SAFETY DATA SHEET

ALECENSA® Capsules (150 mg)

SECTION 1. IDENTIFICATION

Product name : ALECENSA® Capsules (150 mg)
Product code : RO542-4802/F16
Common name(s), synonym(s) of the substance : Alectinib Capsules 150 mg 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 : 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 the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Skin irritation : Category 2
Eye irritation : Category 2A
Germ cell mutagenicity : Category 2
Carcinogenicity : Category 2
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2

GHS label elements
Hazard pictograms : 

Signal Word : Warning
Hazard Statements:
H315 Causes skin irritation.
H319 Causes serious eye irritation.
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 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: 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

Components:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alectinib hydrochloride</td>
<td>1256589-74-8</td>
<td>40.3</td>
</tr>
<tr>
<td>Cellulose, 2-hydroxypropyl methyl ether</td>
<td>9004-65-3</td>
<td>19.2</td>
</tr>
<tr>
<td>Sulfuric acid monododecyl ester sodium salt (1:1)</td>
<td>151-21-3</td>
<td>18.8</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice:
Move out of dangerous area.  
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:
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.  
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 irritation.  
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

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

Unsuitable extinguishing:
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 (NOx)
- 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 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: Blister packages, Stainless steel, glass

### 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>Alectinib hydrochloride</td>
<td>1256589-74-8</td>
<td>IOEL</td>
<td>0.001 mg/m³</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
<tr>
<td>Alectinib</td>
<td>1256589-74-8</td>
<td>IOEL</td>
<td>0.001 mg/m³</td>
<td>Roche Industrial Hygiene Committee (RIHC)</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 dust)</td>
<td>10 mg/m³</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>0.2 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2.5 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alectinib hydrochloride</td>
<td>Surface waters</td>
<td>0.0001 mg/l</td>
</tr>
<tr>
<td>Sodium dodecylsulfate</td>
<td>Fresh water</td>
<td>0.176 mg/l</td>
</tr>
</tbody>
</table>

Remarks: Based on chronic data

### Personal protective equipment

#### Respiratory protection

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

#### Hand protection

In case of contact through splashing:
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>01-29-2024</td>
<td>03-24-2023</td>
<td>06-10-2017</td>
</tr>
</tbody>
</table>

Material: Nitrile rubber
Break through time: > 30 min
Glove thickness: > 0.11 mm

In case of full contact:
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
SAFETY DATA SHEET

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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

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 : Do not expose to temperatures above: 100 °C

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified due to lack of data.

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

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.

Components:

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

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 due to lack of data.

Respiratory sensitization
Not classified due to lack of data.

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.
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Method: OECD Test Guideline 406

Germ cell mutagenicity
Suspected of causing genetic defects.

Components:

Alectinib hydrochloride:
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
Titanium oxide (TiO2):
Carcinogenicity - Assessment: Limited evidence of a carcinogenic effect.

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 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 due to lack of data.

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 due to lack of data.

Further information

Components:

Alectinib hydrochloride:
Test Type: OECD Test Guideline 432
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:
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
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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)): 0.001 mg/l
Exposure time: 36 d
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Analytical monitoring: yes
Method: OECD Test Guideline 210
GLP: yes
Remarks: average measured concentration

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)): >
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Version 4.0

Revision Date: 01-29-2024

Date of last issue: 03-24-2023

Date of first issue: 06-10-2017

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
Test Type: static test
Method: OECD Test Guideline 201

EC50 (Skeletonema costatum (marine diatom)): >10,000 mg/l
Exposure time: 72 h
Method: ISO 10253

NOEC (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

- 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**:

- Remarks: No data available

**Lactose-monohydrate**:

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

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

**Titanium oxide (TiO2)**:

- 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: 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.  
Very 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
SAFETY DATA SHEET

ALECENSA® Capsules (150 mg)

**Version** 4.0  
**Revision Date:** 01-29-2024  
**Date of last issue:** 03-24-2023  
**Date of first issue:** 06-10-2017

**Labels**

**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**

- 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.

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**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.

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 SOCMII Intermediate or Final VO O'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 (TiO2) 13463-67-7

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 (TiO2) 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 dioxide, 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 (TiO2) 13463-67-7

The ingredients of this product are reported in the following inventories:
AIIC : Not in compliance with the inventory
DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
  Alectinib hydrochloride
  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:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

HMIS® IV:

- **HEALTH**: * 2
- **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 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

Additional abbreviations:

- 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
- 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

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SAFETY DATA SHEET

ALECENSA® Capsules (150 mg)

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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; TECI - 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: 01-29-2024

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.

US / Z8 / 2204