

ROZLYTREK Capsules 200 mgVersion
1.0Revision Date:
06/14/2025Date of last issue: -
Date of first issue: 06/14/2025**SECTION 1. IDENTIFICATION**

Product name : ROZLYTREK Capsules 200 mg

Product code : RO710-2122/F24-00

Common name(s),
synonym(s) of the substance : Entrectinib with other ingredients**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

In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Serious eye damage : Category 1

Carcinogenicity : Category 1A

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.
H350 May cause cancer.Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.**Response:**

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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.

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) |
|---|--------------|-----------------------|
| Entrectinib | 1108743-60-7 | 36.6 |
| D-Glucose, 4-O-.beta.-D-galactopyranosyl- | 63-42-3 | 23.8 |
| Butanedioic acid, 2,3-dihydroxy-(2R,3R)- | 87-69-4 | 10.8 |
| 2-Pyrrolidinone, 1-ethenyl-, homopolymer | 9003-39-8 | 4.3 |
| Cellulose, 2-hydroxypropyl methyl ether | 9004-65-3 | 3.3 |
| Cellulose | 9004-34-6 | 2.4 |
| Octadecanoic acid, magnesium salt (2:1) | 557-04-0 | 0.9 |
| Titanium oxide (TiO ₂) | 13463-67-7 | 0.4 |
| Silica | 7631-86-9 | 0.2 |
| non hazardous compounds | Not Assigned | 17.3 |

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 : If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.

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- 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.
- Most important symptoms and effects, both acute and delayed : Causes serious eye damage.
May cause cancer.
- Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing
- Notes to physician : Treat symptomatically.

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 : Nitrogen oxides (NO_x)
Fluorinated hydrocarbons
Carbon 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.

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- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.
Refer to protective measures listed in sections 7 and 8.
- 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.
- Storage temperature : Store at room temperature.
Protect from moisture.
Protect from heat and light
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Polyethylene bag in metal drum, Plastic container of HDPE, PVC, Stainless steel, glass

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

| Components | CAS-No. | Value type | Control | Basis |
|------------|---------|------------|---------|-------|
|------------|---------|------------|---------|-------|

SAFETY DATA SHEET

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| | | (Form of exposure) | parameters / Permissible concentration | |
|-----------------------|--------------|-------------------------------------|--|---|
| Entrectinib | 1108743-60-7 | IOEL | 0.015 mg/m3 | Roche Industrial Hygiene Committee (RIHC) |
| Cellulose | 9004-34-6 | TWA | 10 mg/m3 | ACGIH |
| | | TWA (Respirable) | 5 mg/m3 | NIOSH REL |
| | | TWA (total) | 10 mg/m3 | NIOSH REL |
| | | TWA (total dust) | 15 mg/m3 | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m3 | OSHA Z-1 |
| | | TWA (Total dust) | 15 mg/m3 | OSHA P0 |
| | | TWA (respirable dust fraction) | 5 mg/m3 | OSHA P0 |
| Titanium oxide (TiO2) | 13463-67-7 | TWA (total dust) | 15 mg/m3 | OSHA Z-1 |
| | | TWA (Total dust) | 10 mg/m3 | OSHA P0 |
| | | TWA (Respirable particulate matter) | 0.2 mg/m3 (Titanium dioxide) | ACGIH |
| | | TWA (Respirable particulate matter) | 2.5 mg/m3 (Titanium dioxide) | ACGIH |
| Silica | 7631-86-9 | PEL (respirable) | 0.05 mg/m3 | OSHA CARC |
| | | TWA (Respirable dust) | 0.05 mg/m3 (Silica) | NIOSH REL |
| Substance name | | Environmental Compartment | | Value |
| Entrectinib | | Surface waters | | 0.3 µg/l |
| | | Remarks:Based on chronic data | | |

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled

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release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

In case of contact through splashing:

| | | |
|--------------------|---|----------------|
| 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. |
| 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 | : | No data available |
| 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 | : | Not applicable |
| Evaporation rate | : | No data available |

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| | | |
|--|---|-------------------|
| Self-ignition | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapor pressure | : | No data available |
| Relative vapor density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Autoignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, dynamic | : | Not applicable |
| Viscosity, kinematic | : | Not applicable |
| Explosive properties | : | No data available |
| Oxidizing properties | : | No data available |
| Particle characteristics | | |
| Particle Size Distribution | : | No data available |

SECTION 10. STABILITY AND REACTIVITY

| | | |
|------------------------------------|---|---|
| Reactivity | : | No dangerous reaction known under conditions of normal use. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | No decomposition if stored and applied as directed. |
| Conditions to avoid | : | No data available |
| | | No data available |

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Incompatible materials : No data available
Not applicable

Hazardous decomposition products : No data available
No hazardous decomposition products are known.

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: 120.93 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:**Entrectinib:**

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Cellulose:

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

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

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- Acute oral toxicity : LD50 (Rat, male and female): > 5,000 mg/kg
GLP: yes
- Acute inhalation toxicity : LC50 (Rat, male and female): > 5.01 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 436
GLP: yes
Assessment: The substance or mixture has no acute inhalation toxicity
- Acute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg
Method: No information available.
GLP: No information available.

Skin corrosion/irritation

Not classified due to lack of data.

Product:

- Remarks : Extremely corrosive and destructive to tissue.

Components:**Entrectinib:**

- Species : Rabbit
Result : No skin irritation

Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:

- Remarks : Extremely corrosive and destructive to tissue.

Titanium oxide (TiO2):

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

Silica:

- Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404

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Result : No skin irritation
GLP : No information available.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks : May cause irreversible eye damage.

Components:**Entrectinib:**

Species : Rabbit
Result : Mild eye irritation

Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:

Result : Risk of serious damage to eyes.
Remarks : May cause irreversible eye damage.

Titanium oxide (TiO₂):

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

Silica:

Species : Rabbit
Result : No eye irritation
Exposure time : 24 h
GLP : no

Respiratory or skin sensitization**Skin sensitization**

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Components:**Titanium oxide (TiO₂):**

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

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Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406
Result : Did not cause sensitization on laboratory animals.
GLP : yes

Germ cell mutagenicity

Not classified due to lack of data.

Components:**Entrectinib:**

Genotoxicity in vitro : Result: negative

Genotoxicity in vivo : Result: negative

Silica:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 490
Result: negative
GLP: yes

Genotoxicity in vivo : Species: Rat (male)
Cell type: Bone marrow
Application Route: Oral
Method: OECD Test Guideline 475
Result: negative
GLP: no

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May cause cancer.

Components:**Cellulose:**

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Titanium oxide (TiO₂):

Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

Silica:

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
Method : No information available.
Result : negative
GLP : No information available.

IARC Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO₂) 13463-67-7

OSHA OSHA specifically regulated carcinogen
Silica 7631-86-9
(crystalline silica)

NTP Known to be human carcinogen
Silica 7631-86-9
(Silica, Crystalline (Respirable Size))

Reproductive toxicity

Not classified due to lack of data.

Components:**Entrectinib:**

Effects on fetal development : Species: Rat
Result: May lead to malformations at dose levels that cause maternal toxicity

Silica:

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Effects on fertility : Species: Rat, male and female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
General Toxicity Parent: NOAEL: \geq 1,000 mg/kg body weight
General Toxicity F1: NOAEL: \geq 1,000 mg/kg body weight
Method: OECD Test Guideline 416
GLP: yes

Effects on fetal development : Species: Mouse, female
Application Route: Oral
Dose: 13.4, 62.3, 289, 1340 mg/kg bw/day
Duration of Single Treatment: 6 - 15 d
General Toxicity Maternal: LOAEL: \geq 1,340 mg/kg bw/day
Embryo-fetal toxicity.: NOAEL: \geq 1,340 μ g/kg body weight
Method: No information available.
GLP: No information available.

STOT-single exposure

Not classified due to lack of data.

Components:**Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

Not classified due to lack of data.

Components:**Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity**Components:****Silica:**

Species : Rat, male and female
NOEL : 4000 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Method : OECD Test Guideline 408
GLP : yes

Aspiration toxicity

Not classified due to lack of data.

Components:**Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:**

No data available

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Further information

Product:

Remarks : No data available

Components:**Entrectinib:**

Remarks : Phototoxic (in vitro)

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:**Entrectinib:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 0.266 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

EyC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

NOEC (Desmodesmus subspicatus (green algae)): 0.197 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

Toxicity to fish (Chronic toxicity) : EC10 (Danio rerio (zebra fish)): 0.00311 mg/l
Exposure time: 35 d
Method: OECD Test Guideline 210
GLP: yes
Remarks: average measured concentration

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 0.0645 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

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Remarks: average measured concentration

Toxicity to microorganisms : NOEC (activated sludge): 1,000 mg/l
 Exposure time: 3 h
 Method: OECD Test Guideline 209
 GLP: yes
 Remarks: nominal concentration

(activated sludge): Exposure time: 14 d
 Method: OECD Test Guideline 301F
 GLP: yes
 Remarks: no adverse influence on substrate biodegradation

Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 1,000 mg/l
 Exposure time: 72 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 135 mg/l
 aquatic invertebrates Exposure time: 48 h

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available
 the environment

Cellulose:**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100
 plants 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

Silica:Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 5,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: noToxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 10,000 mg/l
End point: Immobilization
Exposure time: 24 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: yesToxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 173.1 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yesToxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 149.2 mg/l
End point: mortality
Exposure time: 21 d
Test Type: semi-static test
Analytical monitoring: yes
Method: OECD Test Guideline 211
GLP: yesToxicity to microorganisms : NOEC (activated sludge): 1,000 mg/l
End point: Respiration inhibition

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Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes

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:****Entrectinib:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: < 10 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes

Result: Primary biodegradation
Method: OECD Test Guideline 308
GLP: yes

Physico-chemical removability : Method: OECD Test Guideline 301F
Remarks: Not abiotically degradable

Titanium oxide (TiO₂):

Biodegradability : Remarks: Not applicable

Silica:

Biodegradability : Remarks: Not applicable

Bioaccumulative potential**Components:****Entrectinib:**

Bioaccumulation : Species: Danio rerio (zebra fish)
Bioconcentration factor (BCF): 217
Exposure time: 20 d
Temperature: 68 °F / 20 °C
Concentration: 0.00162 mg/l
Method: OECD Test Guideline 305
GLP: yes
Remarks: Does not significantly accumulate in organisms.

Partition coefficient: n-octanol/water : log Pow: 2.7 (68 °F / 20 °C)
pH: 5.0
Method: OECD Test Guideline 107

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log Pow: 4.3 (68 °F / 20 °C)
pH: 7.0
Method: OECD Test Guideline 107
GLP: yeslog Pow: 5.1 (68 °F / 20 °C)
pH: 9.0
Method: OECD Test Guideline 107
GLP: yeslog Pow: 4.43 (77 °F / 25 °C)
pH: 7.0
Method: OECD Test Guideline 123
GLP: yes**Butanedioic acid, 2,3-dihydroxy- (2R,3R)-:**Partition coefficient: n-
octanol/water : log Pow: < 1**Cellulose:**Partition coefficient: n-
octanol/water : Remarks: No data available**Titanium oxide (TiO₂):**Partition coefficient: n-
octanol/water : Remarks: No data available**Silica:**Partition coefficient: n-
octanol/water : Remarks: Not applicable**Mobility in soil****Components:****Entrectinib:**Distribution among
environmental compartments : Medium: Soil
Koc: > 10000
Method: OECD Test Guideline 121**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).

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Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Very toxic to aquatic life with long lasting effects.

Components:**Entrectinib:**

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).
Substance is not very persistent and very bioaccumulative (vPvB).

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.
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.
(Entrectinib)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Entrectinib)
Class : 9
Packing group : III
Labels : Class 9 - Miscellaneous dangerous substances and articles
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

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Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Entrectinib)
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 for product as supplied.

Domestic regulation**49 CFR**

UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Entrectinib)
Class : 9
Packing group : III
Labels : Class 9 - Miscellaneous dangerous substances and articles
ERG Code : 171
Marine pollutant : no

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

| Components | CAS-No. | Component TPQ (lbs) |
|------------|---------|---------------------|
|------------|---------|---------------------|

SARA 311/312 Hazards : Carcinogenicity
Serious eye damage or eye irritation

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

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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

| | |
|-----------|-----------|
| Cellulose | 9004-34-6 |
|-----------|-----------|

Pennsylvania Right To Know

| | |
|---|--------------|
| Entrectinib | 1108743-60-7 |
| D-Glucose, 4-O-.beta.-D-galactopyranosyl- | 63-42-3 |
| non hazardous compounds | Not Assigned |
| Butanedioic acid, 2,3-dihydroxy- (2R,3R)- | 87-69-4 |
| 2-Pyrrolidinone, 1-ethenyl-, homopolymer | 9003-39-8 |
| Cellulose, 2-hydroxypropyl methyl ether | 9004-65-3 |
| Cellulose | 9004-34-6 |

Maine Chemicals of High Concern

| | |
|--------|-----------|
| Silica | 7631-86-9 |
|--------|-----------|

Vermont Chemicals of High Concern
Washington Chemicals of High Concern
California Prop. 65

WARNING: This product can expose you to chemicals including Titanium oxide (TiO₂), Silica, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

| | |
|--|-----------|
| 2-Pyrrolidinone, 1-ethenyl-, homopolymer | 9003-39-8 |
|--|-----------|

California Permissible Exposure Limits for Chemical Contaminants

| | |
|-----------|-----------|
| Cellulose | 9004-34-6 |
|-----------|-----------|

California Regulated Carcinogens

| | |
|--------|-----------|
| Silica | 7631-86-9 |
|--------|-----------|

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. |
| | | Entrectinib |
| | | non hazardous compounds |
| 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 |

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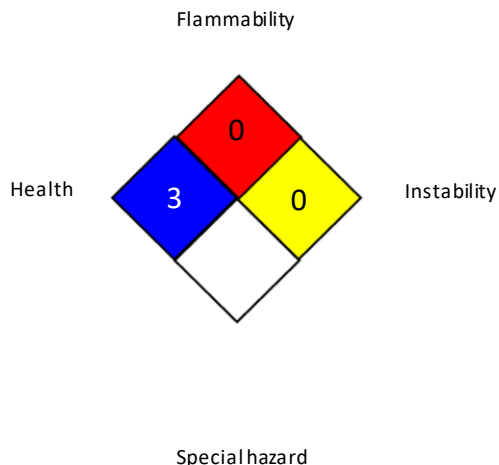
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| | |
|-------|---|
| PICCS | : Not in compliance with the inventory |
| IECSC | : Not in compliance with the inventory |
| TCSI | : Not in compliance with the inventory |
| TSCA | : Product contains substance(s) not listed on TSCA inventory. |
| TECI | : 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
Further 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) |
| NIOSH REL | : USA. NIOSH Recommended Exposure Limits |
| OSHA CARC | : OSHA Specifically Regulated Chemicals/Carcinogens |
| 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 |
| NIOSH REL / TWA | : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |

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OSHA CARC / PEL : Permissible exposure limit (PEL)
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 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; 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.

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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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