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

1.1. Product identifier

Product name: HYPNOVEL Ampoules 5 mg/1mL
Product code: SAP-10065839

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

Use: - pharmaceutical active substance (short-acting hypnotic)

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

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: Midazolam

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
- Not listed on the Australian Inventory of Chemical Substances (AICS)
  *1
- Listed on the Australian Inventory of Chemical Substances (AICS)
  *2

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
HYPNOVEL Ampoules 5 mg/1mL

- no further information available

*1 referring to: Midazolam
*2 referring to: Sodium chloride

SECTION 3: Composition/information on ingredients

Characterization
Midazolam and other inactive ingredients

Synonyms
- DORMICUM Ampoules 5 mg/1mL
- VERSED Ampoules 5 mg/1mL

Ingredient | Concentration | GHS-Classification (pure ingredient)
--- | --- | ---
Midazolam 59467-70-8 | 5 mg/ml | - Acute toxicity (Category 4), H302
Sodium chloride 7647-14-5 | 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

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
- 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
- in severe cases of intoxication: Anexate i. v.
## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media - adapt extinguishing media to surrounding fire conditions

### 5.2. Special hazards arising from the substance or mixture

Specific hazards - no particular hazards known

### 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 - no special precautions required

### 6.2. Environmental precautions

Environmental protection - no special environmental precautions required

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect liquids by means of sand, earth or another suitable material
- flush afterwards with plenty of water

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Suitable materials - glass

Note
- ampoules are for single use only, discard any unused solution
- to reduce microbiological hazard, it is recommended that the infusion commence as soon as possible after preparation and in any case within 24 hours; storage of prepared infusion should be at 2°-8°C
- only clear solutions without particles should be used
- the solution should be visually inspected prior to use

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

Storage conditions - below 30 °C
- protected from light

Validity - see expiry date on the label, after opening the content should be used within a short period
SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 100 µg/m³ (defined as 8-hour time-weighted average)  
- STEL: 400 µg/m³ (defined as 15-minutes 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
- in case of intense formation of aerosols: respirator with independent air supply or particle respectively filter mask (depending on the aerosol composition)

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

Eye protection
- safety glasses

*1 referring to: Midazolam

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour
- colourless, clear

Form
- aqueous solution
- sterile liquid

Odour
- odourless

Partition coefficient
- log P_{ow} 2.73 (n-octanol/water)  
  (HPLC Method, OECD No. 117)  

pH value
- 3.3

9.2. Other information

Note
- no information available

*1 referring to: Midazolam
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 - temperatures above 30 °C
- light

10.5. Incompatible materials
Materials to avoid - acids, oxidizing agents, air

10.6. Hazardous decomposition products
Note - no information available

*1 referrer to: Midazolam

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute toxicity - LD$_{50}$ 500 mg/kg (oral, rat)
Local effects - no information available
Sensitization - no information available
Mutagenicity - not mutagenic (Ames test)
Carcinogenicity - not carcinogenic
Reproductive toxicity - not teratogenic
- not embryotoxic
STOT-single exposure - no information available
STOT-repeated exposure - no information available
Aspiration hazard - no information available
Note
- after intake of substance within a short time (5 - 30 minutes, depending on the dose): tiredness and somnolence *1
- dosage: 7.5 to 15 mg/d (adults) *1
- caution: alcohol potentiates the effect! *1
- elimination half-life: 1.4 to 2.4 hours

*1 referring to: Midazolam

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity
- moderately toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  EbC₅₀ (72 h)  11.4 mg/l
  NOEbC (72 h)  3.7 mg/l
  (OECD No. 201) *1
- strongly toxic for planktonic crustaceans (Daphnia magna)
  EC₅₀ (48 h)  7.1 mg/l
  EC₅₀ (48 h)  1.8 mg/l
  (OECD No. 202) *1
- strongly toxic for fish (rainbow trout)
  LC₅₀ (96 h)  4.3 mg/l
  LC₅₀ (96 h)  3.2 mg/l
  (OECD No. 203) *1
- barely inhibitory on aerobic bacterial respiration (activated sludge)
  EC₅₀ (3 h) > 100 mg/l
  (OECD No. 209) *1

12.2. Persistence and degradability

Ready biodegradability
- not readily biodegradable
  6 %, 28 days
  (CO₂ Evolution Test, Modified Sturm Test, OECD No. 301B) *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: Midazolam

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

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 annex 4 of directive VwVwS of 17.05.1999)

SECTION 16: Other information

Full text of H-Statements referred to under section 3

H302 Harmful if swallowed.

Note - the antidote for an overdose of midazolam (or any other benzodiazepine) is flumazenil (Anexate®) *1
- 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 8

*1 referring to: Midazolam

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.
# HYPNOVEL Ampoules 15 mg/3mL

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

### 1.1. Product identifier

<table>
<thead>
<tr>
<th><strong>Product name</strong></th>
<th>HYPNOVEL Ampoules 15 mg/3mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product code</strong></td>
<td>SAP-10065878</td>
</tr>
</tbody>
</table>

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

| **Use** | - pharmaceutical active substance (short-acting hypnotic) |

### 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><strong>Phone</strong></th>
<th>0061-2-9454-9624</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fax</strong></td>
<td>0061-2-9971-7401</td>
</tr>
<tr>
<td><strong>E-Mail</strong></td>
<td><a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
</tbody>
</table>

**Local representation:**

**Emergency telephone number**

| **Emergency telephone number** | Phone | 0061-2-9454-9624 |

*1 referring to: *Midazolam*

## 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  
- Not listed on the Australian Inventory of Chemical Substances (AICS)  
- Listed on the Australian Inventory of Chemical Substances (AICS)

### 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
HYPNOVEL Ampoules 15 mg/3mL

- no further information available

*1 referring to: Midazolam
*2 referring to: Sodium chloride

SECTION 3: Composition/information on ingredients

Characterization
Midazolam and other inactive ingredients

Synonyms
- DORMICUM Ampoules 15 mg/3mL
- VERSED Ampoules 15 mg/3mL

Ingredient | Concentration | GHS-Classification
|----------|--------------|------------------|
| Midazolam 59467-70-8 | 5 mg/ml | (pure ingredient)
| Sodium chloride 7647-14-5 | | 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

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 - 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 - in severe cases of intoxication: Anexate i. v.
### SECTION 5: Firefighting measures

**5.1. Extinguishing media**

Suitable extinguishing media - adapt extinguishing media to surrounding fire conditions

**5.2. Special hazards arising from the substance or mixture**

Specific hazards - no particular hazards known

**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 - no special precautions required

**6.2. Environmental precautions**

Environmental protection - no special environmental precautions required

**6.3. Methods and material for containment and cleaning up**

Methods for cleaning up - collect liquids by means of sand, earth or another suitable material

- flush afterwards with plenty of water

### SECTION 7: Handling and storage

**7.1. Precautions for safe handling**

Suitable materials - glass

**Note**

- ampoules are for single use only, discard any unused solution
- to reduce microbiological hazard, it is recommended that the infusion commence as soon as possible after preparation and in any case within 24 hours; storage of prepared infusion should be at 2°-8°C
- only clear solutions without particles should be used
- the solution should be visually inspected prior to use

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

Storage conditions - below 30 °C

- protected from light

Validity - see expiry date on the label, after opening the content should be used within a short period
Packaging materials  - store only in the unopened original container  
- keep it in the outer carton in order to protect from light  
- ampoules

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air  - IOEL (Internal Occupational Exposure Limit): 100 µg/m³ (defined as 8-hour time-weighted average)  
- STEL: 400 µg/m³ (defined as 15-minutes 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  
- in case of intense formation of aerosols: respirator with independent air supply or particle respectively filter mask (depending on the aerosol composition)

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

Eye protection  - safety glasses

*1 referring to: Midazolam

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour  colourless, clear

Form  aqueous solution

sterile liquid

Odour  odourless

Partition coefficient  log \( P_{ow} \) 2.73 (n-octanol/water)  
(HPLC Method, OECD No. 117)

pH value  3.3

9.2. Other information

Note  - no information available

*1 referring to: Midazolam
**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 - temperatures above 30 °C
- light

10.5. Incompatible materials

Materials to avoid - acids, oxidizing agents, air

10.6. Hazardous decomposition products

Note - no information available

*1 referring to: Midazolam

**SECTION 11: Toxicological information**

11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Effect</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>LD$_{50}$ 500 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 (Ames test)</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>not carcinogenic</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>
</tbody>
</table>

*1 referring to: Midazolam
Note
- after intake of substance within a short time (5 - 30 minutes, depending on the dose): tiredness and somnolence
- dosage: 7.5 to 15 mg/d (adults)
- caution: alcohol potentiates the effect!
- elimination half-life: 1.4 to 2.4 hours

*1 referring to: Midazolam

SECTION 12: Ecological information

12.1. Toxicity
Ecotoxicity
- moderately toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  EbC50 (72 h) 11.4 mg/l
  NOEbC (72 h) 3.7 mg/l
  (OECD No. 201) *1
- strongly toxic for planktonic crustaceans (Daphnia magna)
  EC50 (48 h) 7.1 mg/l
  EC0 (48 h) 1.8 mg/l
  (OECD No. 202) *1
- strongly toxic for fish (rainbow trout)
  LC50 (96 h) 4.3 mg/l
  LC0 (96 h) 3.2 mg/l
  (OECD No. 203) *1
- barely inhibitory on aerobic bacterial respiration (activated sludge)
  EG50 (3 h) > 100 mg/l
  (OECD No. 209) *1

12.2. Persistence and degradability
Ready biodegradability
- not readily biodegradable
  6 %, 28 days
  (CO2 Evolution Test, Modified Sturm Test, OECD No. 301B) *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: Midazolam

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

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

### 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 annex 4 of directive VwVwS of 17.05.1999)

### SECTION 16: Other information

**Full text of H-Statements referred to under section 3**

<table>
<thead>
<tr>
<th>H-Statement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H302</td>
<td>Harmful if swallowed.</td>
</tr>
</tbody>
</table>

**Note**
- the antidote for an overdose of midazolam (or any other benzodiazepine) is flumazenil (Anexate®) *1
- 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 8

*1 referring to: Midazolam

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: HYPNOVEL Ampoules 50 mg/10mL
Product code: SAP-10077483

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

Use: - pharmaceutical active substance (short-acting hypnotic)

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

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: Midazolam

**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
- Not listed on the Australian Inventory of Chemical Substances (AICS)
- Listed on the Australian Inventory of Chemical Substances (AICS)

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**: Midazolam and other inactive ingredients
- **Synonyms**: - DORMICUM Ampoules 50 mg/10mL - VERSED Ampoules 50 mg/10mL

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midazolam 59467-70-8</td>
<td>5 mg/ml</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>Sodium chloride 7647-14-5</td>
<td></td>
<td>water solution suitable for injection</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**: remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
- **Inhalation**: remove the casualty to fresh air - 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 - in severe cases of intoxication: Anexate i. v.
SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media - adapt extinguishing media to surrounding fire conditions

5.2. Special hazards arising from the substance or mixture

Specific hazards - no particular hazards known

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 - no special precautions required

6.2. Environmental precautions

Environmental protection - no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect liquids by means of sand, earth or another suitable material
- flush afterwards with plenty of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - glass

Note - ampoules are for single use only, discard any unused solution
- to reduce microbiological hazard, it is recommended that the infusion commence as soon as possible after preparation and in any case within 24 hours; storage of prepared infusion should be at 2°-8°C
- only clear solutions without particles should be used
- the solution should be visually inspected prior to use

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - below 30 °C
- protected from light

Validity - see expiry date on the label, after opening the content should be used within a short period
**Packaging materials**  
- store only in the unopened original container  
- keep it in the outer carton in order to protect from light  
- ampoules

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

**Threshold value (Roche) air**
- IOEL (Internal Occupational Exposure Limit): 100 µg/m$^3$ (defined as 8-hour time-weighted average)  
- STEL: 400 µg/m$^3$ (defined as 15-minutes 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  
- in case of intense formation of aerosols: respirator with independent air supply or particle respectively filter mask (depending on the aerosol composition)

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

**Eye protection**
- safety glasses

*1 referring to: Midazolam

## SECTION 9: Physical and chemical properties

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>colourless, clear</td>
</tr>
<tr>
<td>Form</td>
<td>aqueous solution, sterile liquid</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>$\log P_{ow} 2.73$ (n-octanol/water)</td>
</tr>
<tr>
<td></td>
<td>(HPLC Method, OECD No. 117)</td>
</tr>
<tr>
<td>pH value</td>
<td>3.3</td>
</tr>
</tbody>
</table>

### 9.2. Other information

**Note**
- no information available

*1 referring to: Midazolam
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 - temperatures above 30 °C
- light

10.5. Incompatible materials
Materials to avoid - acids, oxidizing agents, air *1

10.6. Hazardous decomposition products
Note - no information available
*1 referring to: Midazolam

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute toxicity - LD$_{50}$ 500 mg/kg (oral, rat) *1
Local effects - no information available
Sensitization - no information available
Mutagenicity - not mutagenic (Ames test) *1
Carcinogenicity - not carcinogenic *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

*1 Midazolam
Note
- after intake of substance within a short time (5 - 30 minutes, depending on the dose): tiredness and somnolence *1
- dosage: 7.5 to 15 mg/d (adults) *1
- caution: alcohol potentiates the effect! *1
- elimination half-life: 1.4 to 2.4 hours

*1 referring to: Midazolam

SECTION 12: Ecological information

12.1. Toxicity
Ecotoxicity
- moderately toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  EbC50 (72 h) 11.4 mg/l
  NOEbC (72 h) 3.7 mg/l
  (OECD No. 201) *1
- strongly toxic for planktonic crustaceans (Daphnia magna)
  EC50 (48 h) 7.1 mg/l
  EC0 (48 h) 1.8 mg/l
  (OECD No. 202) *1
- strongly toxic for fish (rainbow trout)
  LC50 (96 h) 4.3 mg/l
  LC0 (96 h) 3.2 mg/l
  (OECD No. 203) *1
- barely inhibitory on aerobic bacterial respiration (activated sludge)
  EC50 (3 h) > 100 mg/l
  (OECD No. 209) *1

12.2. Persistence and degradability
Ready biodegradability
- not readily biodegradable
  6 %, 28 days
  (CO2 Evolution Test, Modified Sturm Test, OECD No. 301B) *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: Midazolam

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

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 annex 4 of directive VwVwS of 17.05.1999)

SECTION 16: Other information

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

Note - the antidote for an overdose of midazolam (or any other benzodiazepine) is flumazenil (Anexate®)
*1 - 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 8

*1 referring to: Midazolam

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.