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

1.1. **Product identifier**

Product name: BACTRIM oral suspension 200/40mg/5ml

Product code: SAP-10068284

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**
- Enquiries:
  - Roche Products Pty Limited
  - Level 8, 30-34 Hickson Road
  - Millers Point NSW 2000
  - 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**
- no classification and labelling according to GHS

**Australian Remark**
- Poisons Schedule - Schedule 4
- Not listed on the Australian Inventory of Chemical Substances (AICS)
- Poisons Schedule - Schedule 4
- Not listed on the Australian Inventory of Chemical Substances (AICS)
- Listed on the Australian Inventory of Chemical Substances (AICS)
- Listed on the Australian Inventory of Chemical Substances (AICS)
- Listed on the Australian Inventory of Chemical Substances (AICS)
- Listed on the Australian Inventory of Chemical Substances (AICS)
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

Characterization Sulfamethoxazole, Trimethoprim and other inactive ingredients

Synonyms - BACTRIM Syrup

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole</td>
<td>4.0 %</td>
<td></td>
</tr>
<tr>
<td>723-46-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>0.8 %</td>
<td>- Specific target organ toxicity - Repeated exposure (Category 2), H373</td>
</tr>
<tr>
<td>738-70-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sorbitol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-70-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9004-34-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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></th>
</tr>
</thead>
<tbody>
<tr>
<td>IOEL (Internal Occupational Exposure Limit): 1.0 mg/m³</td>
<td>*1</td>
</tr>
<tr>
<td>IOEL (Internal Occupational Exposure Limit): 0.1 mg/m³</td>
<td>*2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PNEC</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0.59 µg/l, surface freshwaters, based on chronic data, surface waters</td>
<td>*1</td>
</tr>
<tr>
<td>16 µg/l, surface freshwaters, based on chronic data, provisional antibiotic resistance PNEC</td>
<td>*1</td>
</tr>
<tr>
<td>0.5 µg/l, surface freshwaters, based on chronic data, provisional antibiotic resistance PNEC</td>
<td>*2</td>
</tr>
<tr>
<td>120 µg/l, surface freshwaters, based on chronic data, surface waters</td>
<td></td>
</tr>
</tbody>
</table>

### 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: 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

Acute toxicity
- \( \text{LD}_{50} \) 6'200 mg/kg (oral, rat) *1
- \( \text{LD}_{50} \) 2'890 mg/kg (oral, rat) *2

Subchronic toxicity
- \( \text{TD}_{lo} \) 1100 mg/kg (oral, several species; 30 d) *2

Local effects
- eye: slightly irritating (rabbit) *1
- skin: non-irritant (rabbit) *1
- eye: slightly irritating (rabbit) *2
- skin: slightly irritating (rabbit) *2
- not phototoxic *2

Sensitization
- non-sensitizing (guinea pig) *1
- may be sensitizing; (man, therapeutic use) *1
- may be sensitizing (man) *2
- not photoallergenic *2

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

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

Reproductive toxicity
- does not lower parental fertility (200 mg/kg/d, rat) *1
- not teratogenic; (man, therapeutic doses) *1
- in animal test, malformations and reduce fertility due to systemic toxicity *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 *2
- rapid and nearly complete resorption after oral application; maximal plasma concentration is reached after about two hours *2
- antibacterial chemotherapeutic, which, through folic acid antagonism, inhibits the synthesis of proteins and nucleic acids essential for cell division *1
- 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

*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
- moderately toxic for microorganisms (activated sludge) \( \text{EC}_{50} \) 17.8 mg/l (OECD No. 209) *2
- activated sludge \( \text{EC}_{50} \) (3 h) > 200 mg/l (highest concentration tested) \( \text{EC}_{20} \) (3 h) 19 mg/l (nominal concentration) \( \text{EC}_{10} \) (3 h) 0.435 mg/l (nominal concentration) (Activated Sludge Respir. Inhib. Test, 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

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

Remarks regarding classification
- The General Administrative Regulation under the Federal Water Act on the Classification of Substances Hazardous to Water in Water Hazard Classes of 17 May 1999 has been nullified.

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 8

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

1.3. Details of the supplier of the safety data sheet

Company information: Roche Products Pty Limited
Level 8, 30-34 Hickson Road
Millers Point NSW 2000
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
### BACTRIM DS Tablets 800/160 mg

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole 723-46-6</td>
<td>79.2 %</td>
<td></td>
</tr>
<tr>
<td>Trimethoprim 738-70-5</td>
<td>15.8 %</td>
<td>- Specific target organ toxicity - Repeated exposure (Category 2), H373</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  

PNEC  - 0.59 µg/l, surface freshwaters, based on chronic data, surface waters  *1  
- 16 µg/l, surface freshwaters, based on chronic data, provisional antibiotic resistance PNEC  *1  
- 0.5 µg/l, surface freshwaters, based on chronic data, provisional antibiotic resistance PNEC  *2  
- 120 µg/l, surface freshwaters, based on chronic data, surface waters  

8.2. Exposure controls

Respiratory protection  - respiratory protection not necessary during normal operations  
- Respiratory protection is recommended for dusty operations.
Hand protection - protective gloves (eg 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Effect</th>
<th>Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>6'200 mg/kg (oral, rat)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>2'890 mg/kg (oral, rat)</td>
<td>2</td>
</tr>
<tr>
<td>Subchronic toxicity</td>
<td>TD&lt;sub&gt;lo&lt;/sub&gt;</td>
<td>1100 mg/kg (oral, several species; 30 d)</td>
<td>2</td>
</tr>
<tr>
<td>Local effects</td>
<td>eye: slightly irritating (rabbit)</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>skin: non-irritant (rabbit)</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>eye: slightly irritating (rabbit)</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>skin: slightly irritating (rabbit)</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>not phototoxic</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Sensitization</td>
<td>non-sensitizing (guinea pig)</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>may be sensitizing; (man, therapeutic use)</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>may be sensitizing (man)</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>not photoallergenic</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>not mutagenic (various in vivo and in vitro test systems)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>not mutagenic</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>IARC: group 3 (unclassifiable as to carcinogenicity to humans)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>no indication for carcinogenicity</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>does not lower parental fertility (200 mg/kg/d, rat)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>not teratogenic; (man, therapeutic doses)</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>in animal test, malformations and reduce fertility due to systemic toxicity</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>no information available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>no information available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>no information available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note</td>
<td>elimination half-life is about 11 hours; elimination is mainly by renal route, 80% being excreted unchanged</td>
<td>2</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>2</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>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>in human cells, therapeutic doses of sulfamethoxazole do not significantly disturb folic acid metabolism</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>biological half-life: 10 hours; rapid and efficient resorption from the intestine; excretion mostly renal</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>rarely, systemic use may induce allergic skin reactions with Stevens-Johnson or Lyell syndrome</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
- other side effects: gastrointestinal disturbances after oral uptake, disorders of liver function; at high doses: urinary stones, disturbances of haematological parameters

*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)

- 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)

- moderately toxic for planktonic crustaceans (Daphnia magna)
  EC₅₀ (48 h) 75 mg/l
  NOEC (48 h) 36 mg/l
  (OECD No. 202)

- barely toxic for planktonic crustaceans (Daphnia magna)
  EC₅₀ (48 h) > 100 mg/l
  NOEC (48 h) 100 mg/l
  (OECD No. 202)

- barely toxic for fish (rainbow trout)
  LC₀ 1000 mg/l

- barely toxic for fish (zebrafish)
  NOEC (72 h) 100 mg/l
  (OECD No. 203)

- 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)

- no adverse influence on substrate biodegradation (activated sludge)
  concentration 3.8 mg/l
  (Closed Bottle Test, OECD No. 301 D)

- 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)

- moderately toxic for microorganisms (activated sludge)
  EC₅₀ 17.8 mg/l
  (OECD No. 209)
## 12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready biodegradability</td>
<td>- not readily biodegradable 0 %, 28 d (Closed Bottle Test, OECD No. 301 D)</td>
<td>*1</td>
</tr>
<tr>
<td></td>
<td>- not readily biodegradable 0 %</td>
<td>*2</td>
</tr>
<tr>
<td>Inherent biodegradability</td>
<td>- not inherently biodegradable 0 %, 28 days (Zahn-Wellens test, OECD No. 302 B)</td>
<td>*6</td>
</tr>
<tr>
<td></td>
<td>- not inherently biodegradable 0 %, 28 d (MITI Test II, OECD No. 302 C)</td>
<td>*2</td>
</tr>
</tbody>
</table>
| 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>- low adsorption to activated sludge, high mobility (water-activated sludge)</td>
<td>*2</td>
</tr>
</tbody>
</table>
  
  \( K_d = 76 \) |

## 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

### 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**

<table>
<thead>
<tr>
<th>IATA</th>
<th>Class</th>
<th>UN/ID</th>
<th>PG</th>
<th>PI</th>
<th>Label</th>
<th>Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>3077</td>
<td>III</td>
<td>956/956</td>
<td>9</td>
<td>EHS</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IMDG</th>
<th>Class</th>
<th>UN</th>
<th>PG</th>
<th>EmS</th>
<th>PI</th>
<th>Label</th>
<th>Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>3077</td>
<td>III</td>
<td>F-A S-F</td>
<td>P002/IBC08</td>
<td>9</td>
<td>marine pollutant</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RID/ADR</th>
<th>Class</th>
<th>UN</th>
<th>PG</th>
<th>Haz.no</th>
<th>PI</th>
<th>Label</th>
<th>Mark</th>
<th>Classif. code</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>3077</td>
<td>III</td>
<td>90</td>
<td>P002/IBC08</td>
<td>9</td>
<td>EHS</td>
<td>M7</td>
<td></td>
</tr>
</tbody>
</table>

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

Remarks regarding classification
- The General Administrative Regulation under the Federal Water Act on the Classification of Substances Hazardous to Water in Water Hazard Classes of 17 May 1999 has been nullified.

**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 8

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.