

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)

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

Use	- pharmaceutical active substance (antineoplastic)	*1
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1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America	Local representation:
	Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	

1.4. Emergency telephone number

Emergency telephone number	US Chemtrec phone: (800)-424-9300
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*1 referring to: Erlotinib hydrochloride

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification	no classification and labelling according to GHS
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Other hazards

Note	- no information available
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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	GHS-Classification (pure ingredient)
Erlotinib hydrochloride 183319-69-9	26 %	- Combustible dust (No category), USH003 - Acute toxicity (Category 4), H302
Microcrystalline cellulose 9004-34-6	33.3 %	
Magnesium stearate 557-04-0	~ 1 %	
Sodium starch glycolate 9063-38-1	~ 8 %	

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	- 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
Flash point (liquid)	not applicable

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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 (USA) air - ACGIH-TLV: 10 mg/m³ *2
- ACGIH-TLV: 10 mg/m³ *3

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- OSHA-PEL: 5 mg/m³ (respirable fraction) *3
- OSHA-PEL: 15 mg/m³ (total dust) *3
- NIOSH-REL: 5 mg/m³ (respirable fraction) *3
- NIOSH-REL: 10 mg/m³ (total dust) *3

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

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: Erlotinib hydrochloride
*2 referring to: Magnesium stearate
*3 referring to: Sodium starch glycolate

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 *1

Partition coefficient log P_{ow} 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

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

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

Sensitization - slightly sensitizing (guinea pig) *1

Mutagenicity - not mutagenic (various test systems) *1

Reproductive toxicity - not teratogenic (several species) *1
- increased embryoletality at doses causing maternal toxicity (several species) *1

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, diarrhea *1

Potential Health Effects - Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Erlotinib hydrochloride

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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, semistatic) *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
K_{oc} = 5470
(OECD No. 121) *1

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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 authorized disposal company
- observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

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

Safety-lab number - BS10396

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Full text of H-Statements referred to under section 3

H302 Harmful if swallowed.

USH003 May form combustible dust concentrations in the air

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, 16

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.