SAFETY DATA SHEET

TARCEVA(R) Tablets (25 mg)

Version: 2.0
Revision Date: 01-27-2020
Date of last issue: 06-10-2017
Date of first issue: 01-25-2017

SECTION 1. IDENTIFICATION

Product name: TARCEVA(R) Tablets (25 mg)
Product code: RO050-8231/F04
Common name(s), synonym(s) of the substance: TARCEVA Film Coated Tablets 25 mg

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: US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use: Formulated pharmaceutical active substance
Restrictions on use: For professional users only.

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erlotinib hydrochloride</td>
<td>183319-69-9</td>
<td>26.5</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>34.0</td>
</tr>
<tr>
<td>Lactose-1-Hydrate</td>
<td>64044-51-5</td>
<td>26.6</td>
</tr>
<tr>
<td>Starch, carboxymethyl ether, sodium salt</td>
<td>9063-38-1</td>
<td>7.8</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>1.2</td>
</tr>
<tr>
<td>Sulfuric acid monododecyl ester sodium salt (1:1)</td>
<td>151-21-3</td>
<td>&lt; 1.0</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>&lt; 0.9</td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>&gt; 2.0</td>
</tr>
</tbody>
</table>

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:
Flush eyes with water as a precaution.
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.
Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.

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: No information available.

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

Further information: Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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 further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.

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: Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling: Avoid contact with skin and eyes. Smoking, eating and drinking should be prohibited in the
Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place. 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>5 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td>Erlotinib hydrochloride</td>
<td>183319-69-9</td>
<td>IOEL</td>
<td>0.05 mg/m3</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total)</td>
<td>10 mg/m3</td>
<td>OSHA P0</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

TARCEVA(R) Tablets (25 mg)

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid monododecyl ester sodium salt (1:1)</td>
<td>Fresh water</td>
<td>0.176 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sea water</td>
<td>0.0176 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>6.97 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Sea sediment</td>
<td>0.697 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>1.29 mg/kg</td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC):**

**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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: tablet

**Color**: white

**Odor**: Not applicable

**Odor Threshold**: Not applicable

**pH**: Not applicable

**Melting point/range**: No data available

**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 : No data available
  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
Explosive properties : No data available
Oxidizing properties : No data available

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 : No data available
Incompatible materials : No data available
Hazardous decomposition products : No data available
SECTION 11. TOXICOLOGICAL INFORMATION

**Acute toxicity**
Not classified based on available information.

**Product:**
- **Acute oral toxicity**
  - Assessment: The substance or mixture has no acute oral toxicity

- **Acute dermal toxicity**
  - Acute toxicity estimate: 4,132 mg/kg
  - Method: Calculation method

**Components:**
- **Cellulose:**
  - **Acute oral toxicity**
    - LD50 Oral (Rat): > 5,000 mg/kg

  - **Acute dermal toxicity**
    - LD50 Dermal (Rabbit): > 2,000 mg/kg

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

  - **Acute dermal toxicity**
    - LD50 Dermal (Rabbit): > 2,000 mg/kg

- **Octadecanoic acid, magnesium salt (2:1):**
  - **Acute oral toxicity**
    - LD50 Oral (Rat): > 2,000 mg/kg

- **Titanium oxide (TiO2):**
  - **Acute oral toxicity**
    - LD50 (Rat): > 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): > 10,000 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Product:**
- **Remarks**
  - May cause skin irritation in susceptible persons.

**Components:**
- **Erlotinib hydrochloride:**
  - **Species**
    - Rabbit

  - **Remarks**
    - Mild skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.
<table>
<thead>
<tr>
<th>Components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Erlotinib hydrochloride:</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Respiratory or skin sensitization</td>
<td></td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Not classified based on available information.</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>Not classified based on available information.</td>
</tr>
<tr>
<td>Components:</td>
<td></td>
</tr>
<tr>
<td>Erlotinib hydrochloride:</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>guinea pig</td>
</tr>
<tr>
<td>Remarks</td>
<td>Causes sensitization.</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td></td>
</tr>
<tr>
<td>Not classified based on available information.</td>
<td></td>
</tr>
<tr>
<td>Components:</td>
<td></td>
</tr>
<tr>
<td>Erlotinib hydrochloride:</td>
<td></td>
</tr>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: in vitro test</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td></td>
</tr>
<tr>
<td>Suspected of causing cancer.</td>
<td></td>
</tr>
<tr>
<td>Components:</td>
<td></td>
</tr>
<tr>
<td>Cellulose:</td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td>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.</td>
</tr>
<tr>
<td>IARC</td>
<td>Group 2B: Possibly carcinogenic to humans</td>
</tr>
<tr>
<td></td>
<td>Titanium oxide (TiO2)</td>
</tr>
<tr>
<td></td>
<td>13463-67-7</td>
</tr>
<tr>
<td>OSHA</td>
<td>No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.</td>
</tr>
<tr>
<td>NTP</td>
<td>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.</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td></td>
</tr>
<tr>
<td>Not classified based on available information.</td>
<td></td>
</tr>
<tr>
<td>Components:</td>
<td></td>
</tr>
<tr>
<td>Erlotinib hydrochloride:</td>
<td></td>
</tr>
<tr>
<td>Effects on fetal development</td>
<td>Species: laboratory animal</td>
</tr>
</tbody>
</table>
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 month

**Aspiration toxicity**
Not classified based on available information.

**Components:**

**Octadecanoic acid, magnesium salt (2:1):**
No data available

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Cellulose:**

**Ecotoxicology Assessment**
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.
Erlotinib hydrochloride:

**Toxicity to fish**
- LC50 (Danio rerio (zebra fish)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - GLP: yes
  - Remarks: nominal concentration

- 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: nominal concentration

- 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 microorganisms**
- NOEC (activated sludge): 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - GLP: yes
  - Remarks: nominal concentration

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 (TiO2):

Toxicity to fish: LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates: EC0 (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

Bioaccumulative potential

Components:

Cellulose:

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

Erlotinib hydrochloride:

Bioaccumulation: Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 7.8
Exposure time: 14 d
Temperature: 14 °C / 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: 14 °C / 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 (20 °C / 20 °C)  
Method: Tested according to Directive 92/69/EEC.  
GLP: yes

Octadecanoic acid, magnesium salt (2:1):  
Partition coefficient: n-octanol/water  
: log Pow: 0.8  
Method: OECD Test Guideline 107

Titanium oxide (TiO2):  
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:

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).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues  
: 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
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

Domestic regulation

49 CFR
Not regulated as a dangerous good

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

<table>
<thead>
<tr>
<th>Components CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 311/312 Hazards</td>
<td>Carcinogenicity</td>
</tr>
</tbody>
</table>

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).
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**

- Cellulose 9004-34-6
- Lactose-1-Hydrate 64044-51-5
- Erlotinib hydrochloride 183319-69-9
- 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.

**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
- 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:**

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
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</table>

**HMIS® IV:**

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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 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; KECl - 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 Oth-
SAFETY DATA SHEET

TARCEVA(R) Tablets (25 mg)

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