<table>
<thead>
<tr>
<th><strong>SECTION 1: Identification of the substance/mixture and of the company/undertaking</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1. Product identifier</strong></td>
</tr>
<tr>
<td><strong>Product name</strong></td>
</tr>
<tr>
<td><strong>Product code</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>1.2. Relevant identified uses of the substance or mixture and uses advised against</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>1.3. Details of the supplier of the safety data sheet</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company information</strong></td>
</tr>
<tr>
<td><strong>Phone</strong></td>
</tr>
<tr>
<td><strong>Fax</strong></td>
</tr>
<tr>
<td><strong>E-Mail</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>1.4. Emergency telephone number</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emergency telephone number</strong></td>
</tr>
<tr>
<td><strong>referring to:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>SECTION 2: Hazards identification</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.1. / 2.2. Classification of the substance or mixture / Label elements</strong></td>
</tr>
<tr>
<td><strong>GHS Classification</strong></td>
</tr>
<tr>
<td><strong>Australian Remark</strong></td>
</tr>
</tbody>
</table>
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: Bromazepam
*2 referring to: Cellulose
*3 referring to: Lactose
*4 referring to: Magnesium stearate
*5 referring to: Talc

SECTION 3: Composition/information on ingredients

**Characterization**
mixture of 1.5% Bromazepam with excipients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bromazepam 1812-30-2</td>
<td>1.5 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>50.0 %</td>
<td></td>
</tr>
<tr>
<td>9004-34-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate 64044-51-5</td>
<td>47.2 %</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate 557-04-0</td>
<td>0.3 %</td>
<td></td>
</tr>
<tr>
<td>Talc 14807-96-6</td>
<td></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
- consult a physician

**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
- 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 Bromazepam is longer than the one of Anexate

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media - water spray jet, dry powder, foam, carbon dioxide
- adapt extinguishing media to surrounding fire conditions

5.2. Special hazards arising from the substance or mixture

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

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 - ensure adequate ventilation

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
- avoid dust formation

Suitable materials
- stainless steel, aluminium, enamel, glass

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions
- below 30 °C
- protected from light and humidity

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

Packaging materials
- tightly closing; material:
  - blister packages
  - high density polyethylene (HDPE) bottles with a child-resistant polypropylene screw cap
  - polyethylene bag in metal drum glass, plastic, aluminium

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 (eg made of neoprene, nitrile or butyl rubber)

Eye protection
- safety glasses

Body protection
- protective clothing

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

*1 referring to: Bromazepam

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour
- pale red
LEXOTAN Tablets 3 mg

Form: cylindrical biplane tablet
Solubility: insoluble, water (20 °C)

9.2. Other information
Note: no information available

*2 referring to: Cellulose

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:
- light
- humidity

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

Acute toxicity
- LD$_{50}$ 879 mg/kg (oral, mouse) *1
- LD$_{50}$ 1’950 mg/kg (oral, rat) *1

Mutagenicity: not mutagenic (various test systems) *1

Carcinogenicity: not carcinogenic, liver (rat) *1

Reproductive toxicity
- not teratogenic *1
- not embryotoxic *1

Date: 28.7.15/LS (SEISMO) Replacing edition of: 5.9.13 Page: 5/7
Note

- therapeutic dose: 1.5 to 36 mg/d (adults) *1
- overdosing results in increase of therapeutical effects (sedation, muscle weakness, deep sleep) *1
- caution: alcohol potentiates the effect! *1
- elimination half-life: 10 to 20 hours *1
- may lead to psychical and physical dependence *1

*1 referring to: Bromazepam

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

- barely toxic for fish (rainbow trout)
  LC_{50} (96 h) > 500 mg/l *1
- barely toxic for microorganisms
  EC_{50} > 100 mg/l *1

12.2. Persistence and degradability

Inherent biodegradability

- not inherently biodegradable
  0 %, 21 days
  (MITI Test II, OECD No. 302 C) *1
- inherently biodegradable *2

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: Bromazepam
*2 referring to: Cellulose
**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

<table>
<thead>
<tr>
<th>Waste from residues</th>
<th>- return to supplier or hand over to authorised disposal company</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- observe local/national regulations regarding waste disposal</td>
</tr>
<tr>
<td></td>
<td>- incinerate in qualified installation with flue gas scrubbing</td>
</tr>
<tr>
<td></td>
<td>- medicines should not be disposed of via wastewater</td>
</tr>
</tbody>
</table>

**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 (own classification according to directive VwVwS of 27.07.2005) |

**SECTION 16: Other information**

<table>
<thead>
<tr>
<th>Safety-lab number</th>
<th>BS-4688</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full text of H-Statements referred to under section 3</td>
<td>H302 Harmful if swallowed.</td>
</tr>
<tr>
<td>Edition documentation</td>
<td>changes from previous version in sections 3, 16</td>
</tr>
</tbody>
</table>

*1 referring to: Bromazepam

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.
LEXOTAN Tablets 6 mg

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

1.1. Product identifier

Product name: LEXOTAN Tablets 6 mg
Product code: SAP-10019052

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: Roche Products Pty Limited
P.O. Box 255
Dee Why, N.S.W. 2099
AUS-Australia
Australia

Enquiries:
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: Bromazepam

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
- 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
LEXOTAN Tablets 6 mg

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: Bromazepam
*2 referring to: Cellulose
*3 referring to: Lactose
*4 referring to: Magnesium stearate
*5 referring to: Talc

SECTION 3: Composition/information on ingredients

Characterization mixture of 3.0% Bromazepam with excipients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bromazepam</td>
<td>3.0 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>1812-30-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>50.0 %</td>
<td></td>
</tr>
<tr>
<td>9004-34-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate</td>
<td>45.4 %</td>
<td></td>
</tr>
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<td>64044-51-5</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>Talc</td>
<td>14807-96-6</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 - consult a physician

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 - get medical treatment
LEXOTAN Tablets 6 mg

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 Bromazepam is longer than the one of Anexate

SECTION 5: Firefighting measures

5.1. Extinguishing media
Suitable extinguishing media - water spray jet, dry powder, foam, carbon dioxide
- adapt extinguishing media to surrounding fire conditions

5.2. Special hazards arising from the substance or mixture
Specific hazards - formation of toxic and corrosive combustion gases (nitrous oxides, hydrogen bromide) possible
- consider dust explosion hazard

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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 - ensure adequate ventilation

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

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>- avoid dust formation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suitable materials</td>
<td>- stainless steel, aluminium, enamel, glass</td>
</tr>
</tbody>
</table>

### 7.2. Conditions for safe storage, including any incompatibilities

<table>
<thead>
<tr>
<th>Storage conditions</th>
<th>- below 30 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- protected from light and humidity</td>
</tr>
<tr>
<td>Validity</td>
<td>- 60 months, ≤30 °C, see &quot;best use before&quot; date stated on the label</td>
</tr>
<tr>
<td>Packaging materials</td>
<td>- tightly closing; material:</td>
</tr>
<tr>
<td></td>
<td>- blister packages</td>
</tr>
<tr>
<td></td>
<td>- high density polyethylene (HDPE) bottles with a child-resistant polypropylene screw cap</td>
</tr>
<tr>
<td></td>
<td>- polyethylene bag in metal drum glass, plastic, aluminium</td>
</tr>
</tbody>
</table>

**SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

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

### 8.2. Exposure controls

<table>
<thead>
<tr>
<th>General protective and hygiene measures</th>
<th>- instruction of employees recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory protection</td>
<td>- in case of open handling or accidental release: particle mask or respirator with independent air supply</td>
</tr>
<tr>
<td>Hand protection</td>
<td>- protective gloves (eg made of neoprene, nitrile or butyl rubber)</td>
</tr>
<tr>
<td>Eye protection</td>
<td>- safety glasses</td>
</tr>
<tr>
<td>Body protection</td>
<td>- protective clothing</td>
</tr>
<tr>
<td>Analytics</td>
<td>- sampling on glass fibre filter and gravimetric or chemical determination</td>
</tr>
</tbody>
</table>

*1 referring to: Bromazepam

**SECTION 9: Physical and chemical properties**

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

| Colour               | greyish green |
LEXOTAN Tablets 6 mg

Form  
cylindrical biplane tablet

Solubility  
insoluble, water (20 °C)

9.2. Other information

Note - no information available

*2 referring to: Cellulose

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 - light
                  - humidity

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

Acute toxicity - LD$_{50}$ 879 mg/kg (oral, mouse)  *1
                 - LD$_{50}$ 1’950 mg/kg (oral, rat)  *1

Mutagenicity - not mutagenic (various test systems)  *1

Carcinogenicity - not carcinogenic, liver (rat)  *1

Reproductive toxicity - not teratogenic  *1
                   - not embryotoxic  *1
Note
- therapeutic dose: 1.5 to 36 mg/d (adults) *1
- overdosing results in increase of therapeutical effects (sedation, muscle weakness, deep sleep) *1
- caution: alcohol potentiates the effect! *1
- elimination half-life: 10 to 20 hours *1
- may lead to psychical and physical dependence *1

*1 referring to: Bromazepam

SECTION 12: Ecological information

12.1. Toxicity
Ecotoxicity
- barely toxic for fish (rainbow trout) 
  $L_C_{50}$ (96 h) > 500 mg/l *1
- barely toxic for microorganisms 
  $E_C_{50}$ > 100 mg/l *1

12.2. Persistence and degradability
Inherent biodegradability
- not inherently biodegradable 
  0 %, 21 days (MITI Test II, OECD No. 302 C) *1
- inherently biodegradable *2

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: Bromazepam
*2 referring to: Cellulose
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 (own classification according to directive VwVwS of 27.07.2005)

SECTION 16: Other information

Safety-lab number
- BS-4688

Full text of H-Statements referred to under section 3
H302 Harmful if swallowed.

Edition documentation
- changes from previous version in sections 2, 3, 13, 16

*1 referring to: Bromazepam

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