# Safety Data Sheet

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

### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>VALIUM Tablets 2 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10017676</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Company information</th>
<th>Local representation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enquiries: Roche Products Pty Limited</td>
<td>Local representation:</td>
</tr>
<tr>
<td>Level 8, 30-34 Hickson Road</td>
<td></td>
</tr>
<tr>
<td>Millers Point NSW 2000</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td>0061-2-9454-9624</td>
</tr>
<tr>
<td>Fax</td>
<td>0061-2-9971-7401</td>
</tr>
<tr>
<td>E-Mail</td>
<td><a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
</tbody>
</table>

### 1.4. Emergency telephone number

<table>
<thead>
<tr>
<th>Emergency telephone number</th>
<th>Phone</th>
<th>Emergency telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0061-2-9454-9624</td>
<td></td>
</tr>
</tbody>
</table>

*1 referring to: Diazepam

## SECTION 2: Hazards identification

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

<table>
<thead>
<tr>
<th>GHS Classification</th>
<th>no classification and labelling according to GHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Remark</td>
<td>- Poisons Schedule - Schedule 4 *1</td>
</tr>
<tr>
<td></td>
<td>- Listed on the Australian Inventory of Chemical Substances (AICS) *1</td>
</tr>
<tr>
<td></td>
<td>- Listed on the Australian Inventory of Chemical Substances (AICS) *2</td>
</tr>
<tr>
<td></td>
<td>- Listed on the Australian Inventory of Chemical Substances (AICS) *3</td>
</tr>
<tr>
<td></td>
<td>- Listed on the Australian Inventory of Chemical Substances (AICS) *4</td>
</tr>
</tbody>
</table>

Date: 4.11.17/LS (SEISMO)  Replacing edition of: 8.6.15  Page: 1/8
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 referring to: Diazepam
*2 referring to: Corn starch
*3 referring to: Lactose
*4 referring to: Magnesium stearate

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</td>
<td>1.2 %</td>
<td>- Acute toxicity (Category 3), H301</td>
</tr>
<tr>
<td>439-14-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate</td>
<td>58.9 %</td>
<td></td>
</tr>
<tr>
<td>10039-26-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corn starch</td>
<td>39.5 %</td>
<td></td>
</tr>
<tr>
<td>9005-25-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>0.4 %</td>
<td></td>
</tr>
<tr>
<td>557-04-0</td>
<td></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
**VALIUM Tablets 2 mg**

**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 referring to: Diazepam

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour
white to practically white

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
- 4 to 6.6 (100 g/l)  
- 4 to 7 (20 g/l)  

### 9.2. Other information
- no information available

**referring to:**
- Diazepam
- Corn starch
- Lactose

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity
- no information available

#### 10.2. Chemical stability
- no information available

#### 10.3. Possibility of hazardous reactions
- no information available

#### 10.4. Conditions to avoid
- warming
- light
- humidity

#### 10.5. Incompatible materials
- oxidizing agents, strong bases, mineral acids

#### 10.6. Hazardous decomposition products
- no information available

**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

**Sensitization**
- no information available

**Mutagenicity**
- not mutagenic (various test systems) \(^1\)

**Carcinogenicity**
- rat; no evidence for carcinogenicity \(^1\)

**Reproductive toxicity**
- not teratogenic \(^1\)

**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 \(^1\)
- 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)
  - \( \text{ErC}_{50} \) (72 h) 3.11 mg/l (average measured concentration)
  - \( \text{ErC}_{50} \) (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) *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)
  \( K_d = 52000 \text{ to } 57000 \text{ l/kg (activated sludge)} \) *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
*2 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

Australian Remark  -  ADG Code: This product is not classified as a dangerous good. No special transport conditions are necessary unless required by other 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 (according to directive AwSV of 18.04.2017)

### SECTION 16: Other information

Full text of H-Statements referred to under section 3

H301  Toxic if swallowed.

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

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.
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:
Roche Products Pty Limited
Level 8, 30-34 Hickson Road
Millers Point NSW 2000
Australia

Phone: 0061-2-9454-9624
Fax: 0061-2-9971-7401
E-Mail: info.sds@roche.com

Local representation:

1.4. Emergency telephone number

Emergency telephone number: Phone: 0061-2-9454-9624

*1 referring to: Diazepam

SECTION 2: Hazards identification

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

GHS Classification: no classification and labelling according to GHS

Australian Remark:
- Poisons Schedule - Schedule 4 *1
- Listed on the Australian Inventory of Chemical Substances (AICS) *1
- Listed on the Australian Inventory of Chemical Substances (AICS) *2
- Listed on the Australian Inventory of Chemical Substances (AICS) *3
- Listed on the Australian Inventory of Chemical Substances (AICS) *4
- Listed on the Australian Inventory of Chemical Substances (AICS) *5
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 referring to: Diazepam
*2 referring to: Corn starch
*3 referring to: Lactose
*4 referring to: Magnesium stearate
*5 referring to: Iron (III) oxide monohydrate, yellow

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</td>
<td>2.9 %</td>
<td>- Acute toxicity (Category 3), H301</td>
</tr>
<tr>
<td>439-14-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate</td>
<td>58.8 %</td>
<td></td>
</tr>
<tr>
<td>10039-26-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corn starch</td>
<td>37.7 %</td>
<td></td>
</tr>
<tr>
<td>9005-25-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>0.4 %</td>
<td></td>
</tr>
<tr>
<td>557-04-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iron (III) oxide monohydrate, yellow</td>
<td>0.1 %</td>
<td></td>
</tr>
<tr>
<td>51274-00-1</td>
<td></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

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 referring to: Diazepam

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour - pale yellow
Form - cylindrical biplane tablet
VALIUM Tablets 5 mg

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

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

<table>
<thead>
<tr>
<th>Effect Type</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute toxicity</strong></td>
<td>- LD&lt;sub&gt;50&lt;/sub&gt; 249 mg/kg (oral, rat) *1</td>
</tr>
<tr>
<td></td>
<td>- LD&lt;sub&gt;50&lt;/sub&gt; &gt; 2'000 mg/kg (oral, rat) *4</td>
</tr>
<tr>
<td><strong>Chronic toxicity</strong></td>
<td>- liver enzyme induction after high doses *1</td>
</tr>
<tr>
<td><strong>Local effects</strong></td>
<td>- no information available</td>
</tr>
<tr>
<td><strong>Sensitization</strong></td>
<td>- no information available</td>
</tr>
<tr>
<td><strong>Mutagenicity</strong></td>
<td>- not mutagenic (various test systems) *1</td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td>- rat; no evidence for carcinogenicity *1</td>
</tr>
<tr>
<td><strong>Reproductive toxicity</strong></td>
<td>- not teratogenic *1</td>
</tr>
<tr>
<td><strong>STOT-single exposure</strong></td>
<td>- no information available</td>
</tr>
<tr>
<td><strong>STOT-repeated exposure</strong></td>
<td>- no information available</td>
</tr>
<tr>
<td><strong>Aspiration hazard</strong></td>
<td>- no information available</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Ecotoxicity</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ecotoxicity</strong></td>
<td>- strongly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)</td>
</tr>
<tr>
<td></td>
<td>ErC&lt;sub&gt;50&lt;/sub&gt; (72 h) 3.11 mg/l (average measured concentration)</td>
</tr>
<tr>
<td></td>
<td>ErC&lt;sub&gt;50&lt;/sub&gt; (72 h) 22.8 mg/l (nominal concentration)</td>
</tr>
<tr>
<td></td>
<td>NOEC (72 h) &lt; 2.56 mg/l (nominal concentration) (OECD No. 201)</td>
</tr>
<tr>
<td></td>
<td>- Daphnia magna NOEC (21 d) 0.8 mg/l (average measured concentration) (OECD No. 211 (semi-static))</td>
</tr>
<tr>
<td></td>
<td>- zebrafish NOEC (35 d) 0.273 mg/l (average measured concentration) (OECD No. 210)</td>
</tr>
</tbody>
</table>

*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)
   $K_d = 52000$ 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

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

Australian Remark

- ADG Code: This product is not classified as a dangerous good. No special transport conditions are necessary unless required by other 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 (according to directive AwSV of 18.04.2017)

SECTION 16: Other information

Full text of H-Statements referred to under section 3

H301 Toxic if swallowed.

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

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

1.1. Product identifier

Product name: VALIUM Tablets 10 mg
Product code: SAP-10018397

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: Roche Products Pty Limited
Level 8, 30-34 Hickson Road
Millers Point NSW 2000
Australia

Phone: 0061-2-9454-9624
Fax: 0061-2-9971-7401
E-Mail: info.sds@roche.com

Local representation:

1.4. Emergency telephone number

Emergency telephone number:
Phone: 0061-2-9454-9624

*1 referring to: Diazepam

SECTION 2: Hazards identification

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

GHS Classification:
- no classification and labelling according to GHS

Australian Remark:
- Poisons Schedule - Schedule 4 *1
- Listed on the Australian Inventory of Chemical Substances (AICS) *1
- Listed on the Australian Inventory of Chemical Substances (AICS) *2
- Listed on the Australian Inventory of Chemical Substances (AICS) *3
- Listed on the Australian Inventory of Chemical Substances (AICS) *4
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 referring to: Diazepam
*2 referring to: Corn starch
*3 referring to: Lactose
*4 referring to: Magnesium stearate

SECTION 3: Composition/information on ingredients

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<th>Ingredient</th>
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<tbody>
<tr>
<td>Diazepam 439-14-5</td>
<td>5.9 %</td>
<td>- Acute toxicity (Category 3), H301</td>
</tr>
<tr>
<td>Lactose monohydrate 10039-26-6</td>
<td>58.9 %</td>
<td></td>
</tr>
<tr>
<td>Corn starch 9005-25-8</td>
<td>34.8 %</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate 557-04-0</td>
<td>0.4 %</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

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)

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 referring to: Diazepam

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour
- pale blue

Form
- cylindrical biplane tablet
VALIUM Tablets 10 mg

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

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
- 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

Local effects
- no information available

Sensitization
- no information available

Mutagenicity
- not mutagenic (various test systems) *1

Carcinogenicity
- rat; no evidence for carcinogenicity *1

Reproductive toxicity
- not teratogenic *1

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 *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
  \(< 5 \% \text{ BOD/ThOD}, 28 \text{ d}\)
  \(< 5 \% \text{ BOD/ThOD}, 84 \text{ d}\)
  (MITI Test II, OECD No. 302 C) \(^1\)
- well inherently biodegradable
  \(\geq 82 \%, 24 \text{ h}\)
  (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)
  \(K_d = 52000 \text{ to } 57000 \text{ l/kg (activated sludge)}\) \(^1\)

**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
\(^2\) 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

Australian Remark
- ADG Code: This product is not classified as a dangerous good. No special transport conditions are necessary unless required by other 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 (according to directive AwSV of 18.04.2017)

SECTION 16: Other information

Full text of H-Statements referred to under section 3
H301 Toxic if swallowed.

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

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

1.1. Product identifier

Product name: VALIUM Ampoules 10 mg/2 ml
Product code: SAP-10050719

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: Roche Products Pty Limited
Level 8, 30-34 Hickson Road
Millers Point NSW 2000
Australia

Local representation:

Phone: 0061-2-9454-9624
Fax: 0061-2-9971-7401
E-Mail: info.sds@roche.com

1.4. Emergency telephone number

Emergency telephone number: Phone 0061-2-9454-9624

*1 referring to: Diazepam

SECTION 2: Hazards identification

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

GHS Classification
Physical Hazards:
2.6 Flammable liquids (Category 3)
H226 Flammable liquid and vapour.

Signalword: Warning
Label: 

Precautionary statements:
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
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 referring to: Diazepam
*2 referring to: Ethyl alcohol
*3 referring to: Benzyl alcohol
*4 referring to: Propylene glycol
*5 referring to: Sodium benzoate

SECTION 3: Composition/information on ingredients

Characterization
diazepam and other 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>5 mg/ml</td>
<td>- Acute toxicity (Category 3), H301</td>
</tr>
<tr>
<td>Ethanol 64-17-5</td>
<td>8 %</td>
<td>- Flammable liquids (Category 2), H225</td>
</tr>
<tr>
<td>Benzyl alcohol 100-51-6</td>
<td>15.7 mg/ml</td>
<td>- Acute toxicity (Category 4), H312</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Acute toxicity (Category 4), H332</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>Propylene glycol 57-55-6</td>
<td>41.4 %</td>
<td></td>
</tr>
<tr>
<td>Sodium benzoate [stabilizer] 532-32-1</td>
<td>4.75 %</td>
<td></td>
</tr>
</tbody>
</table>

water solution suitable for injection

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
VALIUM Ampoules 10 mg/2 ml

Skin contact
- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Inhalation
- remove the casualty to fresh air and keep him/her calm
- 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)
- the benzyl alcohol contained in VALIUM ampoules may lead to irreversible damage in the newborn, especially in the premature

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media
- water spray jet, dry powder, foam, carbon dioxide

5.2. Special hazards arising from the substance or mixture

Specific hazards
- may act as a narcotic and cause loss of consciousness
- may form explosive mixture with air at elevated ambient temperature
- Vapours may be invisible and they are heavier than air. They spread on the soil and could penetrate into the sewerage system and into cellars.
- may ignite on hot surfaces, sparks or open flames

5.3. Advice for firefighters

Protection of fire-fighters
- use self-contained breathing apparatus
- avoid skin contact

Special method of fire-fighting
- cool endangered containers 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 - avoid release to the environment

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect spills with inert adsorbent and hand over to waste removal

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - avoid formation of aerosols
- provide suitable exhaust ventilation at the processing machines

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - below 25 °C
- protected from light

Validity - 36 months, ≤ 30 °C, see "best use before" date stated on the label

Packaging materials - ampoules
- keep it in the outer carton in order to protect from light

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 - respiratory protection not necessary during normal operations

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
### SECTION 9: Physical and chemical properties

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>greenish-yellow</td>
</tr>
<tr>
<td>Form</td>
<td>clear solution</td>
</tr>
<tr>
<td>Density</td>
<td>1.035 g/cm³</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>log $P_{ow}$ -0.92 (n-octanol/water)</td>
</tr>
<tr>
<td>pH value</td>
<td>6.3 to 6.9</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>0.11 mbar (20 °C)</td>
</tr>
<tr>
<td></td>
<td>0.7 mbar (30 °C)</td>
</tr>
<tr>
<td></td>
<td>3.0 mbar (50 °C)</td>
</tr>
<tr>
<td>Flash point (liquid)</td>
<td>53 °C</td>
</tr>
</tbody>
</table>

**9.2. Other information**

| Note                  | no information available                   |

*4 referring to: Propylene glycol

### SECTION 10: Stability and reactivity

**10.1. Reactivity**

| Note                  | no information available                   |

**10.2. Chemical stability**

| Stability              | does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution |

**10.3. Possibility of hazardous reactions**

| Note                  | no information available                   |

**10.4. Conditions to avoid**

| Conditions to avoid   | light                                      |
|                       | warming                                   |

**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

<table>
<thead>
<tr>
<th>Acute toxicity</th>
<th>$\text{LD}_{50}$</th>
<th>mg/kg</th>
<th>(oral, rat)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>249</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>20'000</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1’230</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2’100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Chronic toxicity**: liver enzyme induction after high doses
- **Local effects**: skin: slightly irritating (man)
- **Sensitization**: no information available
- **Mutagenicity**: not mutagenic (various test systems)
- **Carcinogenicity**: rat; no evidence for 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!

*1 referring to: Diazepam
*3 referring to: Benzyl alcohol
*4 referring to: Propylene glycol
*5 referring to: Sodium benzoate
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
- barely toxic for microorganisms (activated sludge)
  NOEC > 100 mg/l *1
- barely toxic for planktonic crustaceans (Daphnia magna)
  EC₅₀ (48 h) 34400 mg/l
  (OECD No. 202) *4
- barely toxic for fish (rainbow trout)
  LCₐ ≥ 1000 mg/l
  (OECD No. 202) *4
- barely toxic for planktonic crustaceans (Daphnia magna)
  EC₅₀ (96 h) > 100 mg/l

12.2. Persistence and degradability

Ready biodegradability
- readily biodegradable
  > 92 %, 28 d *3
- readily biodegradable
  ~ 90 %, 7 d
  (CO₂ Evolution Test, Modified Sturm Test, OECD No. 301B) *5

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
  98 %, 5 d
  (Zahn-Wellens test, OECD No. 302 B) *4

12.3. Bioaccumulative potential

Note
- no information available

12.4. Mobility in soil

Note
- no information available

12.5. Results of PBT and vPvB assessment

Note
- no information available
12.6. Other adverse effects

Air pollution - observe local/national regulations

*1 referring to: Diazepam
*3 referring to: Benzyl alcohol
*4 referring to: Propylene glycol
*5 referring to: Sodium benzoate

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

IATA Remark: - Not subject to the Dangerous Goods Regulations; see SP A58
IATA-DGR according to UN 1170

IMDG Remark: - Not subject to the Dangerous Goods Regulations; see SP 144
IMDG-Code according to UN 1170

RID/ADR Remark: - Not subject to the Dangerous Goods Regulations; see SP 144
RID/ADR according to UN 1170

Australian Remark - ADG Code: This product is not classified as a dangerous good. No special transport conditions are necessary unless required by other 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 (according to directive AwSV of 18.04.2017)

SECTION 16: Other information

Safety-lab number - BS-8645

Full text of H-Statements referred to under section 3

H225 Highly flammable liquid and vapour.
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H332 Harmful if inhaled.
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

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.