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

1.1. Product identifier

Product name: TARCEVA® Tablets 25 mg
Product code: SAP-10077703

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

Use:
- pharmaceutical active substance (antineoplastic) *1

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

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: Erlotinib hydrochloride

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
- 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
- Listed on the Australian Inventory of Chemical Substances (AICS) *6
2.3. Other hazards

Note: no information available

*1 referring to: Erlotinib hydrochloride
*2 referring to: Cellulose
*3 referring to: Lactose
*4 referring to: Magnesium stearate
*5 referring to: Sodium lauryl sulfate
*6 referring to: Sodium carboxymethyl starch

SECTION 3: Composition/information on ingredients

Characterization: each film-coated TARCEVA Tablet contains 27.32 mg Erlotinib hydrochloride equivalent to 25 mg Erlotinib

Synonyms:
- TARCEVA F.C. Tablets 25 mg
- TARCEVA Film Coated Tablets 25 mg

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erlotinib hydrochloride 183319-69-9</td>
<td>26.0 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>Microcrystalline cellulose 9004-34-6</td>
<td>33.3 %</td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate 64044-51-5</td>
<td>26.1 %</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate 557-04-0</td>
<td>1.2 %</td>
<td></td>
</tr>
</tbody>
</table>
| Sodium lauryl sulfate 151-21-3     | 0.95 %        | - Flammable solids (Category 2), H228
|                                    |               | - Acute toxicity (Category 4), H332
|                                    |               | - Acute toxicity (Category 4), H302
|                                    |               | - Skin corrosion/irritation (Category 2), H315
|                                    |               | - Serious eye damage/eye irritation (Category 1), H318
|                                    |               | - Specific target organ toxicity - Single exposure (Category 3), H335
| Sodium carboxymethyl starch 9063-38-1| 7.6 %        |                                      |

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly</td>
</tr>
<tr>
<td>Skin contact</td>
<td>- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents</td>
</tr>
<tr>
<td>Inhalation</td>
<td>- remove the casualty to fresh air - in the event of symptoms get medical treatment</td>
</tr>
</tbody>
</table>

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

- no information available

#### 4.3. Indication of any immediate medical attention and special treatment needed

- 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:
- no particular hazards known

#### 5.3. Advice for firefighters

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

### SECTION 6: Accidental release measures

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

- avoid exposure

#### 6.2. Environmental precautions

Environmental protection:
- do not allow to enter drains or waterways

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

Methods for cleaning up:
- take up mechanically and dispose of
SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures
- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
- avoid formation and deposition of dust

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions
- 15 - 30 °C
- protected from light and humidity

Validity
- 3 years, see “best use before” date stated on the label
- 24 months, > 30 °C, Holding Time (Bulk)

Packaging materials
- blister packages
- polyethylene bag in metal drum

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 0.05 mg/m³ *1

8.2. Exposure controls

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

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

Eye protection
- safety glasses

*1 referring to: Erlotinib hydrochloride

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour
- white

Form
- round, biconvex tablet

Solubility
- 810 mg/l, water *1

Partition coefficient
- log Pₐqₘₐₜ 3.37 (n-octanol/water 20 °C)
  (EC directive 92/69/EEC, A.8 (1992)) *1

Melting temperature
- 230 to 238 °C (with partial decomposition) *1

Date: 2.11.17/LS (SEISMO)  Replacing edition of: 10.1.17  Page: 4/8
9.2. Other information

Note - no information available

*1 referring to: Erlotinib hydrochloride

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Note - no information available

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - warming
- light

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
- LD_{50} 1'000 to 2'000 mg/kg (oral, rat) *1
- LD_{50} > 2'000 mg/kg (oral, mouse) *1
- LD_{50} > 2'000 mg/kg (dermal, rabbit) *1

Local effects - no information available

Sensitization - slightly sensitizing (guinea pig) *1

Mutagenicity - not mutagenic (various test systems) *1

Carcinogenicity - no information available
Reproductive toxicity - not teratogenic (several species) *1
- increased embryolethality at doses causing maternal toxicity (several species) *1

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

Note - selective inhibitor of Epidermal Growth Factor Receptor (EGFR) tyrosine kinase, inhibits EGF-induced mitogenesis *1
- therapeutic dose: 150 mg/d *1
- elimination half-life: 3 to 11 h *1
- excretion mainly through pulmonary first-pass and liver metabolism *1
- high doses cause: headache, nausea, diarrhoea *1

*1 referring to: Erlotinib hydrochloride

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Selenastrum capricornutum)
EC_{50} (72 h) > 100 mg/l (nominal concentration)
NOEC (72 h) 1.39 mg/l (saturation concentration)
(OECD No. 201) *1
- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna)
EC_{50} (48 h) > 100 mg/l (nominal concentration)
EC_{10} (48 h) 1.53 mg/l (saturation concentration)
NOEC (48 h) 0.70 mg/l (average measured concentration)
(OECD No. 202) *1
- barely toxic for fish (nominal concentration = 100 mg/l), test performed with water accommodated fractions (zebrafish)
LC_{50} (96 h) > 100 mg/l (nominal concentration)
LC_{0} (96 h) 1.80 mg/l (saturation concentration)
(OECD No. 203, semi-static) *1
- barely toxic for microorganisms (nominal concentration > 100 mg/l) (activated sludge)
NOEC (3 h) 1000 mg/l (nominal concentration)
(Activated Sludge Respir. Inhib. Test, OECD No. 209) *1

12.2. Persistence and degradability

Ready biodegradability - not readily biodegradable
0 %, 28 d
(MITI Test I, OECD No. 301 C) *1
Inherent biodegradability - not inherently biodegradable
0 %, 28 d
(Roche-internal respirometric inherent biodegradation test)  *1

12.3. Bioaccumulative potential

Bioconcentration - no significant bioaccumulation (rainbow trout)
Bioaccumulation factor:
BCF ~ 7.8, 14 d, ~ 14 °C, 2 μg/l
BCF ~ 10.1, 14 d, ~ 14 °C, 21 μg/l
Depuration:
DT_{50} ≤ 7 d
(Bioconcentration: flow-through fish test, 14 days; OECD no. 305)  *1

12.4. Mobility in soil

Mobility - strong adsorption, immobile
logKOC = 3.7
KOC = 5470
(OECD No. 121)  *1

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Erlotinib hydrochloride

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - return to supplier or hand over to authorised disposal company
- observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing
- medicines should not be disposed of via wastewater

SECTION 14: Transport information

Australian Remark - ADG Code: This product is not classified as a dangerous good. No special transport conditions are necessary unless required by other regulations.
### SECTION 15: Regulatory information

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

| Water hazard class (Germany) | 1: weakly hazardous for water (own classification according to directive VwVwS of 27.07.2005) |

### SECTION 16: Other information

<table>
<thead>
<tr>
<th>Safety-lab number</th>
<th>BS10396</th>
</tr>
</thead>
</table>

**Full text of H-Statements referred to under section 3**

- H228 Flammable solid.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.

**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

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: TARCEVA® Tablets 100 mg
Product code: SAP-10067556

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use: - pharmaceutical active substance (antineoplastic) *1

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
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: Erlotinib hydrochloride

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
- 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
- Listed on the Australian Inventory of Chemical Substances (AICS) *6
2.3. Other hazards

Note - no information available

*1 referring to: Erlo tinib hydrochloride
*2 referring to: Cellulose
*3 referring to: Lactose
*4 referring to: Magnesium stearate
*5 referring to: Sodium lauryl sulfate
*6 referring to: Sodium carboxymethyl starch

SECTION 3: Composition/information on ingredients

Characterization each film-coated TARCEVA Tablet contains 109.29 mg Erlo tinib hydrochloride equivalent to 100 mg Erlo tinib

Synonyms - TARCEVA F.C. Tablets 100 mg
- TARCEVA Film Coated Tablets 100 mg

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erlo tinib hydrochloride</td>
<td>35.4 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>183319-69-9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>28.6 %</td>
<td></td>
</tr>
<tr>
<td>9004-34-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate</td>
<td>22.4 %</td>
<td></td>
</tr>
<tr>
<td>64044-51-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>1.9 %</td>
<td></td>
</tr>
<tr>
<td>557-04-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>0.97 %</td>
<td>- Flammable solids (Category 2), H228</td>
</tr>
<tr>
<td>151-21-3</td>
<td></td>
<td>- Acute toxicity (Category 4), H332</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Skin corrosion/irritation (Category 2), H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Serious eye damage/eye irritation (Category 1), H318</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Specific target organ toxicity - Single exposure (Category 3), H335</td>
</tr>
<tr>
<td>Sodium carboxymethyl starch</td>
<td>7.8 %</td>
<td></td>
</tr>
<tr>
<td>9063-38-1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For the full text of the 'Hazard statements' mentioned in this Section, see Section 16.
SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact
- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly

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

Inhalation
- remove the casualty to fresh air
- 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
- no particular hazards known

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions
- avoid exposure

6.2. Environmental precautions

Environmental protection
- do not allow to enter drains or waterways

6.3. Methods and material for containment and cleaning up

Methods for cleaning up
- take up mechanically and dispose of
SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
- avoid formation and deposition of dust

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 15 - 30 °C
- protected from light and humidity

Validity - 3 years, see "best use before" date stated on the label
- 24 months, > 30 °C, Holding Time (Bulk)

Packaging materials - blister packages
- polyethylene bag in metal drum

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.05 mg/m³ *1

8.2. Exposure controls

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

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

Eye protection - safety glasses

*1 referring to: Erlotinib hydrochloride

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour white

Form round, biconvex tablet

Solubility 810 mg/l, water *1

Partition coefficient log P_{ow} 3.37 (n-octanol/water 20 °C) *1
(EC directive 92/69/EEC, A.8 (1992))

Melting temperature 230 to 238 °C (with partial decomposition) *1
9.2. Other information

Note - no information available

*1 referring to: Erlotinib hydrochloride

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Note - no information available

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - warming - light

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
- \( \text{LD}_{50} \) 1'000 to 2'000 mg/kg (oral, rat) *1
- \( \text{LD}_{50} \) > 2'000 mg/kg (oral, mouse) *1
- \( \text{LD}_{50} \) > 2'000 mg/kg (dermal, rabbit) *1

Local effects - no information available

Sensitization - slightly sensitizing (guinea pig) *1

Mutagenicity - not mutagenic (various test systems) *1

Carcinogenicity - no information available
Reproductive toxicity - not teratogenic (several species) *1
- increased embryolethality at doses causing maternal toxicity (several species) *1

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

Note - selective inhibitor of Epidermal Growth Factor Receptor (EGFR) tyrosine kinase, inhibits EGF-induced mitogenesis *1
- therapeutic dose: 150 mg/d *1
- elimination half-life: 3 to 11 h *1
- excretion mainly through pulmonary first-pass and liver metabolism *1
- high doses cause: headache, nausea, diarrhoea *1

*1 referring to: Erlotinib hydrochloride

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Selenastrum capricornutum)
EC₅₀ (72 h) > 100 mg/l (nominal concentration)
NOEC (72 h) 1.39 mg/l (saturation concentration)
(OECD No. 201) *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)
EC₁₀ (48 h) 1.53 mg/l (saturation concentration)
NOEC (48 h) 0.70 mg/l (average measured concentration)
(OECD No. 202) *1
- barely toxic for fish (nominal concentration = 100 mg/l), test performed with water accommodated fractions (zebrafish)
LC₅₀ (96 h) > 100 mg/l (nominal concentration)
LC₀ (96 h) 1.80 mg/l (saturation concentration)
(OECD No. 203, semi-static) *1
- barely toxic for microorganisms (nominal concentration > 100 mg/l) (activated sludge)
NOEC (3 h) 1000 mg/l (nominal concentration)
(Activated Sludge Respir. Inhib. Test, OECD No. 209) *1

12.2. Persistence and degradability

Ready biodegradability - not readily biodegradable
0 %, 28 d
(MITI Test I, OECD No. 301 C) *1
Inherent biodegradability - not inherently biodegradable
0 %, 28 d
(Roche-internal respirometric inherent biodegradation test) *1

12.3. Bioaccumulative potential

Bioconcentration - no significant bioaccumulation (rainbow trout)
Bioaccumulation factor:
BCF ~ 7.8, 14 d, ~ 14 °C, 2 µg/l
BCF ~ 10.1, 14 d, ~ 14 °C, 21 µg/l
Depuration:
DT50 ≤ 7 d
(Bioconcentration: flow-through fish test, 14 days; OECD no. 305) *1

12.4. Mobility in soil

Mobility - strong adsorption, immobile
logKOC = 3.7
KOC = 5470
(OECD No. 121) *1

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Erlotinib hydrochloride

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - return to supplier or hand over to authorised disposal company
- observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing
- medicines should not be disposed of via wastewater

SECTION 14: Transport information

Australian Remark - ADG Code: This product is not classified as a dangerous good.
No special transport conditions are necessary unless required by other regulations.
**SECTION 15: Regulatory information**

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

| Water hazard class (Germany) | 1: weakly hazardous for water (own classification according to directive VwVwS of 27.07.2005) |

**SECTION 16: Other information**

Full text of H-Statements referred to under section 3

- H228 Flammable solid.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.

**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

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**: TARCEVA® Tablets 150 mg
- **Product code**: SAP-10067577

### 1.2. Relevant identified uses of the substance or mixture and uses advised against
- Use: pharmaceutical active substance (antineoplastic)

### 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
- **Phone**: 0061-2-9454-9624
- **Fax**: 0061-2-9971-7401
- **E-Mail**: info.sds@roche.com

### 1.4. Emergency telephone number
- **Emergency telephone number**: 0061-2-9454-9624

*1 referring to: Erlotinib hydrochloride

## 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)
  - 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)

*1
2.3. Other hazards

Note
- no information available

*1 referring to: Erlotinib hydrochloride
*2 referring to: Cellulose
*3 referring to: Lactose
*4 referring to: Magnesium stearate
*5 referring to: Sodium lauryl sulfate
*6 referring to: Sodium carboxymethyl starch

SECTION 3: Composition/information on ingredients

Characterization
each film-coated TARCEVA Tablet contains 163.93 mg Erlotinib hydrochloride equivalent to 150 mg Erlotinib

Synonyms
- TARCEVA F.C. Tablets 150 mg
- TARCEVA Film Coated Tablets 150 mg

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erlotinib hydrochloride</td>
<td>35.4 %</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td>183319-69-9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>28.6 %</td>
<td></td>
</tr>
<tr>
<td>9004-34-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate</td>
<td>22.4 %</td>
<td></td>
</tr>
<tr>
<td>64044-51-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>1.9 %</td>
<td></td>
</tr>
<tr>
<td>557-04-0</td>
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<td></td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>0.97 %</td>
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<tr>
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<td>- Flammable solids (Category 2), H228</td>
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<tr>
<td>01-2119489461-32</td>
<td></td>
<td>- Acute toxicity (Category 4), H332</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Skin corrosion/irritation (Category 2), H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Serious eye damage/eye irritation (Category 1), H318</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Specific target organ toxicity - Single exposure (Category 3), H335</td>
</tr>
<tr>
<td>Sodium carboxymethyl starch</td>
<td>7.8 %</td>
<td></td>
</tr>
<tr>
<td>9063-38-1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For the full text of the 'Hazard statements' mentioned in this Section, see Section 16.
SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact - rinse immediately with tap water for at least 20 minutes - open eyelids forcibly

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

Inhalation - remove the casualty to fresh air - 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 - no particular hazards known

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - avoid exposure

6.2. Environmental precautions

Environmental protection - do not allow to enter drains or waterways

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - take up mechanically and dispose of
SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures
- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
- avoid formation and deposition of dust

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions
- 15 - 30 °C
- protected from light and humidity

Validity
- 3 years, see "best use before" date stated on the label
- 24 months, > 30 °C, Holding Time (Bulk)

Packaging materials
- blister packages
- polyethylene bag in metal drum

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 0.05 mg/m³

8.2. Exposure controls

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

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

Eye protection
- safety glasses

*1 referring to: Erlotinib hydrochloride

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour
white

Form
round, biconvex tablet

Solubility
810 mg/l, water

Partition coefficient
log P_{ow} 3.37 (n-octanol/water 20 °C)
(EC directive 92/69/EEC, A.8 (1992))

Melting temperature
230 to 238 °C (with partial decomposition)
9.2. Other information

Note - no information available

*1 referring to: Erlotinib hydrochloride

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Note - no information available

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - warming
- light

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
- LD$_{50}$ 1'000 to 2'000 mg/kg (oral, rat) *1
- LD$_{50}$ > 2'000 mg/kg (oral, mouse) *1
- LD$_{50}$ > 2'000 mg/kg (dermal, rabbit) *1

Local effects - no information available

Sensitization - slightly sensitizing (guinea pig) *1

Mutagenicity - not mutagenic (various test systems) *1

Carcinogenicity - no information available
Reproductive toxicity - not teratogenic (several species)  
- increased embryolethality at doses causing maternal toxicity (several species)

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

Note - selective inhibitor of Epidermal Growth Factor Receptor (EGFR) tyrosine kinase, inhibits EGF-induced mitogenesis  
- therapeutic dose: 150 mg/d  
- elimination half-life: 3 to 11 h  
- excretion mainly through pulmonary first-pass and liver metabolism  
- high doses cause: headache, nausea, diarrhoea

*1 referring to: Erlotinib hydrochloride

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity - barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Selenastrum capricornutum)  
EC₅₀ (72 h) > 100 mg/l (nominal concentration)  
NOEC (72 h) 1.39 mg/l (saturation concentration) (OECD No. 201)  
- 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)  
EC₁₀ (48 h) 1.53 mg/l (saturation concentration)  
NOEC (48 h) 0.70 mg/l (average measured concentration) (OECD No. 202)  
- barely toxic for fish (nominal concentration = 100 mg/l), test performed with water accommodated fractions (zebrafish)  
LC₅₀ (96 h) > 100 mg/l (nominal concentration)  
LC₀ (96 h) 1.80 mg/l (saturation concentration) (OECD No. 203, semi-static)  
- barely toxic for microorganisms (nominal concentration > 100 mg/l) (activated sludge)  
NOEC (3 h) 1000 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  
(MITI Test I, OECD No. 301 C)
Inherent biodegradability - not inherently biodegradable
0 %, 28 d
(Roche-internal respirometric inherent biodegradation test) \(^*1\)

12.3. Bioaccumulative potential

Bioconcentration - no significant bioaccumulation (rainbow trout)
Bioaccumulation factor:
BCF ~ 7.8, 14 d, ~ 14 °C, 2 µg/l
BCF ~ 10.1, 14 d, ~ 14 °C, 21 µg/l
Depuration:
DT\(_{50}\) \(\leq\) 7 d
(Bioconcentration: flow-through fish test, 14 days; OECD no. 305) \(^*1\)

12.4. Mobility in soil

Mobility - strong adsorption, immobile
\(\log K_{OC} = 3.7\)
\(K_{OC} = 5470\)
(OECD No. 121) \(^*1\)

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

\(^*1\) referring to: Erlotinib hydrochloride

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - return to supplier or hand over to authorised disposal company
- observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing
- medicines should not be disposed of via wastewater

SECTION 14: Transport information

Australian Remark - ADG Code: This product is not classified as a dangerous good. No special transport conditions are necessary unless required by other regulations.
SECTION 15: Regulatory information

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

Water hazard class (Germany) 1: weakly hazardous for water (own classification according to directive VwVwS of 27.07.2005)

SECTION 16: Other information

Full text of H-Statements referred to under section 3

- H228  Flammable solid.
- H302  Harmful if swallowed.
- H315  Causes skin irritation.
- H318  Causes serious eye damage.
- H332  Harmful if inhaled.
- H335  May cause respiratory irritation.

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

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.