

ALECENSA® Capsules (150 mg)

Version
2.0

Revision Date:
10-03-2022

Date of last issue: 01-16-2020
Date of first issue: 06-10-2017

SECTION 1. IDENTIFICATION

Product name : ALECENSA® Capsules (150 mg)

Product code : RO542-4802/F16

Common name(s), syno- : Alectinib Capsules 150 mg
nym(s) of the substance BS10767

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : 1 DNA Way
South San Francisco, CA 94080
USA

Telephone : 001-(650) 225-1000

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

Emergency telephone

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

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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin irritation : Category 2

Serious eye damage : Category 1

Germ cell mutagenicity : Category 2

Carcinogenicity : Category 2

Reproductive toxicity : Category 2

Specific target organ toxicity : Category 2
- repeated exposure

GHS label elements

Hazard pictograms :



Signal Word : Danger

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Hazard Statements : H315 Causes skin irritation.
H318 Causes serious eye damage.
H341 Suspected of causing genetic defects.
H351 Suspected of causing cancer.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

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)
Alectinib hydrochloride	1256589-74-8	40.3
Cellulose, 2-hydroxypropyl methyl ether	9004-65-3	19.2
Sulfuric acid monododecyl ester sodium salt (1:1)	151-21-3	18.8
Cellulose, carboxymethyl ether, calcium salt	9050-04-8	10.8

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Lactose-monohydrate	10039-26-6	8.4
Titanium oxide (TiO ₂)	13463-67-7	1.1
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.4
non hazardous compounds	Not Assigned	1.0

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Consult a physician.
Show this material safety data sheet to the doctor in attendance.
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 : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
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 induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Causes skin irritation.
Causes serious eye damage.
Suspected of causing genetic defects.
Suspected of causing cancer.
Suspected of damaging fertility. Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

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- 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:
Carbon oxides
Nitrogen oxides (NO_x)
Gaseous hydrogen chloride (HCl).
Sulfur oxides
Sodium oxides
- 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 : Avoid exposure
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.
If the product contaminates rivers and lakes or drains inform respective authorities.
- 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 formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
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

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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 : to 30 °C
Protect against light.
Protect from moisture.

Further information on storage stability : No decomposition if stored and applied as directed.

Packaging material : Suitable material: Blister packages, Stainless steel, glass

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Alectinib hydrochloride The value is given in analogy to the following substances: Alectinib	1256589-74-8	IOEL	0.001 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
Titanium oxide (TiO ₂)	13463-67-7	TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (Total dust)	10 mg/m ³	OSHA P0
		TWA	10 mg/m ³ (Titanium dioxide)	ACGIH

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Alectinib hydrochloride	Surface waters	0.0133 mg/l
	Remarks: Based on chronic data	
Sodium dodecylsulfate	Fresh water	0.176 mg/l

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
Effective dust mask

Hand protection

Material : In case of contact through splashing:
Nitrile rubber

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Break through time : > 30 min
 Glove thickness : > 0.11 mm

Material : butyl-rubber
 Break through time : > 480 min
 Glove thickness : > 0.4 mm

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
 Wear face-shield and protective suit for abnormal processing problems.

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

Protective measures : Instruction of employees recommended

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 : capsules

Color : white, light yellow

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

Flammability (solid, gas) : Not classified as a flammability hazard
 Remarks: Expert judgment

Self-ignition : No data available

Upper explosion limit / Upper : No data available

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flammability limit

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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-
tions : No decomposition if stored and applied as directed.Conditions to avoid : Do not expose to temperatures above: 100 °C
Exposure to moisture.
Exposure to light.

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 : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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Acute inhalation toxicity : Acute toxicity estimate: 7.85 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Alectinib hydrochloride:**

Acute oral toxicity : LD0 (Rat): 2,000 mg/kg
Assessment: The component/mixture is minimally toxic after single ingestion.

Sulfuric acid monododecyl ester sodium salt (1:1):

Acute oral toxicity : LD50 Oral (Rat, male and female): 1,200 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402
GLP: yes
Remarks: No mortality observed at this dose.

Cellulose, carboxymethyl ether, calcium salt:

Acute oral toxicity : LD50 Oral (Rat): > 5,050 mg/kg

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

Lactose-monohydrate:

Acute oral toxicity : LD50 Oral (Rat): > 10,000 mg/kg

Titanium oxide (TiO₂):

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 425

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

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Product:

Remarks : May cause skin irritation in susceptible persons.

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Species : Rabbit
Method : OECD Test Guideline 404
Result : Irritating to skin.
GLP : no

Titanium oxide (TiO₂):

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks : May cause irreversible eye damage.

Components:**Sulfuric acid monododecyl ester sodium salt (1:1):**

Species : Rabbit
Result : Risk of serious damage to eyes.
Method : OECD Test Guideline 405
GLP : no

Titanium oxide (TiO₂):

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Sulfuric acid monododecyl ester sodium salt (1:1):**

Result : Did not cause sensitization on laboratory animals.

Titanium oxide (TiO₂):

Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406

Germ cell mutagenicity

Suspected of causing genetic defects.

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- Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 487
Result: positive
- Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 473
Result: negative
- Test Type: Ames test
Metabolic activation: with and without metabolic activation
Result: negative
- Genotoxicity in vivo : Test Type: In vivo micronucleus test
Application Route: Oral
Method: OECD Test Guideline 474
Result: positive
GLP: yes
Remarks: Not classified due to data which are conclusive although insufficient for classification.
- Germ cell mutagenicity - Assessment : In vitro tests showed mutagenic effects

Sulfuric acid monododecyl ester sodium salt (1:1):

- Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Method: OECD Test Guideline 471
Result: negative
- Genotoxicity in vivo : Test Type: Micronucleus test
Method: OECD Test Guideline 474
Result: negative

Carcinogenicity

Suspected of causing cancer.

Components:**Cellulose, carboxymethyl ether, calcium salt:**

- 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.

Lactose-monohydrate:

- 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

OSHA No component of this product present at levels greater than or equal to 0.1% is

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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.

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:**Alectinib hydrochloride:**

Effects on fetal development : Species: Rat, females
Application Route: Oral
Dose: 3 mg/kg bw/day
Duration of Single Treatment: 11 d
GLP: yes
Remarks: NOAEL (No observed adverse effect level)

Species: laboratory animal
Symptoms: Skeletal and visceral variations ., Skeletal malformations.
Result: Effects on fetal development., Fetal growth retardation

Reproductive toxicity - Assessment : Suspected human reproductive toxicant, Suspected of damaging fertility., Suspected of damaging the unborn child.

STOT-single exposure

Not classified based on available information.

Components:**Sulfuric acid monododecyl ester sodium salt (1:1):**

Routes of exposure : Inhalation
Target Organs : Respiratory Tract
Assessment : May cause respiratory irritation.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:**Alectinib hydrochloride:**

Assessment : May cause damage to organs through prolonged or repeated exposure.

Aspiration toxicity

Not classified based on available information.

Further information**Components:****Alectinib hydrochloride:**

Test Type : OECD Test Guideline 432

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Remarks : Phototoxic (in vitro)
The value is given in analogy to the following substances: Alectinib

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Alectinib hydrochloride:**

- Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10 mg/l
End point: mortality
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
Remarks: nominal concentration
- 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)): 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration
- Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 11.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: average measured concentration
- EyC50 (Raphidocelis subcapitata (freshwater green alga)): > 11.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: average measured concentration
- NOEC (Raphidocelis subcapitata (freshwater green alga)): > 11.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: average measured concentration
- Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 10 mg/l
Exposure time: 36 d
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Analytical monitoring: yes

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GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.133 mg/l
End point: Immobilization
Exposure time: 21 d
Analytical monitoring: yes
Method: OECD Test Guideline 211
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: Barely inhibitory on aerobic bacterial respiration

Sulfuric acid monododecyl ester sodium salt (1:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 3.6 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): > 1.36 mg/l
Exposure time: 42 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l
Exposure time: 7 d

Toxicity to microorganisms : EC0 (Pseudomonas putida): > 100 mg/l
Method: OECD Test Guideline 209

Titanium oxide (TiO₂):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h
Test Type: static test

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h

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Method: OECD Test Guideline 201EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
Method: ISO 10253NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l
Exposure time: 72 h
Method: ISO 10253**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:****Alectinib hydrochloride:**Biodegradability : aerobic
Concentration: 46,95 mg/ml
Theoretical oxygen demand
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes**Sulfuric acid monododecyl ester sodium salt (1:1):**Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Readily biodegradable.
Biodegradation: 95 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes**Titanium oxide (TiO₂):**

Biodegradability : Remarks: Not applicable

Bioaccumulative potential**Components:****Alectinib hydrochloride:**Bioaccumulation : Species: Danio rerio (zebra fish)
Bioconcentration factor (BCF): 147.7
Exposure time: 32 d
Method: OECD Test Guideline 305
GLP: yes

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Partition coefficient: n-octanol/water : log Pow: 3.85
Method: OECD Test Guideline 117
GLP: yes
The value is given in analogy to the following substances:
Alectinib

Sulfuric acid monododecyl ester sodium salt (1:1):

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 3.9 - 5.3
Exposure time: 3 d

Partition coefficient: n-octanol/water : log Pow: -2.03 (68 °F / 20 °C)
Method: OECD Test Guideline 107

Cellulose, carboxymethyl ether, calcium salt:

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

Lactose-monohydrate:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: -5.03

Titanium oxide (TiO₂):

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

Mobility in soil**Components:**

Alectinib hydrochloride:

Distribution among environmental compartments : Medium: Soil
Koc: 14921 - 32878 ml/g
Method: OECD Test Guideline 106
Remarks: immobile

Medium: Sludge
Koc: 5707 - 16634 ml/g
Method: OECD Test Guideline 106
Remarks: immobile

Medium: Sludge
Kd: 1,473 - 4,294 ml/g
Method: OECD Test Guideline 106
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.
 Harmful to aquatic life.
 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.
- 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.
 (Alectinib 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.
 (Alectinib Hydrochloride Mixture)
 Class : 9
 Packing group : III
 Labels : Miscellaneous
 Packing instruction (cargo aircraft) : 956
 Packing instruction (passenger aircraft) : 956
 Environmentally hazardous : yes

IMDG-Code

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UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Alectinib 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.
(Alectinib Hydrochloride Mixture)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : no

Special precautions for user

Remarks : No data available

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**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

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Germ cell mutagenicity
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

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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 SOCOMI 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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations**Massachusetts Right To Know**

Titanium oxide (TiO ₂)	13463-67-7
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Pennsylvania Right To Know

Alectinib hydrochloride	1256589-74-8
Cellulose, 2-hydroxypropyl methyl ether	9004-65-3
Sulfuric acid monododecyl ester sodium salt (1:1)	151-21-3
Cellulose, carboxymethyl ether, calcium salt	9050-04-8
Lactose-monohydrate	10039-26-6
Titanium oxide (TiO ₂)	13463-67-7

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

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

Titanium oxide (TiO ₂)	13463-67-7
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The ingredients of this product are reported in the following inventories:

AICC : Not in compliance with the inventory

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

Alectinib hydrochloride

ALECENSA® Capsules (150 mg)

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non hazardous compounds

Cellulose, carboxymethyl ether, calcium salt

- 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 : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not in compliance with the inventory

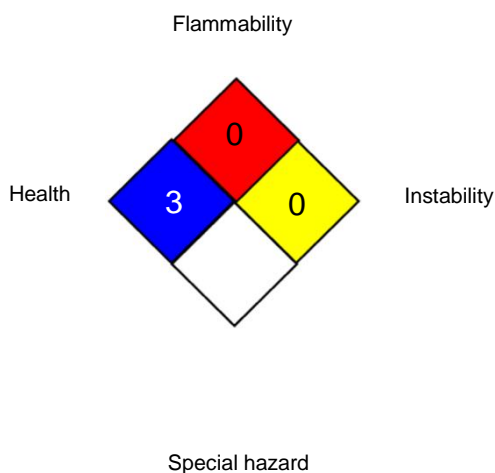
TSCA list

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 704:



HMIS® IV:

HEALTH	*	3
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)
- OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated)

ALECENSA® Capsules (150 mg)
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	values)
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	: 8-hour, time-weighted average
OSHA P0 / TWA	: 8-hour time weighted average
OSHA Z-1 / TWA	: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; 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; 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; TECL - Thailand Existing Chemicals 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

The GHS classification for skin irritation and/or sensitization of the pure ingredients causes a corresponding GHS classification for the whole formulation. In view of the nature of the formulated product (film-coated tablet, capsule, etc.) an over-interpretation of the potential hazard is possible.

Revision Date : 10-03-2022

The information provided in this 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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