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

1.1. Product identifier
Product name: ROCALTROL capsules 0.25 mcg  
Product code: SAP-10067075

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use
- pharmaceutical active substance  
  for the treatment of hypocalcemia

1.3. Details of the supplier of the safety data sheet
Company information:  
Local representation:  
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

1.4. Emergency telephone number
Emergency telephone number:  
  Phone +41-61/688 54 80
*1 referring to: Calcitriol

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

Characterization
Calcitriol and other inactive ingredients
ROCALTROL capsules 0.25 mcg

Synonyms
- ROCALTROL capsules (soft)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcitriol</td>
<td>0.0000961 %</td>
<td>- Acute toxicity (Category 1), H300</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Reproductive toxicity (Category 2), H361d</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Hazardous to the aquatic environment (Category 4), H413</td>
</tr>
<tr>
<td>Medium-chain triglycerides</td>
<td>61.5 %</td>
<td>- Serious eye damage/eye irritation (Category 2A), H319</td>
</tr>
<tr>
<td>Gelatin</td>
<td>27.3 %</td>
<td></td>
</tr>
<tr>
<td>Glycerol</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

Skin contact
- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Ingestion
- if accidentally ingested contact a physician or a Poisons Information Centre

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 - 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

7.2. Conditions for safe storage, including any incompatibilities
Storage conditions - protected from light and humidity
Validity - 36 months, < 25 °C, see "best use before" date stated on the label
Packaging materials - blister packages
- keep it in the outer carton in order to protect from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 µg/m³ (Internal Occupational Exposure Limit, defined as 8-hour time-weighted average)

8.2. Exposure controls
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

*1 referring to: Calcitriol
### SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>country-specific</td>
</tr>
<tr>
<td>Form</td>
<td>gelatin capsule soft</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Value</th>
<th>Reference(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- LD_{50}</td>
<td>&lt; 5 mg/kg</td>
<td>(oral, rat) (OECD No. 423)</td>
</tr>
<tr>
<td>- LD_{50}</td>
<td>1.3 mg/kg</td>
<td>(oral, mouse)</td>
</tr>
</tbody>
</table>

*1
ROCALTROL capsules 0.25 mcg

Chronic toxicity - Chronic overdosages cause loss of body weight, growth inhibition, weakness, sensoric disorders, excessive urination, loss of water, fever with thirst, infections of urinary passages and apathy. They cause, circumstances permitting, formation of renal calculus, demineralization of the bones and formation of fociusses of calcification in lung and kidneys up to renal insufficiency. *1

Local effects - skin: non-irritant (rabbit) *1
- skin: non-irritant (guinea pig) *1
- eye: non-irritant (rabbit) *1

Sensitization - non-sensitizing (guinea pig) *1

Mutagenicity - not mutagenic (Ames test) *1

Carcinogenicity - no information available

Reproductive toxicity - based on secondary effects (hypercalcemia), the substance may eventually lead to teratogenicity when overdosed *1

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

*1 referring to: Calcitriol

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Scenedesmus (=Desmodesmus) subspicatus)
EC$_{50}$ (72 h) > 100 mg/l (nominal concentration)
NOEC (72 h) 0.47 mg/l (average measured concentration)
(OECD No. 201)

EC$_{50}$ (48 h) > 100 mg/l (nominal concentration)
NOEC (48 h) 0.69 mg/l (average measured concentration)
(OECD No. 202) *1

- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna)
EC$_{50}$ (48 h) > 100 mg/l (nominal concentration)
NOEC (48 h) 0.69 mg/l (average measured concentration)
(OECD No. 202) *1

- barely toxic for fish (nominal concentration = 100 mg/l) (zebrafish)
LC$_{50}$ (96 h) > 100 mg/l (nominal concentration)
NOEC (96 h) 100 mg/l (nominal concentration)
(OECD No. 203, semi-static) *2

- no adverse influence on substrate biodegradation (activated sludge)
concentration (28 d) 100 mg/l (nominal concentration)
(Manometric Respirometry Test, OECD No. 301 F) *1
12.2. Persistence and degradability

Ready biodegradability - not readily biodegradable
≤1 %, 28 d
(Manometric Respirometry Test, OECD No. 301 F)

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: Calcitriol
*2 referring to: Vitamin D3

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 (according to directive AwSV of 18.04.2017)
## SECTION 16: Other information

Full text of H-Statements referred to under section 3

<table>
<thead>
<tr>
<th>Code</th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>H300</td>
<td>Fatal if swallowed.</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation.</td>
</tr>
<tr>
<td>H361d</td>
<td>Suspected of damaging the unborn child.</td>
</tr>
<tr>
<td>H413</td>
<td>May cause long lasting harmful effects to aquatic life.</td>
</tr>
</tbody>
</table>

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 15