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

1.1. Product identifier

Product name: ANEXATE Ampoules 0.5 mg/5 mL
Product code: sap-10106659

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

Use: pharmaceutical active substance (benzodiazepine antagonist) for intravenous application

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

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: Flumazenil

SECTION 2: Hazards identification

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

GHS Classification: no classification and labelling according to GHS

Australian Remark:
- Poisons Schedule - Schedule 4 *1
- 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 - no information available

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

SECTION 3: Composition/information on ingredients

Characterization Flumazenil and other inactive ingredients
Synonyms - ROMAZICON Ampoules 0.5 mg/5mL

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flumazenil</td>
<td>0.1 mg/ml</td>
<td>(pure ingredient)</td>
</tr>
<tr>
<td>78755-81-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7647-14-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>water solution suitable for injection</td>
<td>&gt; 98 %</td>
<td></td>
</tr>
</tbody>
</table>

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 and keep him/her calm - in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note - no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician - treat symptomatically

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## 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 - rinse with plenty of water

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Suitable materials - glass

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

Storage conditions - below 30 °C

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): 0.05 mg/m³  

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8.2. Exposure controls

Respiratory protection - breathing apparatus in case of aerosol mist formation
Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection - safety glasses

*1 referring to: Flumazenil

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour clear
colourless to almost colourless
Form sterile liquid
aqueous solution

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

Note - no information available

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**
  - $LD_{50}$: 4'200 mg/kg (oral, rat) *(1)

- **Chronic toxicity**
  - low toxicity; NOAEL ~125 mg/kg/d (several species) *(1)

- **Local effects**
  - no information available

- **Sensitization**
  - not sensitizing epidermally
  - may cause allergic disorders in man when administered intradermally *(1)

- **Mutagenicity**
  - not mutagenic (various in vivo and in vitro test systems) *(1)

- **Carcinogenicity**
  - no information available

- **Reproductive toxicity**
  - not teratogenic, not embryotoxic (several species) *(1)

- **STOT-single exposure**
  - no information available

- **STOT-repeated exposure**
  - no information available

- **Aspiration hazard**
  - no information available

*(1) referring to: Flumazenil

**SECTION 12: Ecological information**

12.1. Toxicity

- **Ecotoxicity**
  - barely toxic for algae (nominal concentration = 100 mg/l) (Desmodesmus (=Scenedesmus) subspicatus)
    - $EC_{50}$ (72 h) > 100 mg/l (nominal concentration)
    - NOEC (72 h) 88.4 mg/l (average measured concentration) (OECD No. 201) *(1)
  - barely toxic for planktonic crustaceans (Daphnia magna)
    - $EC_{50}$ (48 h) > 518 mg/l
    - NOEC (48 h) 65.6 mg/l (FDA Technical Assistance Document No. 4.08) *(1)
  - moderately toxic for fish (guppy)
    - $LC_{50}$ (96 h) ~ 83 mg/l
    - NOEC (96 h) 31.6 mg/l (nominal concentration) (OECD No. 203) *(1)
  - no adverse influence on substrate biodegradation (activated sludge)
    - NOEC 30 mg/l (MITI Test II, OECD No. 302C) *(1)
12.2. Persistence and degradability

Inherent biodegradability - not inherently biodegradable
  6 % BOD/ThOD, 28 d
  -4 % DOC, 28 d
  \( \leq 12 \% \) degradation (HPLC), 28 d
  (MITI Test II, OECD No. 302 C) *1

Abiotic degradation - no significant photodegradation or hydrolysis, stable in water 200 mg/l (nominal concentration), water; HPLC *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: Flumazenil

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 (own classification according to directive VwVwS of 27.07.2005)
## SECTION 16: Other information

**Note**
- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

**Edition documentation**
- changes from previous version in sections 2, 3, 11

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.