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-10118124

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use - pharmaceutical active substance *1
- for the treatment of hypocalcemia *1

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: 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 GHS
Australian Remark: - Poisons Schedule - Schedule 4 *1
- Listed on the Australian Inventory of Chemical Substances (AICS) *1
- Listed on the Australian Inventory of Chemical Substances (AICS) *2
- Listed on the Australian Inventory of Chemical Substances (AICS) *3
- Listed on the Australian Inventory of Chemical Substances (AICS) *4
SECTION 3: Composition/information on ingredients

Characterization  
Calcitriol and other inactive ingredients

Synonyms  
- ROCALTROL capsules (soft)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>EU-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcitriol</td>
<td>0.0000961 %</td>
<td>T+ R28, R63, R53 S22, S28, S36/37, S45, S61</td>
</tr>
<tr>
<td>CAS: 32222-06-3</td>
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<tr>
<td>Medium-chain triglycerides</td>
<td>61.5 %</td>
<td>X  R36 S26</td>
</tr>
<tr>
<td>CAS: 85409-09-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gelatin</td>
<td>27.3 %</td>
<td></td>
</tr>
<tr>
<td>CAS: 9000-70-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS: 56-81-5</td>
<td></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 10 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

Colour country-specific
Form gelatin capsule soft

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$_{50}$ < 5 mg/kg (oral, rat) (OECD No. 423 (Acute Toxic Class Method)) *1
- LD$_{50}$ 1.3 mg/kg (oral, mouse) *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

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 foci of calcification in lung and kidneys up to renal insufficiency. *1

Mutagenicity
- not mutagenic (Ames test) *1

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

*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) *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) *5

  - 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) *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: Calcitriol
*5 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

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**

<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>
</tr>
</thead>
<tbody>
<tr>
<td>Edition documentation</td>
<td>- first edition</td>
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</table>

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.