



Material Safety Data Sheet

TARCEVA(R) Tablets (25 mg)

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

1.1. Product identifier

Product name TARCEVA(R) Tablets (25 mg)
Product code SAP-10077703
Synonyms - TARCEVA F.C. Tablets (25 mg)
- TARCEVA Film Coated Tablets (25 mg)

1.3. Details of the supplier of the safety data sheet

Company information Enquiries: Local representation:
Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America

Phone 001-973/235 50 00
E-Mail info.sds@roche.com

US Emergency phone: (800)-827-6243
US Chemtrec phone: (800)-424-9300

1.4. Emergency telephone number

Emergency telephone number US emergency phone: (800)-827-6243

SECTION 2: Hazards identification

Emergency Overview

Form round, biconvex tablet
Color white
Hazard Overview - May cause allergic reactions.
- May cause gastrointestinal effects.

TARCEVA(R) Tablets (25 mg)

- Potential Health Effects
- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
 - Target Organs: skin, gastrointestinal system, Immune System

 - Acute Effects: May cause skin irritation., May cause allergic reactions., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.

 - Chronic Effects: No adverse effects known

 - Carcinogenicity: not listed by NTP, IARC or OSHA

Classification of the substance or mixture / Label elements

Other hazards

- Note
- no information available

SECTION 3: Composition/information on ingredients

Characterization

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

| Ingredients | Concentration |
|---|---------------|
| Erlotinib hydrochloride CAS: 183319-69-9 | 26 % |
| Avicel PH-200 CAS: 9004-34-6 | ~ 33 % |
| Magnesium stearate CAS: 557-04-0 | ~ 1 % |
| Sodium starch glycolate CAS: 9063-38-1 | ~ 8 % |

SECTION 4: First aid measures

4.1. Description of first aid measures

- Eye contact
- rinse immediately with tap water for 10 minutes - open eyelids forcibly
- Skin contact
- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
- Inhalation
- remove the casualty to fresh air and keep him/her calm
 - in the event of symptoms get medical treatment

TARCEVA(R) Tablets (25 mg)

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

Flash point (liquid) not applicable

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - take up mechanically and dispose of

SECTION 7: Handling and storage

7.2. Conditions for safe storage, including any incompatibilities

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

Validity - 3 years, see "best use before" date stated on the label

Packaging materials - blister packages

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| | | |
|---------------------------|--|----|
| Threshold value (USA) air | - ACGIH-TLV: 10 mg/m ³ | *1 |
| | - ACGIH-TLV: 10 mg/m ³ | *2 |
| | - OSHA-PEL: 5 mg/m ³ (respirable fraction) | *2 |
| | - OSHA-PEL: 15 mg/m ³ (total dust) | *2 |
| | - NIOSH-REL: 5 mg/m ³ (respirable fraction) | *2 |
| | - NIOSH-REL: 10 mg/m ³ (total dust) | *2 |

TARCEVA(R) Tablets (25 mg)

| | | |
|-----------------------------|---|----|
| | - ACGIH-TLV: 10 mg/m ³ | *3 |
| | - OSHA-PEL: 15 mg/m ³ (total dust) | *3 |
| | - OSHA-PEL: 5 mg/m ³ (respirable fraction) | *3 |
| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 0.05 mg/m ³ | *4 |

8.2. Exposure controls

| | |
|------------------------|---|
| Respiratory protection | - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. - 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: | Magnesium stearate |
| *2 referring to: | Sodium starch glycolate |
| *3 referring to: | AVICEL PH-200 |
| *4 referring to: | Erlotinib hydrochloride |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | | |
|-----------------------|--|----|
| Color | white | |
| Form | round, biconvex tablet | |
| Solubility | 810 mg/l, water | *4 |
| Partition coefficient | log P _{ow} 3.37 (n-octanol/water 20 °C) (EC directive 92/69/EEC, A.8 (1992)) | *4 |
| Melting temperature | 230 to 238 °C (with partial decomposition) | *4 |

9.2. Other information

| | |
|------|----------------------------|
| Note | - no information available |
|------|----------------------------|

| | |
|------------------|-------------------------|
| *4 referring to: | Erlotinib hydrochloride |
|------------------|-------------------------|

SECTION 10: Stability and reactivity

10.1. Reactivity

| | |
|------|----------------------------|
| Note | - no information available |
|------|----------------------------|

TARCEVA(R) Tablets (25 mg)

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) | *4 |
| | - LD ₅₀ > 2'000 mg/kg (oral, mouse) | *4 |
| | - LD ₅₀ > 2'000 mg/kg (dermal, rabbit) | *4 |
| Sensitization | - slightly sensitizing (guinea pig) | *4 |
| Mutagenicity | - not mutagenic (various test systems) | *4 |
| Reproductive toxicity | - not teratogenic (several species) | *4 |
| | - increased embryoletality at doses causing maternal toxicity (several species) | *4 |
| Note | - selective inhibitor of Epidermal Growth Factor Receptor (EGFR) tyrosine kinase, inhibits EGF-induced mitogenesis | *4 |
| | - therapeutic dose: 150 mg/d | *4 |
| | - elimination half-life: 3 to 11 h | *4 |
| | - excretion mainly through pulmonary first-pass and liver metabolism | *4 |
| | - high doses cause: headache, nausea, diarrhea | *4 |

*4 referring to: Erlotinib hydrochloride

TARCEVA(R) Tablets (25 mg)

SECTION 12: Ecological information

12.1. Toxicity

| | |
|-------------|---|
| Ecotoxicity | <ul style="list-style-type: none">- barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (<i>Selenastrum capricornutum</i>) EC₅₀ (72 h) > 100 mg/l (nominal concentration) NOEC (72 h) 1.39 mg/l (saturation concentration) (OECD No. 201) *4- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (<i>Daphnia magna</i>) 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) *4- 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, semistatic) *4- 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) *4 |
|-------------|---|

12.2. Persistence and degradability

| | |
|---------------------------|---|
| Ready biodegradability | <ul style="list-style-type: none">- not readily biodegradable 0 %, 28 d (MITI Test I, OECD No. 301 C) *4 |
| Inherent biodegradability | <ul style="list-style-type: none">- not inherently biodegradable 0 %, 28 d (Roche-internal respirometric inherent biodegradation test) *4 |

12.3. Bioaccumulative potential

| | |
|------------------|---|
| Bioconcentration | <ul style="list-style-type: none">- 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) *4 |
|------------------|---|

12.4. Mobility in soil

| | |
|----------|--|
| Mobility | <ul style="list-style-type: none">- strong adsorption, immobile logKOC = 3.7 K_{oc} = 5470 (OECD No. 121) *4 |
|----------|--|

TARCEVA(R) Tablets (25 mg)

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*4 referring to: Erlotinib hydrochloride

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Edition documentation - first edition

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.



Material Safety Data Sheet

TARCEVA(R) Tablets (100 mg)

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

1.1. Product identifier

Product name TARCEVA(R) Tablets (100 mg)
Product code SAP-10067556
Synonyms - TARCEVA F.C. Tablets (100 mg)
- TARCEVA Film Coated Tablets (100 mg)

1.3. Details of the supplier of the safety data sheet

Company information Enquiries: Local representation:
Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America

Phone 001-973/235 50 00
E-Mail info.sds@roche.com

US Emergency phone: (800)-827-6243
US Chemtrec phone: (800)-424-9300

1.4. Emergency telephone number

Emergency telephone number US emergency phone: (800)-827-6243

SECTION 2: Hazards identification

Emergency Overview

Form round, biconvex tablet
Color white
Hazard Overview - May cause allergic reactions.
- May cause gastrointestinal effects.

TARCEVA(R) Tablets (100 mg)

Potential Health Effects

- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Target Organs: skin, gastrointestinal system, Immune System

- Acute Effects: May cause skin irritation., May cause allergic reactions., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.

- Chronic Effects: No adverse effects known

- Carcinogenicity: not listed by NTP, IARC or OSHA

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

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

Signalword: Warning

Label:



Precautionary statements:

- P260 Do not breathe dust
- P309 + P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.
- P273 Avoid release to the environment.

Other hazards

Note

- no information available

SECTION 3: Composition/information on ingredients

Characterization

each film-coated TARCEVA Tablet contains 109.29 mg Erlotinib hydrochloride equivalent to 100 mg Erlotinib

Ingredients

Concentration

Erlotinib hydrochloride

~ 35 %

CAS: 183319-69-9

Avicel PH-200

~ 29 %

CAS: 9004-34-6

Magnesium stearate

~ 2 %

CAS: 557-04-0

Sodium starch glycolate

~ 8 %

CAS: 9063-38-1

TARCEVA(R) Tablets (100 mg)

SECTION 4: First aid measures

4.1. Description of first aid measures

- | | |
|--------------|--|
| Eye contact | - rinse immediately with tap water for 10 minutes - open eyelids forcibly |
| Skin contact | - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents |
| 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 |
| Flash point (liquid) | not applicable |

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.3. Methods and material for containment and cleaning up

- | | |
|-------------------------|---------------------------------------|
| Methods for cleaning up | - take up mechanically and dispose of |
|-------------------------|---------------------------------------|

SECTION 7: Handling and storage

7.2. Conditions for safe storage, including any incompatibilities

- | | |
|---------------------|---|
| Storage conditions | - 15 - 30 °C - protected from light and humidity |
| Validity | - 3 years, see "best use before" date stated on the label |
| Packaging materials | - blister packages |

TARCEVA(R) Tablets (100 mg)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| | | |
|-----------------------------|---|----|
| Threshold value (USA) air | - ACGIH-TLV: 10 mg/m ³ | *1 |
| | - ACGIH-TLV: 10 mg/m ³ | *2 |
| | - OSHA-PEL: 5 mg/m ³ (respirable fraction) | *2 |
| | - OSHA-PEL: 15 mg/m ³ (total dust) | *2 |
| | - NIOSH-REL: 5 mg/m ³ (respirable fraction) | *2 |
| | - NIOSH-REL: 10 mg/m ³ (total dust) | *2 |
| | - ACGIH-TLV: 10 mg/m ³ | *3 |
| | - OSHA-PEL: 15 mg/m ³ (total dust) | *3 |
| | - OSHA-PEL: 5 mg/m ³ (respirable fraction) | *3 |
| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 0.05 mg/m ³ | *4 |

8.2. Exposure controls

| | |
|------------------------|---|
| Respiratory protection | - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. - 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: | Magnesium stearate |
| *2 referring to: | Sodium starch glycolate |
| *3 referring to: | AVICEL PH-200 |
| *4 referring to: | Erlotinib hydrochloride |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | | |
|-----------------------|--|----|
| Color | white | |
| Form | round, biconvex tablet | |
| Solubility | 810 mg/l, water | *4 |
| Partition coefficient | log P _{ow} 3.37 (n-octanol/water 20 °C) (EC directive 92/69/EEC, A.8 (1992)) | *4 |
| Melting temperature | 230 to 238 °C (with partial decomposition) | *4 |

9.2. Other information

| | |
|------|----------------------------|
| Note | - no information available |
|------|----------------------------|

| | |
|------------------|-------------------------|
| *4 referring to: | Erlotinib hydrochloride |
|------------------|-------------------------|

TARCEVA(R) Tablets (100 mg)

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 - LD₅₀ 1'000 to 2'000 mg/kg (oral, rat) *4
- LD₅₀ > 2'000 mg/kg (oral, mouse) *4
- LD₅₀ > 2'000 mg/kg (dermal, rabbit) *4

Sensitization - slightly sensitizing (guinea pig) *4

Mutagenicity - not mutagenic (various test systems) *4

Reproductive toxicity - not teratogenic (several species) *4
- increased embryoletality at doses causing maternal toxicity (several species) *4

Note - selective inhibitor of Epidermal Growth Factor Receptor (EGFR) tyrosine kinase, inhibits EGF-induced mitogenesis *4
- therapeutic dose: 150 mg/d *4
- elimination half-life: 3 to 11 h *4
- excretion mainly through pulmonary first-pass and liver metabolism *4
- high doses cause: headache, nausea, diarrhea *4

*4 referring to: Erlotinib hydrochloride

TARCEVA(R) Tablets (100 mg)

SECTION 12: Ecological information

12.1. Toxicity

| | |
|-------------|---|
| Ecotoxicity | <ul style="list-style-type: none">- barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (<i>Selenastrum capricornutum</i>) EC₅₀ (72 h) > 100 mg/l (nominal concentration) NOEC (72 h) 1.39 mg/l (saturation concentration) (OECD No. 201) *4- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (<i>Daphnia magna</i>) 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) *4- 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, semistatic) *4- 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) *4 |
|-------------|---|

12.2. Persistence and degradability

| | |
|---------------------------|---|
| Ready biodegradability | <ul style="list-style-type: none">- not readily biodegradable 0 %, 28 d (MITI Test I, OECD No. 301 C) *4 |
| Inherent biodegradability | <ul style="list-style-type: none">- not inherently biodegradable 0 %, 28 d (Roche-internal respirometric inherent biodegradation test) *4 |

12.3. Bioaccumulative potential

| | |
|------------------|---|
| Bioconcentration | <ul style="list-style-type: none">- 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) *4 |
|------------------|---|

12.4. Mobility in soil

| | |
|----------|--|
| Mobility | <ul style="list-style-type: none">- strong adsorption, immobile logKOC = 3.7 K_{oc} = 5470 (OECD No. 121) *4 |
|----------|--|

TARCEVA(R) Tablets (100 mg)

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*4 referring to: Erlotinib hydrochloride

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Edition documentation - changes from previous version in sections 2, 3, 14, 15

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.



Material Safety Data Sheet

TARCEVA(R) Tablets (150 mg)

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

1.1. Product identifier

Product name TARCEVA(R) Tablets (150 mg)
Product code SAP-10067577
Synonyms - TARCEVA F.C. Tablets (150 mg)
- TARCEVA Film Coated Tablets (150 mg)

1.3. Details of the supplier of the safety data sheet

Company information Enquiries: Local representation:
Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America

Phone 001-973/235 50 00
E-Mail info.sds@roche.com

US Emergency phone: (800)-827-6243
US Chemtrec phone: (800)-424-9300

1.4. Emergency telephone number

Emergency telephone number US emergency phone: (800)-827-6243

SECTION 2: Hazards identification

Emergency Overview

Form round, biconvex tablet
Color white
Hazard Overview - May cause allergic reactions.
- May cause gastrointestinal effects.

TARCEVA(R) Tablets (150 mg)

Potential Health Effects

- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Target Organs: skin, gastrointestinal system, Immune System

- Acute Effects: May cause skin irritation., May cause allergic reactions., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.

- Chronic Effects: No adverse effects known

- Carcinogenicity: not listed by NTP, IARC or OSHA

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

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

Signalword: Warning

Label:



Precautionary statements:

- P260 Do not breathe dust
- P309 + P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.
- P273 Avoid release to the environment.

Other hazards

Note

- no information available

SECTION 3: Composition/information on ingredients

Characterization

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

Ingredients

Concentration

Erlotinib hydrochloride

~ 35 %

CAS: 183319-69-9

Avicel PH-200

~ 29 %

CAS: 9004-34-6

Magnesium stearate

~ 2 %

CAS: 557-04-0

Sodium starch glycolate

~ 8 %

CAS: 9063-38-1

TARCEVA(R) Tablets (150 mg)

SECTION 4: First aid measures

4.1. Description of first aid measures

- | | |
|--------------|--|
| Eye contact | - rinse immediately with tap water for 10 minutes - open eyelids forcibly |
| Skin contact | - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents |
| 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 |
| Flash point (liquid) | not applicable |

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.3. Methods and material for containment and cleaning up

- | | |
|-------------------------|---------------------------------------|
| Methods for cleaning up | - take up mechanically and dispose of |
|-------------------------|---------------------------------------|

SECTION 7: Handling and storage

7.2. Conditions for safe storage, including any incompatibilities

- | | |
|---------------------|---|
| Storage conditions | - 15 - 30 °C - protected from light and humidity |
| Validity | - 3 years, see "best use before" date stated on the label |
| Packaging materials | - blister packages |

TARCEVA(R) Tablets (150 mg)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| | | |
|-----------------------------|---|----|
| Threshold value (USA) air | - ACGIH-TLV: 10 mg/m ³ | *1 |
| | - ACGIH-TLV: 10 mg/m ³ | *2 |
| | - OSHA-PEL: 5 mg/m ³ (respirable fraction) | *2 |
| | - OSHA-PEL: 15 mg/m ³ (total dust) | *2 |
| | - NIOSH-REL: 5 mg/m ³ (respirable fraction) | *2 |
| | - NIOSH-REL: 10 mg/m ³ (total dust) | *2 |
| | - ACGIH-TLV: 10 mg/m ³ | *3 |
| | - OSHA-PEL: 15 mg/m ³ (total dust) | *3 |
| | - OSHA-PEL: 5 mg/m ³ (respirable fraction) | *3 |
| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 0.05 mg/m ³ | *4 |

8.2. Exposure controls

| | |
|------------------------|---|
| Respiratory protection | - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. - 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: | Magnesium stearate |
| *2 referring to: | Sodium starch glycolate |
| *3 referring to: | AVICEL PH-200 |
| *4 referring to: | Erlotinib hydrochloride |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | | |
|-----------------------|--|----|
| Color | white | |
| Form | round, biconvex tablet | |
| Solubility | 810 mg/l, water | *4 |
| Partition coefficient | log P _{ow} 3.37 (n-octanol/water 20 °C) (EC directive 92/69/EEC, A.8 (1992)) | *4 |
| Melting temperature | 230 to 238 °C (with partial decomposition) | *4 |

9.2. Other information

| | |
|------|----------------------------|
| Note | - no information available |
|------|----------------------------|

| | |
|------------------|-------------------------|
| *4 referring to: | Erlotinib hydrochloride |
|------------------|-------------------------|

TARCEVA(R) Tablets (150 mg)

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 - LD₅₀ 1'000 to 2'000 mg/kg (oral, rat) *4
- LD₅₀ > 2'000 mg/kg (oral, mouse) *4
- LD₅₀ > 2'000 mg/kg (dermal, rabbit) *4

Sensitization - slightly sensitizing (guinea pig) *4

Mutagenicity - not mutagenic (various test systems) *4

Reproductive toxicity - not teratogenic (several species) *4
- increased embryoletality at doses causing maternal toxicity (several species) *4

Note - selective inhibitor of Epidermal Growth Factor Receptor (EGFR) tyrosine kinase, inhibits EGF-induced mitogenesis *4
- therapeutic dose: 150 mg/d *4
- elimination half-life: 3 to 11 h *4
- excretion mainly through pulmonary first-pass and liver metabolism *4
- high doses cause: headache, nausea, diarrhea *4

*4 referring to: Erlotinib hydrochloride

TARCEVA(R) Tablets (150 mg)

SECTION 12: Ecological information

12.1. Toxicity

| | |
|-------------|---|
| Ecotoxicity | <ul style="list-style-type: none">- barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (<i>Selenastrum capricornutum</i>) EC₅₀ (72 h) > 100 mg/l (nominal concentration) NOEC (72 h) 1.39 mg/l (saturation concentration) (OECD No. 201) *4- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (<i>Daphnia magna</i>) 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) *4- 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, semistatic) *4- 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) *4 |
|-------------|---|

12.2. Persistence and degradability

| | |
|---------------------------|---|
| Ready biodegradability | <ul style="list-style-type: none">- not readily biodegradable 0 %, 28 d (MITI Test I, OECD No. 301 C) *4 |
| Inherent biodegradability | <ul style="list-style-type: none">- not inherently biodegradable 0 %, 28 d (Roche-internal respirometric inherent biodegradation test) *4 |

12.3. Bioaccumulative potential

| | |
|------------------|---|
| Bioconcentration | <ul style="list-style-type: none">- 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) *4 |
|------------------|---|

12.4. Mobility in soil

| | |
|----------|--|
| Mobility | <ul style="list-style-type: none">- strong adsorption, immobile logKOC = 3.7 K_{oc} = 5470 (OECD No. 121) *4 |
|----------|--|

TARCEVA(R) Tablets (150 mg)

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*4 referring to: Erlotinib hydrochloride

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Edition documentation - changes from previous version in sections 2, 3, 15

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.