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

1.1. Product identifier

Product name: LEXOTAN Capsules 1.5 mg
Product code: SAP-10136285

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:

1.4. Emergency telephone number

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

*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 CLP (EC Regulation 1272/2008)

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.

SECTION 3: Composition/information on ingredients

Characterization: Bromazepam with other inactive ingredients
LEXOTAN Capsules 1.5 mg

Synonyms
- LEXOTAN Capsules (hard) 1.5 mg

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bromazepam</td>
<td>0.83 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>1812-30-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose</td>
<td>60.3 %</td>
<td></td>
</tr>
<tr>
<td>64044-51-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>11.1 %</td>
<td></td>
</tr>
<tr>
<td>9005-84-9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talc</td>
<td>5.0 %</td>
<td></td>
</tr>
<tr>
<td>14807-96-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>0.6 %</td>
<td></td>
</tr>
<tr>
<td>557-04-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gelatin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9000-70-8</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 with tap water for 20 minutes - open eyelids forcibly

Skin contact
- when in contact with the skin, clean with soap and water

Inhalation
- 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 Bromazepam is longer than the one of Anexate
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 - formation of toxic and corrosive combustion gases (nitrous oxides, hydrogen bromide) 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 - 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 - take up mechanically and dispose of

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 - see expiry date on the label
Packaging materials - polyethylene bag in metal drum
- tightly closing
- blister packages
LEXOTAN Capsules 1.5 mg

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 (eg made of neoprene, nitrile or butyl rubber)
Eye protection - safety glasses
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 - country-specific
Form - oblong capsules

9.2. Other information
Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity
Note - no information available

10.2. Chemical stability
Stability - stable under the conditions mentioned in chapter 7

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

Local effects
- no information available

Sensitization
- no information available

Mutagenicity
- not mutagenic (various test systems) *1

Carcinogenicity
- not carcinogenic, liver (rat) *1

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

STOT-single exposure
- no information available

STOT-repeated exposure
- no information available

Aspiration hazard
- no information available

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

12.2. Persistence and degradability

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

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

Note
- no information available

*1 referring to: Bromazepam

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 as Dangerous Good according to the Dangerous Goods 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.

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

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

1.1. Product identifier

Product name: LEXOTAN Capsules 3 mg
Product code: SAP-10136286

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

Use: - pharmaceutical active substance (anxiolytic)

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:

1.4. Emergency telephone number

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

*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 CLP (EC Regulation 1272/2008)

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.

SECTION 3: Composition/information on ingredients

Characterization: Bromazepam with other inactive ingredients
# LEXOTAN Capsules 3 mg

## Synonyms
- LEXOTAN Capsules (hard) 3 mg

## Ingredient

<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>1.7 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>Lactose 64044-51-5</td>
<td>59.4 %</td>
<td></td>
</tr>
<tr>
<td>Starch 9005-84-9</td>
<td>11.1 %</td>
<td></td>
</tr>
<tr>
<td>Talc 14807-96-6</td>
<td>5.0 %</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate 557-04-0</td>
<td>0.6 %</td>
<td></td>
</tr>
<tr>
<td>Gelatin 9000-70-8</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 with tap water for 20 minutes - open eyelids forcibly

- **Skin contact**
  - when in contact with the skin, clean with soap and water

- **Inhalation**
  - 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 Bromazepam is longer than the one of Anexate
## 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: formation of toxic and corrosive combustion gases (nitrous oxides, hydrogen bromide) 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: 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: take up mechanically and dispose of

## 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: see expiry date on the label

Packaging materials: polyethylene bag in metal drum, tightly closing, blister packages
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 - respiratory protection not necessary during normal operations

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

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

*1 referring to: Bromazepam

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour - country-specific

Form - oblong capsules

9.2. Other information

Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

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

<table>
<thead>
<tr>
<th></th>
<th>LD50</th>
<th>mg/kg</th>
<th>(oral, mouse)</th>
<th>*1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>879</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1'950</td>
<td></td>
<td>(oral, rat)</td>
<td></td>
</tr>
</tbody>
</table>

Local effects
- no information available

Sensitization
- no information available

Mutagenicity
- not mutagenic (various test systems) *1

Carcinogenicity
- not carcinogenic, liver (rat) *1

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

STOT-single exposure
- no information available

STOT-repeated exposure
- no information available

Aspiration hazard
- no information available

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
\( \text{(MITI Test II, OECD No. 302 C)} \) *1

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

Note - no information available

*1 referring to: Bromazepam

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 as Dangerous Good according to the Dangerous Goods 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.

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

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

1.1. Product identifier

Product name: LEXOTAN Capsules 6 mg
Product code: SAP-10136287

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

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

1.4. Emergency telephone number

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

*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 CLP (EC Regulation 1272/2008)

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.

SECTION 3: Composition/information on ingredients

Characterization: Bromazepam with other inactive ingredients
LEXOTAN Capsules 6 mg

Synonyms

LEXOTAN Capsules (hard) 6 mg

Ingredient | Concentration | GHS-Classification (pure ingredient)
---|---|---
Bromazepam 1812-30-2 | 3.3 % | Acute toxicity (Category 4), H302
Lactose 64044-51-5 | 57.8 % | 
Starch 9005-84-9 | 11.1 % | 
Talc 14807-96-6 | 5.0 % | 
Magnesium stearate 557-04-0 | 0.6 % | 
Gelatin 9000-70-8 | 

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 with tap water for 20 minutes - open eyelids forcibly
Skin contact
- when in contact with the skin, clean with soap and water
Inhalation
- 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 Bromazepam is longer than the one of Anexate
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 - formation of toxic and corrosive combustion gases (nitrous oxides, hydrogen bromide) 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 - 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 - take up mechanically and dispose of

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 - see expiry date on the label
Packaging materials - polyethylene bag in metal drum
- tightly closing
- blister packages
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 (e.g., made of neoprene, nitrile or butyl rubber)
Eye protection - safety glasses
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 - country-specific
Form - oblong capsules

9.2. Other information
Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity
Note - no information available

10.2. Chemical stability
Stability - stable under the conditions mentioned in chapter 7

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

Local effects
- no information available

Sensitization
- no information available

Mutagenicity
- not mutagenic (various test systems) *1

Carcinogenicity
- not carcinogenic, liver (rat) *1

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

STOT-single exposure
- no information available

STOT-repeated exposure
- no information available

Aspiration hazard
- no information available

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

Date: 4.12.17/LS (SEISMO)        Replacing edition of: 1.9.15        Page: 5/7
## 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

### 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

**Note**
- no information available

*1 referring to: Bromazepam

## 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 as Dangerous Good according to the Dangerous Goods 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.

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

*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 1.5 mg

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

1.1. Product identifier

Product name: LEXOTAN Tablets 1.5 mg
Product code: SAP-10094462

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

Local representation:

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

1.4. Emergency telephone number

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

*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 CLP (EC Regulation 1272/2008)

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.

SECTION 3: Composition/information on ingredients

Characterization: mixture of 0.75% Bromazepam with excipients
LEXOTAN Tablets 1.5 mg

<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>0.75 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>Microcrystalline cellulose 9004-34-6</td>
<td>50.0 %</td>
<td></td>
</tr>
<tr>
<td>Lactose 64044-51-5</td>
<td>48.1 %</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 ‘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
  - 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, administer 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
LEXOTAN Tablets 1.5 mg

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

white

Form

round, biplanar tablet

Solubility

insoluble, water (20 °C) *2

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**

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt; 879 mg/kg (oral, mouse)</td>
</tr>
<tr>
<td></td>
<td>LD&lt;sub&gt;50&lt;/sub&gt; 1950 mg/kg (oral, rat)</td>
</tr>
<tr>
<td>Local effects</td>
<td>no information available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>no information available</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>not mutagenic (various test systems)</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>not carcinogenic, liver (rat)</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>not teratogenic</td>
</tr>
<tr>
<td></td>
<td>not embryotoxic</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>no information available</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>no information available</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>no information available</td>
</tr>
<tr>
<td>Note</td>
<td>therapeutic dose: 1.5 to 36 mg/d (adults)</td>
</tr>
<tr>
<td></td>
<td>overdosing results in increase of therapeutical effects (sedation, muscle weakness, deep sleep)</td>
</tr>
<tr>
<td></td>
<td>caution: alcohol potentiates the effect!</td>
</tr>
<tr>
<td></td>
<td>elimination half-life: 10 to 20 hours</td>
</tr>
<tr>
<td></td>
<td>may lead to psychical and physical dependence</td>
</tr>
</tbody>
</table>

*<sup>1</sup>* referring to: Bromazepam

---

Date: 4.12.17/LS (SEISMO)  
Replacing edition of: 31.8.15  
Page: 5/7
SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - barely toxic for fish (rainbow trout)
  LC₅₀ (96 h) > 500 mg/l *1
- barely toxic for microorganisms
  EC₅₀ > 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

Note - not classified as Dangerous Good according to the Dangerous Goods 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>
</table>

Full text of H-Statements referred to under section 3

| H302  | Harmful 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 2

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

1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>LEXOTAN Tablets 3 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10018367</td>
</tr>
</tbody>
</table>

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

| Use                                      | - pharmaceutical active substance (anxiolytic) |

1.3. Details of the supplier of the safety data sheet

| Company information | Enquiries: Roche Products Pty Limited  
P.O. Box 255  
Dee Why, N.S.W. 2099  
AUS-Australia  
Australia |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Local representation:</td>
</tr>
<tr>
<td></td>
<td>Phone 0061-2-9454-9624</td>
</tr>
<tr>
<td></td>
<td>Fax 0061-2-9971-7401</td>
</tr>
<tr>
<td></td>
<td>E-Mail <a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
</tbody>
</table>

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

<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</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>
<tr>
<td></td>
<td>- Listed on the Australian Inventory of Chemical Substances (AICS) *5</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</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bromazepam</strong></td>
<td>1.5 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>1812-30-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Microcrystalline cellulose</strong></td>
<td>50.0 %</td>
<td></td>
</tr>
<tr>
<td>9004-34-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lactose monohydrate</strong></td>
<td>47.2 %</td>
<td></td>
</tr>
<tr>
<td>64044-51-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Magnesium stearate</strong></td>
<td>0.3 %</td>
<td></td>
</tr>
<tr>
<td>557-04-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Talc</strong></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
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
**LEXOTAN Tablets 3 mg**

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

*1 referring to: Bromazepam

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Ecotoxicity**
- barely toxic for fish (rainbow trout)
  \[ \text{LC}_{50} \ (96 \text{ h}) > 500 \text{ mg/l} \] *1
- barely toxic for microorganisms
  \[ \text{EC}_{50} > 100 \text{ mg/l} \] *1

#### 12.2. Persistence and degradability

**Inherent biodegradability**
- not inherently biodegradable
  0 %, 21 days
  \[(\text{MITI Test II, OECD No. 302 C}) \] *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

Date: 28.7.15/LS (SEISMO)  Replacing edition of: 5.9.13  Page: 6/7
## 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 3, 16 |

*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:
Enquiries: Roche Products Pty Limited
P.O. Box 255
Dee Why, N.S.W. 2099
AUS-Australia
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: 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
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 1812-30-2</td>
<td>3.0 %</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>45.4 %</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate 557-04-0</td>
<td>0.4 %</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
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

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

Date: 28.7.15/LS (SEISMO)  Replacing edition of: 5.9.13  Page: 3/7
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
- greyish green
LEXOTAN Tablets 6 mg

<table>
<thead>
<tr>
<th>Form</th>
<th>cylindrical biplane tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility</td>
<td>insoluble, water (20 °C)</td>
</tr>
</tbody>
</table>

**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) |
|                             | - $LD_{50}$ 1'950 mg/kg (oral, rat) |
| Mutagenicity                 | - not mutagenic (various test systems) |
| Carcinogenicity              | - not carcinogenic, liver (rat) |
| Reproductive toxicity        | - not teratogenic |
|                             | - not embryotoxic |

Date: 28.7.15/LS (SEISMO)   Replacing edition of: 5.9.13   Page: 5/7
LEXOTAN Tablets 6 mg

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

| 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 |

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.