

**ROZLYTREK Capsules 200 mg**Version  
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:**

**ROZLYTREK Capsules 200 mg**
Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

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 (TiO2)	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.

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

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 (NOx)  
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.

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025**SECTION 6. ACCIDENTAL RELEASE MEASURES**

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

Genentech  
A Member of the Roche Group

## ROZLYTREK Capsules 200 mg

Version  
1.0

Revision Date:  
06/14/2025

Date of last issue: -  
Date of first issue: 06/14/2025

		(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

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

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

**Hand protection**

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

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

Remarks : Wear appropriate protective gloves to prevent skin contact.  
Replace torn or punctured gloves promptly.

**Eye protection** : Eye wash bottle with pure water  
Tightly fitting safety goggles  
Wear face-shield and protective suit for abnormal processing problems.

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

**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

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

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

**ROZLYTREK Capsules 200 mg**

Version 1.0 Revision Date: 06/14/2025 Date of last issue: - Date of first issue: 06/14/2025

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

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025**Silica:**

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

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

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

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025**Silica:**

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

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025**Carcinogenicity**

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  
(crystalline silica)

7631-86-9

**NTP** Known to be human carcinogen  
Silica  
(Silica, Crystalline (Respirable Size))

7631-86-9

**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:**

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

Effects on fertility : Species: Rat, male and female  
Application Route: Oral  
Dose: 100, 300, 1000 mg/kg bw/day  
General Toxicity Parent: NOAEL: >= 1,000 mg/kg body weight  
General Toxicity F1: NOAEL: >= 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: >= 1,340 mg/kg bw/day  
Embryo-fetal toxicity.: NOAEL: >= 1,340 µg/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

**ROZLYTREK Capsules 200 mg**

Version 1.0 Revision Date: 06/14/2025 Date of last issue: - Date of first issue: 06/14/2025

**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

**ROZLYTREK Capsules 200 mg**
Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025
 GLP: yes  
 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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 135 mg/l  
 Exposure time: 48 h

**Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

**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 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

**ROZLYTREK Capsules 200 mg**
Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

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

**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: no

Toxicity 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: yes

Toxicity 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: yes

Toxicity 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: yes

Toxicity to microorganisms : NOEC (activated sludge): 1,000 mg/l  
 End point: Respiration inhibition

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

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

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

GLP: yes

log Pow: 4.3 (68 °F / 20 °C)  
pH: 7.0  
Method: OECD Test Guideline 107  
GLP: yes

log Pow: 5.1 (68 °F / 20 °C)  
pH: 9.0  
Method: OECD Test Guideline 107  
GLP: yes

log 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).

**ROZLYTREK Capsules 200 mg**Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

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

**ROZLYTREK Capsules 200 mg**

Version 1.0 Revision Date: 06/14/2025 Date of last issue: -  
 Date of first issue: 06/14/2025

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)
<b>SARA 311/312 Hazards</b>	: 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 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

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

## ROZLYTREK Capsules 200 mg

Version  
1.0

Revision Date:  
06/14/2025

Date of last issue: -  
Date of first issue: 06/14/2025

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- non hazardous compounds	63-42-3
Butanedioic acid, 2,3-dihydroxy- (2R,3R)-	Not Assigned
2-Pyrrolidinone, 1-ethenyl-, homopolymer	87-69-4
Cellulose, 2-hydroxypropyl methyl ether	9003-39-8
Cellulose	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 (TiO<sub>2</sub>), Silica, which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://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

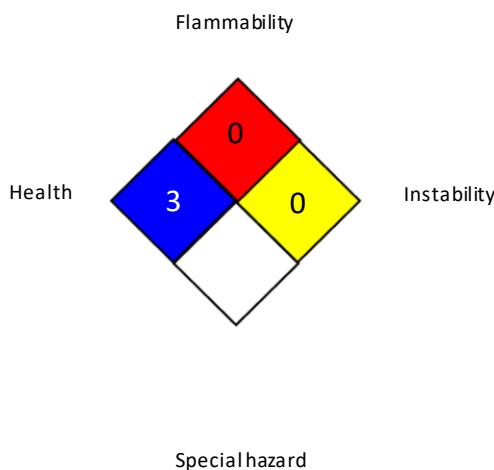
**ROZLYTREK Capsules 200 mg**
Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

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:**

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

## ROZLYTREK Capsules 200 mg

Version  
1.0Revision Date:  
06/14/2025Date of last issue: -  
Date of first issue: 06/14/2025

OSHA CARC / PEL : Permissible exposure limit (PEL)  
OSHA P0 / TWA : 8-hour time weighted average  
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - 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.

Revision Date : 06/14/2025

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 / EN / 2404