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

1.1. Product identifier

Product name: KONAKION MM Ampoules 2mg/0.2mL
Product code: SAP-10130997

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

Use: - pharmaceutical active substance

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

1.4. Emergency telephone number

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

*1 referring to: Phytomenadione

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 - Not scheduled
- Listed on the Australian Inventory of Chemical Substances (AICS) *1
- Not listed on the Australian Inventory of Chemical Substances (AICS) *2
- Listed on the Australian Inventory of Chemical Substances (AICS) *3
2.3. Other hazards

Note  - no information available

*1 referring to:  Phytomenadione
*2 referring to:  Glycocholic acid
*3 referring to:  Lecithin

SECTION 3: Composition/information on ingredients

Characterization  Phytomenadione and other inactive ingredients
Synonyms  - KONAKION MM PAEDIATRIC Ampoules

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytomenadione</td>
<td>10 mg/ml</td>
<td></td>
</tr>
<tr>
<td>84-80-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycocholic acid</td>
<td>5.5 %</td>
<td></td>
</tr>
<tr>
<td>475-31-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lecithin</td>
<td>7.6 %</td>
<td></td>
</tr>
<tr>
<td>8002-43-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>water solution suitable for injection</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact  - rinse with tap water for 10 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
### 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

Note - ampoules are for single use only, discard any unused solution
- 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 25 °C
- protected from light
- do not freeze

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
- amber glass ampoules
# SECTION 8: Exposure controls/personal protection

## 8.1. Control parameters

| Threshold value (Roche) air | IOEL (Internal Occupational Exposure Limit): 0.1 mg/m³ |

## 8.2. Exposure controls

| 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: Phytomenadione

# SECTION 9: Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

| Colour | yellow |
| Form | clear solution |
| Odour | odourless or nearly odourless |

## 9.2. Other information

| Note | - no information available |

# 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

| Note | - no information available |
10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - for stability reasons, the unused contents of open ampoules cannot be used and should be discarded

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
- \( LD_{50} \) > 25'000 mg/kg (oral, mouse) \(^1\)
- \( LD_{50} \) > 6'600 mg/kg (i.v., mouse) \(^1\)
- \( LD_{50} \) 3'880 mg/kg (oral, rat) \(^2\)

Sensitization
- very rare cases of skin rashes might be attributed to genuine sensibilisation, especially after parenteral application \(^1\)

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

Reproductive toxicity
- not teratogenic, not embryotoxic \(^1\)
- no suspicious fact for teratogenic effect \(^2\)

Note
- antagonist and antidote of choice against coumarin-based anticoagulants \(^1\)
- biological half-life of vitamin K1 is approx. 100 to 110 min \(^1\)
- K1 hypervitaminosis is unknown \(^1\)
- no toxic effects have been observed during occupational handling \(^1\)
- RDA (recommended daily dietary allowance): 60-80\(\mu\)g for adults \(^1\)
- oral doses of up to 1000 mg were well tolerated \(^1\)

\(^1\) referring to: Phytomenadione
\(^2\) referring to: Glycocholic acid

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity
- barely toxic for fish (rainbow trout)
  NOEC (96 h) \(\geq\) 100 mg/l
  LC\(_{50}\) (96 h) > 100 mg/l
  (OECD No. 203) \(^1\)
- barely toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  EbC\(_{50}\) (72 h) > 100 mg/l
  NOEbC (72 h) 100 mg/l \(^2\)
12.2. Persistence and degradability

Ready biodegradability  - readily biodegradable
67 %, 29 days
(CO₂ Evolution Test, Modified Sturm Test, OECD No. 301B)  *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

Note - no information available

*1 referring to: Phytomenadione
*2 referring to: Glycocholic acid

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

<table>
<thead>
<tr>
<th>Note</th>
<th>Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.</th>
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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.
# KONAKION MM Ampoules 10mg/1mL

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

### 1.1. Product identifier

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<th>KONAKION MM Ampoules 10mg/1mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10065933</td>
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</table>

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

<table>
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<tr>
<th>Use</th>
<th>pharmaceutical active substance</th>
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<tr>
<td></td>
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*1 *2 *3
2.3. Other hazards

Note - no information available

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SECTION 3: Composition/information on ingredients

Characterization Phytomenadione and other inactive ingredients
Synonyms - KONAKION MM Ampoules for use in adults

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

Note - no information available

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Personal precautions - no special precautions required

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Note - ampoules are for single use only, discard any unused solution
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Storage conditions - below 25 °C
- protected from light
- do not freeze

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
- amber glass ampoules
## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Threshold value (Roche) air

- IOEL (Internal Occupational Exposure Limit): 0.1 mg/m³

### 8.2. Exposure controls

**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: Phytomenadione

## SECTION 9: Physical and chemical properties

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

**Colour**
- yellow

**Form**
- clear solution

**Odour**
- odourless or nearly odourless

### 9.2. Other information

**Note**
- no information available

## 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

**Note**
- no information available
10.5. Incompatible materials

Note - no information available

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Note - for stability reasons, the unused contents of open ampoules cannot be used and should be discarded

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- LD$_{50}$ > 25,000 mg/kg (oral, mouse) *1
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  EbC$_{50}$ (72 h) > 100 mg/l
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Note - no information available

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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

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**Edition documentation**
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