.07.2005)
SECTION 16: Other information

Full text of H-Statements referred to under section 3

H301 Toxic if swallowed.
H411 Toxic to aquatic life with long lasting effects.

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.