SAFETY DATA SHEET

ALECENSA® Capsules (150 mg)

Version: 3.0
Revision Date: 03-24-2023
Date of last issue: 10-03-2022
Date of first issue: 06-10-2017

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
Serious eye damage: Category 1
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: 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

<table>
<thead>
<tr>
<th>Components</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>
<tr>
<td>Cellulose, carboxymethyl ether, cal-</td>
<td>9050-04-8</td>
<td>10.8</td>
</tr>
</tbody>
</table>
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
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 (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
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/PERSOAL 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>The value is given in analogy to the following substances: Alectinib</td>
<td></td>
<td></td>
<td></td>
<td></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

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
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
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

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 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.

Components:

Alectinib hydrochloride:
Genotoxicity in vitro:
Method: OECD Test Guideline 487
Result: positive
Method: OECD Test Guideline 473
Result: negative
Method: Ames test
Metabolic activation: with and without metabolic activation
Result: negative

Genotoxicity in vivo:
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:
Method: OECD Test Guideline 471
Result: negative

Genotoxicity in vivo:
Method: OECD Test Guideline 474
Result: negative

Carcinogenicity
Suspected of causing cancer.

Components:

Cellulose, carboxymethyl ether, calcium salt:
### ALECENSA® Capsules (150 mg)

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tbody>
<tr>
<td>3.0</td>
<td>03-24-2023</td>
<td>10-03-2022</td>
<td>06-10-2017</td>
</tr>
</tbody>
</table>

**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:**

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**

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 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

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
### ALECENSA® Capsules (150 mg)

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- **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)): 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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (mg/l)</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pimephales promelas (fathead minnow)</td>
<td>&gt; 1,000</td>
<td>96 h</td>
<td>Static test</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td>Cyprinodon variegatus (sheepshead minnow)</td>
<td>&gt; 10,000</td>
<td>96 h</td>
<td>Semi-static test</td>
<td>ISO 10253</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (mg/l)</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>&gt; 1,000</td>
<td>48 h</td>
<td>Static test</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (mg/l)</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>&gt; 100</td>
<td>72 h</td>
<td>Static test</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Skeletonema costatum (marine diatom)</td>
<td>&gt; 10,000</td>
<td>72 h</td>
<td>Static test</td>
<td>ISO 10253</td>
</tr>
<tr>
<td>NOEC (marine diatom)</td>
<td>5,600</td>
<td>72 h</td>
<td>Static test</td>
<td>ISO 10253</td>
</tr>
</tbody>
</table>

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 %
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:
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:

<table>
<thead>
<tr>
<th>Medium</th>
<th>Koc Value</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soil</td>
<td>14921 - 32878 ml/g</td>
<td>OECD Test Guideline 106</td>
<td>immobile</td>
</tr>
<tr>
<td>Sludge</td>
<td>5707 - 16634 ml/g</td>
<td>OECD Test Guideline 106</td>
<td>immobile</td>
</tr>
</tbody>
</table>

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
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
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.
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.

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. Clean Water Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water 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:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Compliance Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIIC</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>DSL</td>
<td>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</td>
</tr>
<tr>
<td>NZIoC</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>ENCS</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>ISHL</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>KECI</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>PICCS</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>IECSC</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>TCSI</td>
<td>Not in compliance with the inventory</td>
</tr>
<tr>
<td>TSCA</td>
<td>Product contains substance(s) not listed on TSCA inventory.</td>
</tr>
<tr>
<td>TECI</td>
<td>Not in compliance with the inventory</td>
</tr>
</tbody>
</table>

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:

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

AIIIC - 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
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