# Safety Data Sheet

**KONAKION MM Ampoules 2mg/0.2mL**

according to Regulation (EU) nr. 1907/2006

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

### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>KONAKION MM Ampoules 2mg/0.2mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10130997</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: F. Hoffmann-La Roche AG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Postfach</td>
</tr>
<tr>
<td></td>
<td>CH-4070 Basel</td>
</tr>
<tr>
<td></td>
<td>Switzerland</td>
</tr>
<tr>
<td></td>
<td>Phone</td>
</tr>
<tr>
<td></td>
<td>+41-61/688 54 80</td>
</tr>
<tr>
<td></td>
<td>Fax</td>
</tr>
<tr>
<td></td>
<td>+41-61/681 72 76</td>
</tr>
<tr>
<td></td>
<td>E-Mail</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
</tbody>
</table>

### 1.4. Emergency telephone number

<table>
<thead>
<tr>
<th>Emergency telephone number</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+41-61/688 54 80</td>
</tr>
</tbody>
</table>

*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 CLP (EC Regulation 1272/2008) |

### 2.3. Other hazards

| Note | no information available |

## SECTION 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Characterization</th>
<th>Phytomenadione and other inactive ingredients</th>
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</thead>
<tbody>
<tr>
<td>Synonyms</td>
<td>- KONAKION MM PAEDIATRIC Ampoules</td>
</tr>
</tbody>
</table>
### Ingredient, Concentration, GHS-Classification

<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>Glycocholic acid</td>
<td>5.5 %</td>
<td></td>
</tr>
<tr>
<td>Lecithin</td>
<td>7.6 %</td>
<td></td>
</tr>
</tbody>
</table>

Water solution suitable for injection

### 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**
  - 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)
KONAKION MM Ampoules 2mg/0.2mL

**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
- $\text{LD}_{50} > 25\,000 \text{ mg/kg}$ (oral, mouse) $^1$
- $\text{LD}_{50} > 6\,600 \text{ mg/kg}$ (i.v., mouse) $^1$
- $\text{LD}_{50} 3\,880 \text{ mg/kg}$ (oral, rat) $^2$

Local effects
- no information available

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) $^1$

Carcinogenicity
- no information available

Reproductive toxicity
- not teratogenic, not embryotoxic $^1$
- no suspicious fact for teratogenic effect $^2$

STOT-single exposure
- no information available

STOT-repeated exposure
- no information available

Aspiration hazard
- no information available

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 µg for adults $^1$
- oral doses of up to 1000 mg were well tolerated $^1$

$^1$ referring to: Phytonedrone
$^2$ referring to: Glycocholic acid

SECTION 12: Ecological information

12.1. Toxicity

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

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

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 (according to annex 4 of directive VvVwS of 17.05.1999)
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

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.
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Product name: KONAKION MM Ampoules 10mg/1mL
Product code: SAP-10065933

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

Use: - pharmaceutical active substance

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Company information:
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Postfach
CH-4070 Basel
Switzerland

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

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Synonyms: - KONAKION MM Ampoules for use in adults
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Eye protection - safety glasses

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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

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