

## TARCEVA(R) Tablets (100 mg)

Version  
4.1

Revision Date:  
06-15-2020

Date of last issue: 01-27-2020  
Date of first issue: 12-11-2015

### SECTION 1. IDENTIFICATION

Product name : TARCEVA(R) Tablets (100 mg)

Product code : RO050-8231/F05

Common name(s),  
synonym(s) of the substance : TARCEVA Film Coated Tablets

#### Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : DNA Way 1  
94080 South San Francisco  
CA  
USA

Telephone : 001-(650) 225-1000

E-mail address : info.sds@roche.com

Emergency telephone

Emergency telephone : US Chemtrec phone (800)-424-9300  
number

#### Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

Restrictions on use : For professional users only.

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with 29 CFR 1910.1200

Carcinogenicity : Category 2

#### GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H351 Suspected of causing cancer.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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P308 + P313 IF exposed or concerned: Get medical advice/attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

| Chemical name                                     | CAS-No.      | Concentration (% w/w) |
|---|--------------|-----------------------|
| Erlotinib hydrochloride                           | 183319-69-9  | 35.4                  |
| Cellulose   | 9004-34-6    | 28.6                  |
| Lactose-1-Hydrate                                 | 64044-51-5   | 22.4                  |
| Starch, carboxymethyl ether, sodium salt          | 9063-38-1    | 7.8                   |
| Octadecanoic acid, magnesium salt (2:1)           | 557-04-0     | 1.9                   |
| Sulfuric acid monododecyl ester sodium salt (1:1) | 151-21-3     | < 1.0                 |
| Titanium oxide (TiO <sub>2</sub> )                | 13463-67-7   | < 0.9                 |
| non hazardous compounds                           | Not Assigned | > 2.0                 |

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**SECTION 4. FIRST AID MEASURES**

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If skin irritation persists, call a physician.  
If on skin, rinse well with water.  
If on clothes, remove clothes.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.

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Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed : Suspected of causing cancer.

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:  
Gaseous hydrogen chloride (HCl).  
Nitrogen oxides (NOx)

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.

Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE**

Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid contact with skin and eyes.

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For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.

- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Containers which are opened must be carefully resealed and kept upright to prevent leakage.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Storage temperature : Protected from heat and light  
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass, Polyethylene bag in metal drum, Blister packages

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components                              | CAS-No.     | Value type (Form of exposure)  | Control parameters / Permissible concentration | Basis                                     |
|---|-------------|--------------------------------|--|---|
| Erlotinib hydrochloride                 | 183319-69-9 | IOEL                           | 0.05 mg/m <sup>3</sup>                         | Roche Industrial Hygiene Committee (RIHC) |
| Cellulose                               | 9004-34-6   | TWA                            | 10 mg/m <sup>3</sup>                           | ACGIH                                     |
|   |             | TWA (Respirable)               | 5 mg/m <sup>3</sup>                            | NIOSH REL                                 |
|   |             | TWA (total)                    | 10 mg/m <sup>3</sup>                           | NIOSH REL                                 |
|   |             | TWA (total dust)               | 15 mg/m <sup>3</sup>                           | OSHA Z-1                                  |
|   |             | TWA (respirable fraction)      | 5 mg/m <sup>3</sup>                            | OSHA Z-1                                  |
|   |             | TWA (Total dust)               | 15 mg/m <sup>3</sup>                           | OSHA P0                                   |
|   |             | TWA (respirable dust fraction) | 5 mg/m <sup>3</sup>                            | OSHA P0                                   |
| Octadecanoic acid, magnesium salt (2:1) | 557-04-0    | TWA (Inhalable fraction)       | 10 mg/m <sup>3</sup>                           | ACGIH                                     |

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|                       |            |                                 |                                |          |
|-----------------------|------------|---------------------------------|--------------------------------|----------|
|                       |            | TWA<br>(Respirable<br>fraction) | 3 mg/m3                        | ACGIH    |
| Titanium oxide (TiO2) | 13463-67-7 | TWA (total<br>dust)             | 15 mg/m3                       | OSHA Z-1 |
|                       |            | TWA (Total<br>dust)             | 10 mg/m3                       | OSHA P0  |
|                       |            | TWA                             | 10 mg/m3<br>(Titanium dioxide) | ACGIH    |

### Predicted No Effect Concentration (PNEC):

| Substance name                                       | Environmental Compartment         | Value       |
|--|-----------------------------------|-------------|
| Erlotinib hydrochloride                              | Surface waters                    | 56 µg/l     |
|  | Remarks:<br>Based on chronic data |             |
| Sulfuric acid monododecyl ester<br>sodium salt (1:1) | Fresh water                       | 0.176 mg/l  |
|  | Sea water                         | 0.0176 mg/l |
|  | Fresh water sediment              | 6.97 mg/kg  |
|  | Sea sediment                      | 0.697 mg/kg |
|  | Soil                              | 1.29 mg/kg  |

**Engineering measures** : No data available

### Personal protective equipment

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.  
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles

Skin and body protection : Dust impervious protective suit  
Choose body protection according to the amount and  
concentration of the dangerous substance at the work place.

Hygiene measures : When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and at the end of workday.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Color : white

Odor : Not applicable

Odor Threshold : Not applicable

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|  |   |                             |
|--|---|-----------------------------|
| pH   | : | Not applicable              |
| Melting point/range                              | : | 446 - 460 °F / 230 - 238 °C |
| Boiling point/boiling range                      | : | No data available           |
| Flash point                                      | : | does not flash              |
| Evaporation rate                                 | : | No data available           |
| Self-ignition                                    | : | No data available           |
| Upper explosion limit / Upper flammability limit | : | No data available           |
| Lower explosion limit / Lower flammability limit | : | No data available           |
| Vapor pressure                                   | : | No data available           |
| Relative vapor density                           | : | Not applicable              |
| Relative density                                 | : | No data available           |
| Solubility(ies)                                  |   |                             |
| Water solubility                                 | : | 0.81 g/l slightly soluble   |
| Solubility in other solvents                     | : | No data available           |
| Partition coefficient: n-octanol/water           | : | No data available           |
| Autoignition temperature                         | : | No data available           |
| Decomposition temperature                        | : | No data available           |
| Viscosity  |   |                             |
| Viscosity, dynamic                               | : | Not applicable              |
| Viscosity, kinematic                             | : | Not applicable              |

**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |   |
|------------------------------------|---|---|
| Reactivity                         | : | No dangerous reaction known under conditions of normal use. |
| Chemical stability                 | : | Stable under normal conditions.                             |
| Possibility of hazardous reactions | : | No decomposition if stored and applied as directed.         |
| Conditions to avoid                | : | Exposure to light.<br>Heat.                                 |
| Incompatible materials             | : | No data available   |

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Hazardous decomposition products : No data available

**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Assessment: The component/mixture is minimally toxic after single ingestion.

Acute dermal toxicity : Acute toxicity estimate: 3,906 mg/kg  
Method: Calculation method**Components:****Erlotinib hydrochloride:**

Acute oral toxicity : LD50 Oral (Rat): 1,000 - 2,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): &gt; 2,000 mg/kg

**Cellulose:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 5,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): &gt; 2,000 mg/kg

**Octadecanoic acid, magnesium salt (2:1):**

Acute oral toxicity : LD50 Oral (Rat): &gt; 2,000 mg/kg

**Titanium oxide (TiO<sub>2</sub>):**

Acute oral toxicity : LD50 (Rat): &gt; 7,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): &gt; 10,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

Remarks : May cause skin irritation and/or dermatitis.

**Components:****Erlotinib hydrochloride:**Species : Rabbit  
Result : Mild skin irritation

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**Serious eye damage/eye irritation**

Not classified based on available information.

**Product:**

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

**Components:**

**Erlotinib hydrochloride:**

Species : Rabbit  
Result : No eye irritation

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**Erlotinib hydrochloride:**

Species : guinea pig  
Remarks : Causes sensitization.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Erlotinib hydrochloride:**

Genotoxicity in vitro : Test Type: in vitro test  
Result: negative

**Carcinogenicity**

Suspected of causing cancer.

**Components:**

**Cellulose:**

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**IARC** Group 2B: Possibly carcinogenic to humans  
Titanium oxide (TiO<sub>2</sub>) 13463-67-7

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.



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### Reproductive toxicity

Not classified based on available information.

#### Components:

#### Erlotinib hydrochloride:

Effects on fetal development : Species: laboratory animal  
Result: No teratogenic effects., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

### STOT-single exposure

Not classified based on available information.

#### Components:

#### Octadecanoic acid, magnesium salt (2:1):

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

### STOT-repeated exposure

Not classified based on available information.

#### Components:

#### Octadecanoic acid, magnesium salt (2:1):

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

### Repeated dose toxicity

#### Components:

#### Erlotinib hydrochloride:

Species : Rat  
NOAEL : mg/kg bw/day, 1  
Application Route : Oral  
Exposure time : 6 Months

### Aspiration toxicity

Not classified based on available information.

#### Components:

#### Octadecanoic acid, magnesium salt (2:1):

No data available

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Erlotinib hydrochloride:

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- Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
GLP: yes
- LC0 (Danio rerio (zebra fish)): 1.8 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
GLP: yes
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: Measured value
- NOEC (Daphnia magna (Water flea)): 0.70 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: Measured value
- EC10 (Daphnia magna (Water flea)): 1.53 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: Measured value
- Toxicity to algae/aquatic plants : ErC50 (Selenastrum capricornutum (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration
- NOEC (Selenastrum capricornutum (green algae)): 1.39 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes
- Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 0.56 mg/l  
Exposure time: 30 d  
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)  
Method: OECD Test Guideline 210  
GLP: yes  
Remarks: nominal concentration
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.6 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
GLP: yes  
Remarks: nominal concentration
- Toxicity to microorganisms : NOEC (activated sludge): 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

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Method: OECD Test Guideline 209  
GLP: yes  
Remarks: nominal concentration

### Cellulose:

#### Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

### Octadecanoic acid, magnesium salt (2:1):

#### Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

### Titanium oxide (TiO<sub>2</sub>):

Toxicity to fish : LC<sub>0</sub> (Leuciscus idus (Golden orfe)): > 1,000 mg/l  
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates : EC<sub>0</sub> (Daphnia magna (Water flea)): 3 mg/l  
Exposure time: 720 h

#### Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

### Persistence and degradability

#### Components:

#### Erlotinib hydrochloride:

Biodegradability : Concentration: 100 mg/l  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C  
GLP: yes

Concentration: 30 mg/l  
Result: Not inherently biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
GLP: no

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Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)  
 Bioconcentration factor (BCF): 7.8  
 Exposure time: 14 d  
 Temperature: 57 °F / 14 °C  
 Concentration: ca. 2 µg/l  
 Method: OECD Test Guideline 305  
 GLP: yes  
 Remarks: Does not significantly accumulate in organisms.

Species: Oncorhynchus mykiss (rainbow trout)  
 Bioconcentration factor (BCF): 10.1  
 Exposure time: 14 d  
 Temperature: 57 °F / 14 °C  
 Concentration: ca. 21 µg/l  
 Method: OECD Test Guideline 305  
 GLP: yes  
 Remarks: Does not significantly accumulate in organisms.

Partition coefficient: n-octanol/water : log Pow: 3.37 (68 °F / 20 °C)  
 Method: Tested according to Directive 92/69/EEC.  
 GLP: yes

**Cellulose:**

Partition coefficient: n-octanol/water : Remarks: No data available

**Octadecanoic acid, magnesium salt (2:1):**

Partition coefficient: n-octanol/water : log Pow: 0.8  
 Method: OECD Test Guideline 107

**Titanium oxide (TiO<sub>2</sub>):**

Partition coefficient: n-octanol/water : Remarks: No data available

**Mobility in soil****Components:****Erlotinib hydrochloride:**

Distribution among environmental compartments : Koc: 5470, log Koc: 3.7  
 Method: OECD Test Guideline 121  
 Remarks: immobile

**Other adverse effects****Product:**

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Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82  
Protection of Stratospheric Ozone - CAA Section 602 Class I  
Substances  
Remarks: This product neither contains, nor was  
manufactured with a Class I or Class II ODS as defined by the  
U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +  
B).

Additional ecological information : An environmental hazard cannot be excluded in the event of  
unprofessional handling or disposal.  
Toxic to aquatic life with long lasting effects.

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : The product should not be allowed to enter drains, water  
courses or the soil.  
Do not contaminate ponds, waterways or ditches with  
chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with  
local regulations.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste  
handling site for recycling or disposal.  
Do not re-use empty containers.

**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Erlotinib hydrochloride mixture)  
Class : 9  
Packing group : III  
Labels : 9

**IATA-DGR**

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Erlotinib hydrochloride mixture)  
Class : 9  
Packing group : III  
Labels :  
Packing instruction (cargo  
aircraft) : 956  
Packing instruction  
(passenger aircraft) : 956  
Environmentally hazardous : yes

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**IMDG-Code**

UN number : UN 3077  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Erlotinib hydrochloride mixture)  
 Class : 9  
 Packing group : III  
 Labels : 9  
 EmS Code : F-A, S-F  
 Marine pollutant : yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable

**Domestic regulation**

**49 CFR**

UN/ID/NA number : UN 3077  
 Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Erlotinib hydrochloride mixture)  
 Class : 9  
 Packing group : III  
 Labels : Class 9 - Miscellaneous dangerous substances and articles  
 ERG Code : 171  
 Marine pollutant : no

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

**SECTION 15. REGULATORY INFORMATION**

**EPCRA - Emergency Planning and Community Right-to-Know**

**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

| Components | CAS-No. | Component TPQ (lbs) |
|------------|---------|---------------------|
|------------|---------|---------------------|

**SARA 311/312 Hazards** : Carcinogenicity

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

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This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**US State Regulations**

**Massachusetts Right To Know**

Cellulose 9004-34-6

**Pennsylvania Right To Know**

Erlotinib hydrochloride 183319-69-9  
Cellulose 9004-34-6  
Lactose-1-Hydrate 64044-51-5  
Starch, carboxymethyl ether, sodium salt 9063-38-1

**Maine Chemicals of High Concern**

**Vermont Chemicals of High Concern**

**Washington Chemicals of High Concern**

**California Prop. 65**

WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose 9004-34-6  
Octadecanoic acid, magnesium salt (2:1) 557-04-0

**The ingredients of this product are reported in the following inventories:**

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Erlotinib hydrochloride  
non hazardous compounds

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

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TCSI : Not in compliance with the inventory

TSCA : Substance(s) not listed on TSCA inventory

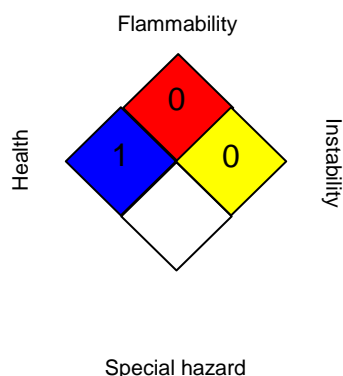
### TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

## SECTION 16. OTHER INFORMATION

### NFPA:



### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | * | 1 |
| FLAMMABILITY    |   | 0 |
| PHYSICAL HAZARD |   | 0 |

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL : USA. NIOSH Recommended Exposure Limits
- OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA : 8-hour, time-weighted average
- NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification



## TARCEVA(R) Tablets (100 mg)

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4.1

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System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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