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

1.1. Product identifier

Product name: CELLCEPT® Capsules 250 mg
Product code: SAP-10093418

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

Use: pharmaceutical active substance (immunosuppressant) *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: Mycophenolate mofetil
SECTION 2: Hazards identification

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

GHS Classification

<table>
<thead>
<tr>
<th>Health Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Acute toxicity (Category 4)</td>
</tr>
<tr>
<td>H302 Harmful if swallowed.</td>
</tr>
<tr>
<td>3.5 Germ cell mutagenicity (Category 2)</td>
</tr>
<tr>
<td>H341 Suspected of causing genetic defects.</td>
</tr>
<tr>
<td>3.7 Reproductive toxicity (Category 1B)</td>
</tr>
<tr>
<td>H360D May damage the unborn child.</td>
</tr>
<tr>
<td>3.9 Specific target organ toxicity - Repeated exposure (Category 1)</td>
</tr>
<tr>
<td>H372 Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

Signalword: Danger

Label:

Precautionary statements:
- P201 Obtain special instructions before use.
- P260 Do not breathe dust
- P273 Avoid release to the environment.
- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P405 Store locked up.

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

2.3. Other hazards

Note
- no information available

*1 referring to: Mycophenolate mofetil
*2 referring to: Starch
*3 referring to: Croscarmellose sodium
*4 referring to: Magnesium stearate
*5 referring to: Povidone K 90

SECTION 3: Composition/information on ingredients

Characterization
Mycophenolate mofetil and other inactive ingredients
UN number 3077

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycophenolate mofetil</td>
<td>82.7 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>128794-94-5</td>
<td></td>
<td>- Germ cell mutagenicity (Category 2), H341</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Reproductive toxicity (Category 1B), H360D</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Specific target organ toxicity - Repeated exposure (Category 1), H372</td>
</tr>
<tr>
<td>Starch</td>
<td>9.8 %</td>
<td></td>
</tr>
<tr>
<td>9005-84-9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>3.9 %</td>
<td></td>
</tr>
<tr>
<td>74811-65-7</td>
<td></td>
<td></td>
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<tr>
<td>Magnesium stearate</td>
<td>1.5 %</td>
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<tr>
<td>557-04-0</td>
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<tr>
<td>Povidone K 90</td>
<td>2 %</td>
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<tr>
<td>9003-39-8</td>
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</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 - drench affected skin with water

Inhalation - remove the casualty to fresh air - in the event of symptoms get medical treatment

Ingestion - consult physician

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 - Toxic emissions may be given off in a fire

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 - ensure adequate ventilation

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
- the solvent should be held back due to environmental protection

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - no special measures necessary if stored and handled as prescribed

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - keep containers tightly closed
- room temperature
- store in a dry place
- protected from light

Packaging materials - drums
- lined with polyethylene bag

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³ *1
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
Analytics - sampling on glass fibre filter, desorption with methanol; basify with NaOH, heat; neutralize with HCl, HPLC analysis

*1 referring to: Mycophenolate mofetil

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour
brown
blue

Form
oblong capsules

Solubility
≤ 22 mg/l, water (~ 22 °C, pH 6.3, HPLC, 24 h) *1
≤ 36 mg/l, aquatic ecotoxicity media (~ 22 °C, HPLC, 24 h) *1

9.2. Other information

Note - no information available

*1 referring to: Mycophenolate mofetil

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

Conditions to avoid - warming
- light
- humidity
10.5. Incompatible materials

Materials to avoid - strong oxidizing agents *1

10.6. Hazardous decomposition products

Note - no information available

*1 referring to: Mycophenolate mofetil

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - LD$_{50}$ 353 mg/kg (oral, rat); females, "trimmed Spearman-Karber method" *1
- LD$_{50}$ 500 mg/kg (oral, rat); males, "trimmed Spearman-Karber method" *1
- LD$_0$ 250 mg/kg (oral, rat) *1
- LD$_{50}$ > 2'000 mg/kg (oral, rat) *4

Local effects - skin: non-irritant *1
- eye: non-irritant *1

Sensitization - non-sensitizing *1

Mutagenicity - mutagenic (OECD No. 474 (Micronucleus Test)); threshold dose response *6
- mutagenic (mouse lymphoma cell mutation test; OECD No. 476 (Mammalian Cell Gene Mutation Test)) *6
- does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test)) *6
- not mutagenic (Ames test) *6

Carcinogenicity - not carcinogenic (several species) *1

Reproductive toxicity - teratogenic (several species) *1

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

Note - immunosuppressive agent *1
- average therapeutic dose 1 g twice/day *1
- elimination half-life: 16-18 h *1
- excretion predominantly renal *1
- Adverse effect at therapeutic dose: diarrhoea, drop of white blood cell count, susceptibility to infections, vomiting *1
SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

- adaptation/recovery of organisms upon prolongation of test duration (Scenedesmus (=Desmodesmus) subspicatus)
  LOEC (14 d) 1.6 mg/l (nominal concentration) (OECD No. 201, prolonged) *1

- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna)
  EC50 (48 h) > 100 mg/l (nominal concentration)
  NOEC (48 h) 27.7 mg/l (average measured concentration) (OECD No. 202) *1

- highly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  ErC50 (72 h) 0.6 mg/l (average measured concentration)
  EbC50 (72 h) 0.2 mg/l (average measured concentration)
  NOEC (72 h) 0.1 mg/l (nominal concentration) (OECD No. 201) *1

- acute fish toxicity in a limit test is lower than daphnid or algal toxicity, hence not relevant for classification (guppy)
  NOEC (96 h) 1.7 mg/l (highest concentration tested) (OECD No. 203) *1

- no adverse influence on substrate biodegradation (activated sludge)
  concentration (14 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F) *1

12.2. Persistence and degradability

Ready biodegradability

- not readily biodegradable
  ~ 14 %, 64 d (FDA Technical Assistance Document No. 3.11) *1

- not readily biodegradable primary degradation evidenced by HPLC
  < 6 %, 28 d (Manometric Respirometry Test, OECD No. 301 F) *1

Inherent biodegradability

- evidence for medium-term biodegradation in surface waters (analogous to OECD 308, Transformation in natural water/sediment systems) *1

Abiotic degradation

- rapid degradation, photodegradation, hydrolysis 22.3 mg/l, water; HPLC
  ~ 37 %, 120 h, ~ 22 °C, dark
  ~ 67 %, 120 h, ~ 22 °C, under illumination *1

*1 referring to: Mycophenolate mofetil
*4 referring to: Magnesium stearate
*6 referring to: Mycophenolic acid

- high doses may irritate the digestive tract
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

Air pollution - observe local/national regulations  

*1 referring to: Mycophenolate mofetil

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - incinerate in qualified installation with flue gas scrubbing  
- observe local/national regulations regarding waste disposal  
- medicines should not be disposed of via wastewater

SECTION 14: Transport information

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<thead>
<tr>
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<td>III</td>
<td>F-A S-F</td>
<td>P002/IBC08</td>
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<td>marine pollutant</td>
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<th>PI</th>
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<td>3077</td>
<td>III</td>
<td>90</td>
<td>P002/IBC08</td>
<td>9</td>
<td>EHS</td>
<td>M7</td>
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</tr>
</tbody>
</table>

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

Technical name  
mixture with 83% Mycophenolate mofetil
SECTION 15: Regulatory information

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

Water hazard class (Germany) 3: strongly hazardous for water (own classification according to directive VwVwS of 17.05.1999)

Regulatory status (Australia) - This product has been approved by the Therapeutic Goods Administration (TGA); AUST R 67313

SECTION 16: Other information

Safety-lab number - BS-8818
- BS-9333

Full text of H-Statements referred to under section 3
H302 Harmful if swallowed.
H341 Suspected of causing genetic defects.
H360D May damage the unborn child.
H372 Causes 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 1, 2, 9

*1 referring to: Mycophenolate mofetil

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: CELLCEPT Tablets 500 mg
Product code: SAP-10062347

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

Use: - pharmaceutical active substance (immunosuppressant) *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

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: Mycophenolate mofetil
SECTION 2: Hazards identification

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

GHS Classification

Health Hazards:
- 3.1 Acute toxicity (Category 4)
  H302 Harmful if swallowed.
- 3.5 Germ cell mutagenicity (Category 2)
  H341 Suspected of causing genetic defects.
- 3.7 Reproductive toxicity (Category 1B)
  H360D May damage the unborn child.
- 3.9 Specific target organ toxicity - Repeated exposure (Category 1)
  H372 Causes damage to organs through prolonged or repeated exposure.

Signalword: Danger

Label:

Precautionary statements:
- P201 Obtain special instructions before use.
- P260 Do not breathe dust
- P273 Avoid release to the environment.
- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P405 Store locked up.

Australian Remark
- HAZARDOUS SUBSTANCE. DANGEROUS GOODS.
- 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) *

2.3. Other hazards

Note
- no further information available

*1 referring to: Mycophenolate mofetil
*2 referring to: Cellulose
*3 referring to: Polyvinylpyrrolidone
*4 referring to: Magnesium stearate

SECTION 3: Composition/information on ingredients

Characterization
Mycophenolate mofetil and other inactive ingredients

Synonyms
- CELLCEPT F.C. Tablets
CELLCEPT Tablets 500 mg

- CELLCEPT Film Coated Tablets

UN number 3077

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycophenolate mofetil</td>
<td>~ 60 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>128794-94-5</td>
<td></td>
<td>- Germ cell mutagenicity (Category 2), H341</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Reproductive toxicity (Category 1B), H360D</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Specific target organ toxicity - Repeated exposure (Category 1), H372</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td></td>
</tr>
<tr>
<td>Polyvinylpyrrolidone</td>
<td>9003-39-8</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td></td>
</tr>
</tbody>
</table>

For the full text of the H-phrases 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 10 minutes - open eyelids forcibly
Skin contact  - drench affected skin with water
Inhalation   - in case of inhalation remove to fresh air and seek medical aid
Ingestion    - consult physician

4.2. Most important symptoms and effects, both acute and delayed

Note  - no information available

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  - Toxic emissions may be given off in a fire
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 - ensure adequate ventilation
- keep people away and stay on the upwind side

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
- the solvent should be held back due to environmental protection

6.3. Methods and material for containment and cleaning up
Methods for cleaning up - collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Technical measures - provide suitable exhaust ventilation at the processing machines

7.2. Conditions for safe storage, including any incompatibilities
Storage conditions - keep containers tightly closed
- room temperature
- store in a dry place
- protected from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³

8.2. Exposure controls
Respiratory protection - in case of open handling or accidental release:
- particle mask or respirator with independent air supply
- respiratory protection not necessary during normal operations
Hand protection - protective gloves (e.g. made of neoprene, nitrile or butyl rubber)
Eye protection - safety glasses
Analytics - sampling on glass fibre filter, desorption with methanol; basify with NaOH, heat; neutralize with HCl; HPLC analysis

*1 referring to: Mycophenolate mofetil

SECTION 9: 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>capsule-shaped tablet</td>
</tr>
<tr>
<td>Solubility</td>
<td>≤ 22 mg/l, water (~ 22 °C, pH 6.3, HPLC, 24 h)</td>
</tr>
<tr>
<td></td>
<td>≤ 36 mg/l, aquatic ecotoxicity media (~ 22 °C, HPLC, 24 h)</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>log $P_{ow}$ 1.45 (n-octanol/water) pH 7.4</td>
</tr>
</tbody>
</table>

9.2. Other information

Note - no information available

*1 referring to: Mycophenolate mofetil

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

Materials to avoid - strong oxidizing agents

*1
10.6. Hazardous decomposition products

Note: - no information available

*1 referring to: Mycophenolate mofetil

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
- \( \text{LD}_{50} \) 353 mg/kg (oral, rat); females, "trimmed Spearman-Karber method" *1
- \( \text{LD}_{50} \) 500 mg/kg (oral, rat); males, "trimmed Spearman-Karber method" *1
- \( \text{LD}_0 \) 250 mg/kg (oral, rat) *1
- \( \text{LD}_{50} \) > 2'000 mg/kg (oral, rat) *4

Local effects
- skin: non-irritant *1
- eye: non-irritant *1

Sensitization
- non-sensitizing *1

Mutagenicity
- mutagenic (OECD No. 474 (Micronucleus Test)); threshold dose response *5
- mutagenic (mouse lymphoma cell mutation test; OECD No. 476 (Mammalian Cell Gene Mutation Test)) *5
- does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test)) *5
- not mutagenic (Ames test) *5

Carcinogenicity
- not carcinogenic (several species) *1

Reproductive toxicity
- teratogenic (several species) *1

Note
- immunosuppressive agent *1
- average therapeutic dose 1 g twice/day *1
- elimination half-life: 16-18 h *1
- excretion predominantly renal *1
- Adverse effect at therapeutic dose: diarrhoea, drop of white blood cell count, susceptibility to infections, vomiting *1
- high doses may irritate the digestive tract *1

*1 referring to: Mycophenolate mofetil
*4 referring to: Magnesium stearate
*5 referring to: Mycophenolic acid
SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

- adaptation/recovery of organisms upon prolongation of test duration (Scenedesmus (=Desmodesmus) subspicatus)
  LOEC (14 d) 1.6 mg/l (nominal concentration)
  (OECD No. 201, prolonged) *1
- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna)
  EC50 (48 h) > 100 mg/l (nominal concentration)
  NOEC (48 h) 27.7 mg/l (average measured concentration)
  (OECD No. 202) *1
- highly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  ErC50 (72 h) 0.6 mg/l (average measured concentration)
  EbC50 (72 h) 0.2 mg/l (average measured concentration)
  NOEC (72 h) 0.1 mg/l (nominal concentration)
  (OECD No. 201) *1
- acute fish toxicity in a limit test is lower than daphnid or algal toxicity, hence not relevant for classification (guppy)
  NOEC (96 h) 1.7 mg/l (highest concentration tested)
  (OECD No. 203) *1
- no adverse influence on substrate biodegradation (activated sludge)
  concentration (14 d) 100 mg/l (nominal concentration)
  (Manometric Respirometry Test, OECD No. 301 F) *1

12.2. Persistence and degradability

Ready biodegradability

- not readily biodegradable
  ~ 14 %, 64 d
  (FDA Technical Assistance Document No. 3.11) *1
- not readily biodegradable primary degradation evidenced by HPLC
  < 6 %, 28 d
  (Manometric Respirometry Test, OECD No. 301 F) *1

Inherent biodegradability

- evidence for medium-term biodegradation in surface waters (analogous to OECD 308, Transformation in natural water/sediment systems) *1
- inherently biodegradable *2

Abiotic degradation

- rapid degradation, photodegradation, hydrolysis 22.3 mg/l, water; HPLC
  ~ 37 %, 120 h, ~ 22 °C, dark
  ~ 67 %, 120 h, ~ 22 °C, under illumination *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**

Air pollution: observe local/national regulations

*1 referring to: Mycophenolate mofetil

*2 referring to: Cellulose

---

**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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<td>III</td>
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<td>956/956</td>
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<td>EHS</td>
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Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Technical name: mixture with 60% Mycophenolate mofetil
SECTION 15: Regulatory information

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

Water hazard class (Germany) 3: strongly hazardous for water (own classification according to directive VwVwS of 17.05.1999)

SECTION 16: Other information

Safety-lab number
- BS-8818
- BS-9333

Full text of H-Statements referred to under section 3

H302 Harmful if swallowed.
H341 Suspected of causing genetic defects.
H360D May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

Full text of H-Statements referred to under section 3

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, 13, 16

*1 referring to: Mycophenolate mofetil

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          CELLCEPT® Vials 500 mg
Product code          SAP-10051336

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

Use                         - pharmaceutical active substance (immunosuppressant)

1.3. Details of the supplier of the safety data sheet

Company information  Enquiries:
Roche Products Pty Limited  Local representation:
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.sdss@roche.com

1.4. Emergency telephone number

Emergency telephone number Phone        0061-2-9454-9624
SECTION 2: Hazards identification

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

GHS Classification

Health Hazards:

3.1 Acute toxicity (Category 4)
   H302 Harmful if swallowed.

3.5 Germ cell mutagenicity (Category 2)
   H341 Suspected of causing genetic defects.

3.7 Reproductive toxicity (Category 1B)
   H360D May damage the unborn child.

3.9 Specific target organ toxicity - Repeated exposure (Category 1)
   H372 Causes damage to organs through prolonged or repeated exposure.

Signalword: Danger

Label:

Precautionary statements:
- P201 Obtain special instructions before use.
- P273 Avoid release to the environment.
- P281 Use personal protective equipment as required.
- P309 + P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.

Australian Remark
- HAZARDOUS SUBSTANCE. DANGEROUS GOODS.
- Poisons Schedule - Schedule 4 *1
- Not 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

2.3. Other hazards

Note
- may form explosible dust-air mixture if dispersed

*1 referring to: Mycophenolate mofetil
*2 referring to: Citric acid anhydrous
*3 referring to: Polysorbate 80

SECTION 3: Composition/information on ingredients

Characterization
Mycophenolate mofetil and other ingredients

Synonyms
- CELLCEPT Lyophilized Vials 500 mg
- contains 87% Mycophenolate mofetil

UN number
3077
Ingredient | Concentration | GHS-Classification (pure ingredient)
--- | --- | ---
Mycophenolate mofetil 128794-94-5 | 87 % | - Acute toxicity (Category 4), H302
- Germ cell mutagenicity (Category 2), H341
- Reproductive toxicity (Category 1B), H360D
- Specific target organ toxicity - Repeated exposure (Category 1), H372
Citric acid 77-92-9 01-2119457026-42 | < 1 % | - Serious eye damage/eye irritation (Category 2A), H319
Polysorbate 80 9005-65-6

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
- 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
- after accidental exposure women should get medical advice from a physician

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media - water spray jet, dry powder, foam, carbon dioxide

5.2. Special hazards arising from the substance or mixture

Specific hazards - consider dust explosion hazard
- consider danger for the environment: dike spilled liquid
- formation of toxic and corrosive combustion gases (nitrogen oxides (NOx)) possible

### 5.3. Advice forfighters

**Protection of fire-fighters**
- precipitate gases/vapours/mists with water spray

**Special method of fire-fighting**
- for reasons of environmental protection hold the extinguishing agent back

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions**
- ensure adequate ventilation

#### 6.2. Environmental precautions

**Environmental protection**
- if the substance reaches waters or the sewer system, inform the competent authority
- dilute the leaked substance by a water spray jet as far as necessary in order to minimize the hazard; hold the draining water/mixture of substances back by all means available

#### 6.3. Methods and material for containment and cleaning up

**Methods for cleaning up**
- collect solids (avoid dust formation) and hand over to waste removal
- collect spilled solutions with inert adsorbent and hand over to waste removal

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

**Technical measures**
- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
- local exhaust ventilation necessary
- avoid dust formation; consider dust explosion hazard
- take precautionary measures against electrostatic charging

#### 7.2. Conditions for safe storage, including any incompatibilities

**Storage conditions**
- room temperature

**Validity**
- see expiry date on the label
SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m\(^3\) *1

8.2. Exposure controls

General protective and hygiene measures - instruction of employees mandatory

Respiratory protection - in case of open handling or accidental release:
particle mask or respirator with independent air supply

Hand protection - protective gloves (neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

Body protection - protective clothing

Analytics - sampling on glass fibre filter, desorption with methanol; basify with NaOH, heat; neutralize with HCl, HPLC analysis *1

*1 referring to: Mycophenolate mofetil

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour white to off-white

Form powder

Solubility ≤ 22 mg/l, water (~ 22 °C, pH 6.3, HPLC, 24 h) *1
≤ 36 mg/l, aquatic ecotoxicity media (~ 22 °C, HPLC, 24 h) *1

Partition coefficient \( \log P_{ow} 2.38 \) (n-octanol/water) pH 7.4 *1

Melting temperature 93 to 99 °C *1

9.2. Other information

Note - no information available

*1 referring to: Mycophenolate mofetil

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available
10.2. Chemical stability

Stability - stable under normal conditions

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Materials to avoid - strong oxidizing agents

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
- \(LD_{50}\) 353 mg/kg (oral, rat); females, "trimmed Spearman-Karber method" *1
- \(LD_{50}\) 500 mg/kg (oral, rat); males, "trimmed Spearman-Karber method" *1
- \(LD_{50}\) 250 mg/kg (oral, rat) *1
- \(LD_{50}\) > 4'000 mg/kg (oral, mouse) *1

Local effects - skin: non-irritant *1
- eye: non-irritant *1

Sensitization - non-sensitizing *1

Mutagenicity - mutagenic (OECD No. 474 (Micronucleus Test)); threshold dose response *4
- mutagenic (mouse lymphoma cell mutation test; OECD No. 476 (Mammalian Cell Gene Mutation Test)) *4
- does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test)) *4
- not mutagenic (Ames test) *4

Carcinogenicity - not carcinogenic (several species) *1

Reproductive toxicity - teratogenic (several species) *1

STOT-single exposure - no information available

STOT-repeated exposure - no information available
SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity
- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna)
  - EC₅₀ (48 h) > 100 mg/l (nominal concentration)
  - NOEC (48 h) 27.7 mg/l (average measured concentration)
  (OECD No. 202)
- highly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  - ErC₅₀ (72 h) 0.6 mg/l (average measured concentration)
  - EbC₅₀ (72 h) 0.2 mg/l (average measured concentration)
  - NOEC (72 h) 0.1 mg/l (nominal concentration)
  (OECD No. 201)
- adaptation/recovery of organisms upon prolongation of test duration (Scenedesmus (=Desmodesmus) subspicatus)
  - LOEC (14 d) 1.6 mg/l (nominal concentration)
  (OECD No. 201, prolonged)
- acute fish toxicity in a limit test is lower than daphnid or algal toxicity, hence not relevant for classification (guppy)
  - NOEC (96 h) 1.7 mg/l (highest concentration tested)
  (OECD No. 203)
- no adverse influence on substrate biodegradation (activated sludge)
  - concentration (14 d) 100 mg/l (nominal concentration)
  (Manometric Respirometry Test, OECD No. 301 F)

12.2. Persistence and degradability

Ready biodegradability
- not readily biodegradable
  ~ 14 %, 64 d
  (FDA Technical Assistance Document No. 3.11)
- not readily biodegradable
  primary degradation evidenced by HPLC
  < 6 %, 28 d
  (Manometric Respirometry Test, OECD No. 301 F)
Inherent biodegradability - evidence for medium-term biodegradation in surface waters (analogous to OECD 308, Transformation in natural water/sediment systems) *1

Abiotic degradation - rapid degradation, photodegradation, hydrolysis 22.3 mg/l, water; HPLC ~ 37 %, 120 h, ~ 22 °C, dark ~ 67 %, 120 h, ~ 22 °C, under illumination *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: Mycophenolate mofetil

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste from residues - observe local/national regulations regarding waste disposal - incinerate in qualified installation with flue gas scrubbing

SECTION 14: Transport information

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CELLCEPT® Vials 500 mg

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

Technical name Mycophenolate mofetil

SECTION 15: Regulatory information

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

Water hazard class (Germany) 3: strongly hazardous for water (own classification according to directive VvVwS of 17.05.1999)

SECTION 16: Other information

Full text of H-Statements referred to under section 3

- H302  Harmful if swallowed.
- H319  Causes serious eye irritation.
- H341  Suspected of causing genetic defects.
- H360D May damage the unborn child.
- H372  Causes 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 1, 2, 9

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.
CellCept Powder for oral suspension (1g/5mL)

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

1.1. Product identifier

Product name  CellCept Powder for oral suspension (1g/5mL)
Product code  SAP-10041443

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

Use  - pharmaceutical active substance (immunosuppressant)

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

1.4. Emergency telephone number

Emergency telephone number  Phone  0061-2-9454-9624

*1 referring to: Mycophenolate mofetil

Date:  28.1.16/LS (SEISMO)  Replacing edition of:  19.8.15
SECTION 2: Hazards identification

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

GHS Classification
Health Hazards:
- 3.1 Acute toxicity (Category 4)
  H302 Harmful if swallowed.
- 3.5 Germ cell mutagenicity (Category 2)
  H341 Suspected of causing genetic defects.
- 3.7 Reproductive toxicity (Category 1B)
  H360D May damage the unborn child.
- 3.9 Specific target organ toxicity - Repeated exposure (Category 1)
  H372 Causes damage to organs through prolonged or repeated exposure.

Signalword: Danger
Label:

Precautionary statements:
- P201 Obtain special instructions before use.
- P273 Avoid release to the environment.
- P281 Use personal protective equipment as required.
- P309 + P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.

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

2.3. Other hazards

Note
- may form explosible dust-air mixture if dispersed

*1 referring to: Mycophenolate mofetil
*2 referring to: Sorbitol

SECTION 3: Composition/information on ingredients

Characterization
Mycophenolate mofetil 1g/5mL and other inactive ingredients

UN number
3077
CellCept Powder for oral suspension (1g/5mL)

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<td>- Germ cell mutagenicity (Category 2), H341</td>
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<tr>
<td></td>
<td></td>
<td>- Reproductive toxicity (Category 1B), H360D</td>
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<tr>
<td></td>
<td></td>
<td>- Specific target organ toxicity - Repeated exposure (Category 1), H372</td>
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<td>Sorbitol</td>
<td>63.5 %</td>
<td>- Germ cell mutagenicity (Category 2), H341</td>
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For the full text of the H-phrases 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
- 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
- after accidental exposure women should get medical advice from a physician

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media
- water spray jet, dry powder, foam, carbon dioxide

5.2. Special hazards arising from the substance or mixture

Specific hazards
- consider dust explosion hazard
- consider danger for the environment: dike spilled liquid
- formation of toxic and corrosive combustion gases (nitrogen oxides (NOx)) possible
## 5.3. Advice for firefighters

Protection of fire-fighters  
- precipitate gases/vapours/mists with water spray

Special method of fire-fighting  
- for reasons of environmental protection hold the extinguishing agent back

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions  
- ensure adequate ventilation

#### 6.2. Environmental precautions

Environmental protection  
- if the substance reaches waters or the sewer system, inform the competent authority
- dilute the leaked substance by a water spray jet as far as necessary in order to minimize the hazard; hold the draining water/mixture of substances back by all means available

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up  
- collect solids (avoid dust formation) and hand over to waste removal
- collect spilled solutions with inert adsorbent and hand over to waste removal

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Technical measures  
- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
- local exhaust ventilation necessary
- avoid dust formation; consider dust explosion hazard
- take precautionary measures against electrostatic charging

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions  
- room temperature
- dry and ventilated place

Validity  
- see expiry date on the label
SECTION 8: Exposure controls/personal protection

8.1. Control parameters
Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.01 mg/m³

8.2. Exposure controls
General protective and hygiene measures - instruction of employees mandatory
Respiratory protection - in case of open handling or accidental release:
  particle mask or respirator with independent air supply
Hand protection - protective gloves (neoprene, nitrile or butyl rubber)
Eye protection - safety glasses
Body protection - protective clothing
Analytics - sampling on glass fibre filter, desorption with methanol; basify with NaOH, heat; neutralize with HCl, HPLC analysis

*1 referring to: Mycophenolate mofetil

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Colour - white to off-white
Form - powder
Solubility ≤ 22 mg/l, water (~ 22 °C, pH 6.3, HPLC, 24 h)
  ≤ 36 mg/l, aquatic ecotoxicity media (~ 22 °C, HPLC, 24 h)
Partition coefficient log Pow 1.45 (n-octanol/water) pH 7.4
Melting temperature 93 to 99 °C

9.2. Other information
Note - no information available

*1 referring to: Mycophenolate mofetil

SECTION 10: Stability and reactivity

10.1. Reactivity
Note - no information available
CellCept Powder for oral suspension (1g/5mL)

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

Materials to avoid - strong oxidizing agents

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

- $LD_{50}$ 353 mg/kg (oral, rat); females, "trimmed Spearman-Karber method" *1
- $LD_{50}$ 500 mg/kg (oral, rat); males, "trimmed Spearman-Karber method" *1
- $LD_0$ 250 mg/kg (oral, rat) *1
- $LD_{50}$ > 4'000 mg/kg (oral, mouse) *1

Local effects

- skin: non-irritant *1
- eye: non-irritant *1

Sensitization

- non-sensitizing *1

Mutagenicity

- mutagenic (OECD No. 474 (Micronucleus Test)); threshold dose response *3
- mutagenic (mouse lymphoma cell mutation test; OECD No. 476 (Mammalian Cell Gene Mutation Test)) *3
- does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test)) *3
- not mutagenic (Ames test) *3

Carcinogenicity

- not carcinogenic (several species) *1

Reproductive toxicity

- teratogenic (several species) *1

STOT-single exposure

- no information available

STOT-repeated exposure

- no information available
**CellCept Powder for oral suspension (1g/5mL)**

**Aspiration hazard**
- no information available

**Note**
- immunosuppressive agent
- average therapeutic dose 1 g twice/day
- elimination half-life: 16-18 h
- Adverse effect at therapeutic dose: diarrhoea, drop of white blood cell count, susceptibility to infections, vomiting
- high doses may irritate the digestive tract
- excretion predominantly renal

*1 referring to: Mycophenolate mofetil
*3 referring to: Mycophenolic acid

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Ecotoxicity**
- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna)
  - EC₅₀ (48 h) > 100 mg/l (nominal concentration)
  - NOEC (48 h) 27.7 mg/l (average measured concentration) (OECD No. 202)
- highly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)
  - ErC₅₀ (72 h) 0.6 mg/l (average measured concentration)
  - EbC₅₀ (72 h) 0.2 mg/l (average measured concentration)
  - NOEC (72 h) 0.1 mg/l (nominal concentration) (OECD No. 201)
- adaptation/recovery of organisms upon prolongation of test duration (Scenedesmus (=Desmodesmus) subspicatus)
  - LOEC (14 d) 1.6 mg/l (nominal concentration) (OECD No. 201, prolonged)
- acute fish toxicity in a limit test is lower than daphnid or algal toxicity, hence not relevant for classification (guppy)
  - NOEC (96 h) 1.7 mg/l (highest concentration tested) (OECD No. 203)
- no adverse influence on substrate biodegradation (activated sludge)
  - concentration (14 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F)

#### 12.2. Persistence and degradability

**Ready biodegradability**
- not readily biodegradable
  - ~ 14 %, 64 d
  - not readily biodegradable
  - primary degradation evidenced by HPLC
    - < 6 %, 28 d
      - (Manometric Respirometry Test, OECD No. 301 F)
CellCept Powder for oral suspension (1g/5mL)

Inherent biodegradability  
- evidence for medium-term biodegradation in surface waters  
  (analogous to OECD 308, Transformation in natural water/sediment systems)  
  *1

Abiotic degradation  
- rapid degradation, photodegradation, hydrolysis  22.3 mg/l, water; HPLC  
  ~ 37 %, 120 h, ~ 22 °C, dark  
  ~ 67 %, 120 h, ~ 22 °C, under illumination  
  *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: Mycophenolate mofetil

SECTION 13: Disposal considerations

13.1. Waste treatment methods  
Waste from residues  
- observe local/national regulations regarding waste disposal  
- incinerate in qualified installation with flue gas scrubbing

SECTION 14: Transport information

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CellCept Powder for oral suspension (1g/5mL)

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

Technical name Mycophenolate mofetil mixture 32%

SECTION 15: Regulatory information

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

Water hazard class (Germany) 3: strongly hazardous for water (own classification according to directive VwVwS of 17.05.1999)

SECTION 16: Other information

Full text of H-Statements referred to under section 3

- H302 Harmful if swallowed.
- H341 Suspected of causing genetic defects.
- H360D May damage the unborn child.
- H372 Causes 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 10

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.