# BACTRIM oral suspension

## 200/40mg/5ml

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

#### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>BACTRIM oral suspension 200/40mg/5ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10068284</td>
</tr>
</tbody>
</table>

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

- Pharmaceutical active substance: bacteriostatic, especially in combination with trimethoprim

#### 1.3. Details of the supplier of the safety data sheet

<table>
<thead>
<tr>
<th>Company information</th>
<th>Local representation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche Products Pty Limited</td>
<td>P.O. Box 255</td>
</tr>
<tr>
<td>Dee Why, N.S.W. 2099</td>
<td>AUS-Australia</td>
</tr>
<tr>
<td>Australia</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td>0061-2-9454-9624</td>
</tr>
<tr>
<td>Fax</td>
<td>0061-2-9971-7401</td>
</tr>
<tr>
<td>E-Mail</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>0061-2-9454-9624</td>
</tr>
</tbody>
</table>

*1 referring to: Sulfamethoxazole

### 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
  - Poisons Schedule - Schedule 4 *2
  - Not 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
  - Listed on the Australian Inventory of Chemical Substances (AICS) *5
BACTRIM oral suspension 200/40mg/5ml

2.3. Other hazards

Note - no information available

*1 referring to: Sulfamethoxazole
*2 referring to: Trimethoprim
*3 referring to: Sorbitol
*4 referring to: Cellulose
*5 referring to: Croscarmellose sodium

SECTION 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Characterization</th>
<th>Sulfamethoxazole, Trimethoprim and other inactive ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms</td>
<td>BACTRIM Syrup</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole 723-46-6</td>
<td>4.0 %</td>
<td></td>
</tr>
<tr>
<td>Trimethoprim 738-70-5</td>
<td>0.8 %</td>
<td>Specific target organ toxicity - Repeated exposure (Category 2), H373</td>
</tr>
<tr>
<td>Sorbitol 50-70-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose 9004-34-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Croscarmellose sodium 74811-65-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water</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 - consult a physician

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 - water spray jet, dry powder, foam, carbon dioxide, adapt extinguishing media to surrounding fire conditions

5.2. Special hazards arising from the substance or mixture

Specific hazards - substance is hazardous for water: contain fire-fighting wastewater

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
- if the substance reaches waters or the sewer system, inform the competent authority

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

Validity - 60 months, < 30 °C, see expiry date on the label

Packaging materials - amber glass bottles with child resistant plastic closure
### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

<table>
<thead>
<tr>
<th>Threshold value (Roche) air</th>
<th>Internal Occupational Exposure Limit: 1.0 mg/m³</th>
<th>Internal Occupational Exposure Limit: 0.1 mg/m³</th>
</tr>
</thead>
</table>

#### 8.2. Exposure controls

- **Respiratory protection**: respiratory protection not necessary during normal operations
- **Hand protection**: protective gloves (e.g., made of neoprene, nitrile or butyl rubber)
- **Eye protection**: safety glasses

*1 referring to: Sulfamethoxazole  
*2 referring to: Trimethoprim

### SECTION 9: Physical and chemical properties

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

- **Colour**: light beige
- **Form**: liquid

#### 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>Category</th>
<th>Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute toxicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>LD₅₀</strong></td>
<td>6'200 mg/kg (oral, rat)</td>
</tr>
<tr>
<td></td>
<td><strong>LD₅₀</strong></td>
<td>2'890 mg/kg (oral, rat)</td>
</tr>
<tr>
<td><strong>Subchronic toxicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>TDₙ₀</strong></td>
<td>1100 mg/kg (oral, several species; 30 d)</td>
</tr>
<tr>
<td><strong>Local effects</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>eye:</td>
<td>slightly irritating (rabbit)</td>
</tr>
<tr>
<td></td>
<td>skin:</td>
<td>non-irritant (rabbit)</td>
</tr>
<tr>
<td></td>
<td>eye:</td>
<td>slightly irritating (rabbit)</td>
</tr>
<tr>
<td></td>
<td>skin:</td>
<td>slightly irritating (rabbit)</td>
</tr>
<tr>
<td></td>
<td>not</td>
<td>phototoxic</td>
</tr>
<tr>
<td><strong>Sensitization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>non-sensitizing (guinea pig)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>may be</td>
<td>sensitizing; (man, therapeutic use)</td>
</tr>
<tr>
<td></td>
<td>may be</td>
<td>sensitizing (man)</td>
</tr>
<tr>
<td></td>
<td>not</td>
<td>photoallergenic</td>
</tr>
<tr>
<td><strong>Mutagenicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>not</td>
<td>mutagenic (various in vivo and in vitro test systems)</td>
</tr>
<tr>
<td></td>
<td>not</td>
<td>mutagenic</td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IARC:</td>
<td>group 3 (unclassifiable as to carcinogenicity to humans)</td>
</tr>
<tr>
<td></td>
<td>no</td>
<td>indication for carcinogenicity</td>
</tr>
<tr>
<td><strong>Reproductive toxicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>does not lower parental fertility (200 mg/kg/d, rat)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>not</td>
<td>teratogenic; (man, therapeutic doses)</td>
</tr>
<tr>
<td></td>
<td>in</td>
<td>animal test, malformations and reduce fertility due to systemic toxicity</td>
</tr>
<tr>
<td><strong>STOT-single exposure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>no</td>
<td>information available</td>
</tr>
<tr>
<td><strong>STOT-repeated exposure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>no</td>
<td>information available</td>
</tr>
<tr>
<td><strong>Aspiration hazard</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>no</td>
<td>information available</td>
</tr>
<tr>
<td><strong>Note</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>elimination half-life is about 11 hours; elimination is mainly by renal route, 80% being excreted unchanged</td>
<td></td>
</tr>
<tr>
<td></td>
<td>rapid and nearly complete resorption after oral application; maximal plasma concentration is reached after about two hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>antibacterial chemotherapeutic, which, through folic acid antagonism, inhibits the synthesis of proteins and nucleic acids essential for cell division</td>
<td></td>
</tr>
</tbody>
</table>
- in human cells, therapeutic doses of sulfamethoxazole do not significantly disturb folic acid metabolism *1
- biological half-life: 10 hours; rapid and efficient resorption from the intestine; excretion mostly renal *1
- rarely, systemic use may induce allergic skin reactions with Stevens-Johnson or Lyell syndrome *1
- other side effects: gastrointestinal disturbances after oral uptake, disorders of liver function; at high doses: urinary stones, disturbances of haematological parameters *1

*S1 referring to: Sulfamethoxazole
*S2 referring to: Trimethoprim

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity
- strongly toxic for algae (Selenastrum capricornutum)
  EbC₅₀ (72 h) 0.81 mg/l
  NOEbC (72 h) 0.22 mg/l
  ErC₅₀ (72 h) 3.4 mg/l
  NOErC (72 h) 0.45 mg/l
  (OECD No. 201) *1
- moderately toxic for algae (Selenastrum capricornutum)
  EbC₅₀ (72 h) 70 mg/l
  ErC₅₀ (72 h) 98 mg/l
  NOEC (72 h) 32 mg/l
  (OECD No. 201) *2
- moderately toxic for planktonic crustaceans (Daphnia magna)
  EC₅₀ (48 h) 75 mg/l
  NOEC (48 h) 36 mg/l
  (OECD No. 202) *1
- barely toxic for planktonic crustaceans (Daphnia magna)
  EC₅₀ (48 h) > 100 mg/l
  NOEC (48 h) 100 mg/l
  (OECD No. 202) *2
- barely toxic for fish (rainbow trout)
  LC₀ 1000 mg/l
  *6
- barely toxic for fish (zebrafish)
  NOEC (72 h) 100 mg/l
  (OECD No. 203) *2
- barely inhibitory on aerobic bacterial reproduction (activated sludge), no adverse influence on substrate biodegradation (activated sludge)
  NOEC 3.76 mg/l (highest concentration tested)
  (Closed Bottle Test, OECD No. 301 D) *1
- no adverse influence on substrate biodegradation (activated sludge)
  concentration 3.8 mg/l
  (Closed Bottle Test, OECD No. 301 D) *1
- moderately toxic for microorganisms (activated sludge)
  EC₅₀ 17.8 mg/l
  (OECD No. 209) *2
**BACTRIM oral suspension 200/40mg/5ml**

- activated sludge
  EC$_{50}$ (3 h) > 200 mg/l (highest concentration tested)
  EC$_{20}$ (3 h) 19 mg/l (nominal concentration)
  EC$_{10}$ (3 h) 0.435 mg/l (nominal concentration)
  (Activated Sludge Respir. Inhib. Test, OECD No. 209)  

**12.2. Persistence and degradability**

**Ready biodegradability**
- not readily biodegradable
  0 %, 28 d
  (Closed Bottle Test, OECD No. 301 D)  
- not readily biodegradable
  0 %  

**Inherent biodegradability**
- not inherently biodegradable
  0 %, 28 days
  (Zahn-Wellens test, OECD No. 302 B)  
- not inherently biodegradable
  0 %, 28 d
  (MITI Test II, OECD No. 302 C)  
- long half-life for primary degradation, rather persistent
  $\geq$ 22 d half-life  

**Abiotic degradation**
- rapid degradation, photodegradation surface waters
  $t_{1/2}$ 10 h, summer, 50° N
  $t_{1/2}$ 58 h, winter, 50° N
  (literature citation)  

**12.3. Bioaccumulative potential**

**Note**
- no information available

**12.4. Mobility in soil**

**Mobility**
- low adsorption to activated sludge, high mobility (water-activated sludge)
  $K_d = 76$  

**12.5. Results of PBT and vPvB assessment**

**Note**
- no information available

**12.6. Other adverse effects**

**Note**
- no information available

*1 referring to: Sulfamethoxazole
*2 referring to: Trimethoprim
*6 referring to: Sulfamethoxazole Sodium

---

Date: 1.3.17/LS (SEISMO)  
Replacing edition of: 27.2.17  
Page: 7/8
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

SECTION 16: Other information

Full text of H-Statements referred to under section 3
H373 May cause damage to organs through prolonged or repeated exposure.

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

1.1. Product identifier

Product name: BACTRIM DS Tablets 800/160 mg
Product code: SAP-10113505

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

Use: - pharmaceutical active substance: bacteriostatic, especially in combination with trimethoprim

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

Local representation:

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: Sulfamethoxazole
SECTION 2: Hazards identification

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

GHS Classification

Health Hazards:
3.9 Specific target organ toxicity - Repeated exposure (Category 2)
   H373 May cause damage to organs through prolonged or repeated exposure.

Signalword: Warning

Label:

Precautionary statements:
- P273 Avoid release to the environment.
- P201 Obtain special instructions before use.

Australian Remark
- NON-HAZARDOUS SUBSTANCE. DANGEROUS GOODS.
- Poisons Schedule - Schedule 4 *1
- Not listed on the Australian Inventory of Chemical Substances (AICS) *1
- Poisons Schedule - Schedule 4 *2
- Not 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
- Listed on the Australian Inventory of Chemical Substances (AICS) *5

2.3. Other hazards

Note
- no information available

*1 referring to: Sulfamethoxazole
*2 referring to: Trimethoprim
*3 referring to: Sodium carboxymethyl starch
*4 referring to: Povidone K30
*5 referring to: Magnesium stearate

SECTION 3: Composition/information on ingredients

Characterization
Sulfamethoxazole, Trimethoprim and other inactive ingredients

Synonyms
- BACTRIM Forte Tablets 800/160 mg

UN number
3077
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole 723-46-6</td>
<td>79.2 %</td>
<td>- Specific target organ toxicity - Repeated exposure (Category 2), H373</td>
</tr>
<tr>
<td>Trimethoprim 738-70-5</td>
<td>15.8 %</td>
<td></td>
</tr>
<tr>
<td>Sodium carboxymethyl starch 9063-38-1</td>
<td>2.4 %</td>
<td></td>
</tr>
<tr>
<td>Povidone K30 9003-39-8</td>
<td>2.0 %</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate 557-04-0</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
- consult a physician

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
- water spray jet, dry powder, foam, carbon dioxide, adapt extinguishing media to surrounding fire conditions

5.2. Special hazards arising from the substance or mixture

Specific hazards
- substance is hazardous for water: contain fire-fighting wastewater
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
- if the substance reaches waters or the sewer system, inform the competent authority

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

Validity - 60 months, < 30 °C, see expiry date on the label

Packaging materials - blister packages
- amber glass bottles with child resistant plastic closure
- polyethylene bag in metal drum

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 1.0 mg/m³ *1
- IOEL (Internal Occupational Exposure Limit): 0.1 mg/m³ *2

8.2. Exposure controls

Respiratory protection - respiratory protection not necessary during normal operations
- Respiratory protection is recommended for dusty operations.

Hand protection - protective gloves (e.g., made of neoprene, nitrile, or butyl rubber)

Eye protection - safety glasses

*1 referring to: Sulfamethoxazole
*2 referring to: Trimethoprim
SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Colour white to practically white
Form oblong, biconvex tablet

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
- LD50 6200 mg/kg (oral, rat) *1
- LD50 2890 mg/kg (oral, rat) *2
Subchronic toxicity
- TDlo 1100 mg/kg (oral, several species; 30 d) *2
Local effects
- eye: slightly irritating (rabbit) *1
- skin: non-irritant (rabbit) *1
**BACTRIM DS Tablets 800/160 mg**

| **Sensitization** | - eye: slightly irritating (rabbit)  
|                   | - skin: slightly irritating (rabbit)  
|                   | - not phototoxic  
|                   | *2  
|                   | *2  

| **Mutagenicity** | - not mutagenic (various in vivo and in vitro test systems)  
|                  | - not mutagenic  
|                  | *1  
|                  | *2  

| **Carcinogenicity** | - IARC: group 3 (unclassifiable as to carcinogenicity to humans)  
|                    | - no indication for carcinogenicity  
|                    | *1  
|                    | *2  

| **Reproductive toxicity** | - does not lower parental fertility (200 mg/kg/d, rat)  
|                           | - not teratogenic; (man, therapeutic doses)  
|                           | - in animal test, malformations and reduce fertility due to systemic toxicity  
|                           | *1  
|                           | *2  

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

| **Aspiration hazard** | - no information available  

| **Note** | - elimination half-life is about 11 hours; elimination is mainly by renal route, 80% being excreted unchanged  
|          | - rapid and nearly complete resorption after oral application; maximal plasma concentration is reached after about two hours  
|          | - antibacterial chemotherapeutic, which, through folic acid antagonism, inhibits the synthesis of proteins and nucleic acids essential for cell division  
|          | - in human cells, therapeutic doses of sulfamethoxazole do not significantly disturb folic acid metabolism  
|          | - biological half-life: 10 hours; rapid and efficient resorption from the intestine; excretion mostly renal  
|          | - rarely, systemic use may induce allergic skin reactions with Stevens-Johnson or Lyell syndrome  
|          | - other side effects: gastrointestinal disturbances after oral uptake, disorders of liver function; at high doses: urinary stones, disturbances of haematological parameters  
|          | *1  
|          | *2  

*1 referring to: Sulfamethoxazole  
*2 referring to: Trimethoprim
SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity
- strongly toxic for algae (Selenastrum capricornutum)
  EbC₅₀ (72 h) 0.81 mg/l
  NOEbC (72 h) 0.22 mg/l
  ErC₅₀ (72 h) 3.4 mg/l
  NOErC (72 h) 0.45 mg/l
  (OECD No. 201) *1
- moderately toxic for algae (Selenastrum capricornutum)
  EbC₅₀ (72 h) 70 mg/l
  ErC₅₀ (72 h) 98 mg/l
  NOEC (72 h) 32 mg/l
  (OECD No. 201) *2
- moderately toxic for planktonic crustaceans (Daphnia magna)
  EC₅₀ (48 h) 75 mg/l
  NOEC (48 h) 36 mg/l
  (OECD No. 202) *1
- barely toxic for planktonic crustaceans (Daphnia magna)
  EC₅₀ (48 h) > 100 mg/l
  NOEC (48 h) 100 mg/l
  (OECD No. 202) *2
- barely toxic for fish (rainbow trout)
  LC₀ 1000 mg/l
  (OECD No. 203) *6
- barely toxic for fish (zebrafish)
  NOEC (72 h) 100 mg/l
  (OECD No. 203) *2
- barely inhibitory on aerobic bacterial reproduction (activated sludge), no adverse influence on substrate biodegradation (activated sludge)
  NOEC 3.76 mg/l (highest concentration tested)
  (Closed Bottle Test, OECD No. 301 D) *1
- no adverse influence on substrate biodegradation (activated sludge)
  concentration 3.8 mg/l
  (Closed Bottle Test, OECD No. 301 D) *1
- activated sludge
  EC₅₀ (3 h) > 200 mg/l (highest concentration tested)
  EC₂₀ (3 h) 19 mg/l (nominal concentration)
  EC₁₀ (3 h) 0.435 mg/l (nominal concentration)
  (Activated Sludge Respir. Inhib. Test, OECD No. 209) *2
- moderately toxic for microorganisms (activated sludge)
  EC₅₀ 17.8 mg/l
  (OECD No. 209) *2

12.2. Persistence and degradability

Ready biodegradability
- not readily biodegradable
  0 %, 28 d
  (Closed Bottle Test, OECD No. 301 D) *1
- not readily biodegradable
  0 % *2
Inherent biodegradability
- not inherently biodegradable
  0 %, 28 days
  (Zahn-Wellens test, OECD No. 302 B)  \(^*6\)
- not inherently biodegradable
  0 %, 28 d
  (MITI Test II, OECD No. 302 C)  \(^*2\)
- long half-life for primary degradation, rather persistent
  \(\geq 22\) d half-life  \(^*2\)

Abiotic degradation
- rapid degradation, photodegradation surface waters
  \(t_{1/2}\) 10 h, summer, 50° N
  \(t_{1/2}\) 58 h, winter, 50° N
  (literature citation)  \(^*1\)

12.3. Bioaccumulative potential
Note - no information available

12.4. Mobility in soil
Mobility
- low adsorption to activated sludge, high mobility (water-activated sludge)
  \(K_d = 76\)  \(^*2\)

12.5. Results of PBT and vPvB assessment
Note - no information available

12.6. Other adverse effects
Note - no information available

\(^*1\) referring to: Sulfamethoxazole
\(^*2\) referring to: Trimethoprim
\(^*6\) referring to: Sulfamethoxazole Sodium

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

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## BACTRIM DS Tablets 800/160 mg

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Proper shipping name  
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Technical name  
Sulfamethoxazole mixture

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water hazard class (Germany)  
2: hazardous for water (own classification according to directive VwVwS of 27.07.2005)

### SECTION 16: Other information

Full text of H-Statements referred to under section 3  
H373 May cause damage to organs through prolonged or repeated exposure.

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.