

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)

### 1.2. 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: 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
----------------------------	-----------------------------------

\*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
--------------------	--

### Other hazards

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

## TARCEVA(R) Tablets (100 mg)

### 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	GHS-Classification (pure ingredient)
Erlotinib hydrochloride 183319-69-9	~ 35 %	- Combustible dust (No category), USH003 - Acute toxicity (Category 4), H302
Microcrystalline cellulose 9004-34-6	28.6 %	
Magnesium stearate 557-04-0	~ 2 %	
Sodium starch glycolate 9063-38-1	~ 8 %	

*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
Flash point (liquid)	not applicable

# TARCEVA(R) Tablets (100 mg)

## 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/m<sup>3</sup> \*2  
- ACGIH-TLV: 10 mg/m<sup>3</sup> \*3

## TARCEVA(R) Tablets (100 mg)

- OSHA-PEL: 5 mg/m<sup>3</sup> (respirable fraction) \*3
- OSHA-PEL: 15 mg/m<sup>3</sup> (total dust) \*3
- NIOSH-REL: 5 mg/m<sup>3</sup> (respirable fraction) \*3
- NIOSH-REL: 10 mg/m<sup>3</sup> (total dust) \*3

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.05 mg/m<sup>3</sup> \*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 <sub>ow</sub> 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

## TARCEVA(R) Tablets (100 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 <sub>50</sub> 1'000 to 2'000 mg/kg (oral, rat)	*1
	- LD <sub>50</sub> > 2'000 mg/kg (oral, mouse)	*1
	- LD <sub>50</sub> > 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 embryoletality 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

## TARCEVA(R) Tablets (100 mg)

- Potential Health Effects
- excretion mainly through pulmonary first-pass and liver metabolism\*1
  - high doses cause: headache, nausea, diarrhea \*1
  - Exposure: Inhalation, Ingestion, Skin contact, Eye contact
  - Carcinogenicity: not listed by NTP, IARC or OSHA

\*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<sub>50</sub> (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<sub>50</sub> (48 h) > 100 mg/l (nominal concentration)  
EC<sub>10</sub> (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<sub>50</sub> (96 h) > 100 mg/l (nominal concentration)  
LC<sub>0</sub> (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:  
DT<sub>50</sub> ≤ 7 d  
(Bioconcentration: flow-through fish test, 14 days; OECD no. 305) \*1

## TARCEVA(R) Tablets (100 mg)

### 12.4. Mobility in soil

Mobility - strong adsorption, immobile  
logKOC = 3.7  
K<sub>oc</sub> = 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 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 as Dangerous Good according to the Dangerous Goods 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

## TARCEVA(R) Tablets (100 mg)

### 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 and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

## SECTION 16: Other information

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 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.