

TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 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), : TARCEVA Film Coated Tablets 25 mg

synonym(s) of the substance BS10396

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.

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:



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

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

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

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.



TARCEVA(R) Tablets (25 mg)

Version **Revision Date:** Date of last issue: 01-27-2020 2.1 06-15-2020 Date of first issue: 01-25-2017

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.

The first aid procedure should be established in consultation Notes to physician

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 (HCI).

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.

For personal protection see section 8.



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 O6-15-2020 Date of first issue: 01-25-2017

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
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
Erlotinib hydrochloride	183319-69-9	IOEL	0.05 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable fraction)	10 mg/m3	ACGIH
_		TWA	3 mg/m3	ACGIH



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

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

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Erlotinib hydrochloride	Surface waters	56 μg/l
	Remarks:	
	Based on chronic data	
Sulfuric acid monododecyl ester 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

pH : Not applicable



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

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



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

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 component/mixture is minimally toxic after

single ingestion.

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 and/or dermatitis.

Components:

Erlotinib hydrochloride:

Species : Rabbit

Result : Mild skin irritation



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

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 (TiO2) 13463-67-7

OSHANo 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



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

identified as a known or anticipated carcinogen by NTP.

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



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

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

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



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

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 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



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

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: 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

Octadecanoic acid, magnesium salt (2:1):

Partition coefficient: n- : log Pow: 0.8

octanol/water 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 : Koc: 5470, log Koc: 3.7



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

environmental compartments 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).

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 307

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Erlotinib hydrochloride mixture)

Class : 9



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 O6-15-2020 Date of first issue: 01-25-2017

Packing group : III Labels :

Packing instruction (cargo : 956

aircraft)

Packing instruction : 956

(passenger aircraft)

Environmentally hazardous : yes

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



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 O6-15-2020 Date of first issue: 01-25-2017

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 SOCMI 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



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 O6-15-2020 Date of first issue: 01-25-2017

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

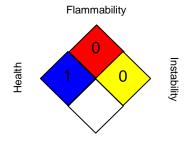
TSCA list

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:



Special hazard

HMIS® IV:



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 PO : 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,



TARCEVA(R) Tablets (25 mg)

Version Revision Date: Date of last issue: 01-27-2020 2.1 Date of first issue: 01-25-2017

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; 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 Cooperation 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

Revision Date : 06-15-2020

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.

US / Z8 / 1810