SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Genentech
A Member of the Roche Group

ROZLYTREK Capsules 100 mg

Version	Revision Date:	Date of last issue: 06/14/2025
2.0	09/03/2026	Date of first issue: 06/14/2025

SECTION 1. IDENTIFICATION

Product name	:	ROZLYTREK Capsules 100 mg
Product code	:	RO710-2122/F25-00
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)

Hazards for the product as supplied

Serious eye damage	:	Category 1

Other hazards

None known.

GHS label elements

Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H318 Causes serious eye damage.
Supplemental Hazard Statements	:	Corrosive to the respiratory tract.
Precautionary Statements	:	**Prevention:** P280 Wear eye protection/ face protection. **Response:** 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Entrectinib	1108743-60-7*	35	-
D-Glucose, 4-O-.beta.-D-galactopyranosyl-	63-42-3*	22.7	-
Butanedioic acid, 2,3-dihydroxy- (2R,3R)-	87-69-4*	10.3	-

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8*	4.1	-
Cellulose, 2-hydroxypropyl methyl ether	9004-65-3*	3.2	-
Cellulose	9004-34-6*	2.3	-
Silica	7631-86-9*	0.2	-
Octadecanoic acid, magnesium salt (2:1)	557-04-0*	0.8	-
Titanium oxide (TiO2)	13463-67-7*	0.4	-
non hazardous compounds	-	21	-

* Indicates that the identifier is a CAS No.

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.

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.

Corrosive to the respiratory tract.

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.

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 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 (Form of exposure)	Control parameters / Permissible concentration	Basis
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

Predicted No Effect Concentration (PNEC):

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 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
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
Incompatible materials	:	Not applicable
Hazardous decomposition products	:	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: 126.83 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

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

Acute oral toxicity : LD50 Oral (Rat, female): > 2,000 - 5,000 mg/kg

Method: OECD Test Guideline 423

GLP: yes

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

Method: OECD Test Guideline 402

GLP: yes

Assessment: The substance or mixture has no acute dermal toxicity

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

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)-:

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

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
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:

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

Test Type	:	Local lymph node assay (LLNA)
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	Not a skin sensitizer.
GLP	:	yes

Titanium oxide (TiO2):

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

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

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

Germ cell mutagenicity - Assessment	:	In vivo tests did not show mutagenic effects

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

Carcinogenicity
Not classified due to lack of data.

Components:

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

Carcinogenicity - Assessment	:	Animal testing did not show any carcinogenic effects.

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.

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 1: Carcinogenic to humans**	
	Silica	7631-86-9
	(Silica dust, crystalline)	
	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

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

Reproductive toxicity - Assessment	:	No toxicity to reproduction

Silica:

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
Corrosive to the respiratory tract.

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

Further information

Product:

Remarks	:	No data available

Components:

Entrectinib:

Remarks	:	Phototoxic (in vitro)

Endocrine disrupting properties

Components:

Entrectinib:

Assessment : Does not have endocrine disrupting properties.

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

Assessment : Does not have endocrine disrupting properties.

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

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 daphnia and other aquatic invertebrates	:	NOEC (Daphnia magna (Water flea)): >= 100 mg/l Exposure time: 48 h Test Type: static test Method: OECD Test Guideline 202 GLP: yes
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): >= 100 mg/l Exposure time: 72 h Test Type: semi-static test Method: OECD Test Guideline 201 GLP: yes

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

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

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

Biodegradation Simulation Tests : Environmental Compartment: Soil

Measurement method: OECD Test Guideline 307

Remarks: Primary biodegradation

Physico-chemical removability : Method: OECD Test Guideline 301F

Remarks: Not abiotically degradable

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

Biodegradability	:	aerobic Inoculum: activated sludge Result: Readily biodegradable. Biodegradation: 96.3 % Exposure time: 3 d Method: OECD Test Guideline 301D GLP: yes

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 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: -3.6 (68 °F / 20 °C)

pH: 7

Method: OECD Test Guideline 107

GLP: yes

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).
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	:	Not persistent, bioaccumulative, and toxic (PBT).

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

Results of PBT and vPvB assessment	:	Not persistent, bioaccumulative, and toxic (PBT).

Endocrine disrupting properties

Components:

Entrectinib:

Assessment	:	Does not have endocrine disrupting properties.

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

Assessment	:	Does not have endocrine disrupting properties.

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
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 IMO instruments
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

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

SARA 311/312 Hazards : 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. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

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

US State Regulations

Massachusetts Right To Know

Cellulose	9004-34-6
Titanium oxide (TiO2)	13463-67-7

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
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 includingTitanium 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
Titanium oxide (TiO2)	13463-67-7

The ingredients of this product are reported in the following inventories:

AU AIIC	:	Not in compliance with the inventory
CA. DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.
		Entrectinib
		non hazardous compounds
NZ NZIoC	:	Not in compliance with the inventory
JP ENCS	:	Not in compliance with the inventory

JP ISHL	:	Not in compliance with the inventory
KR KECI	:	Not in compliance with the inventory
PH PICCS	:	Not in compliance with the inventory
CN IECSC	:	Not in compliance with the inventory
TW TCSI	:	Not in compliance with the inventory
US TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TH 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.

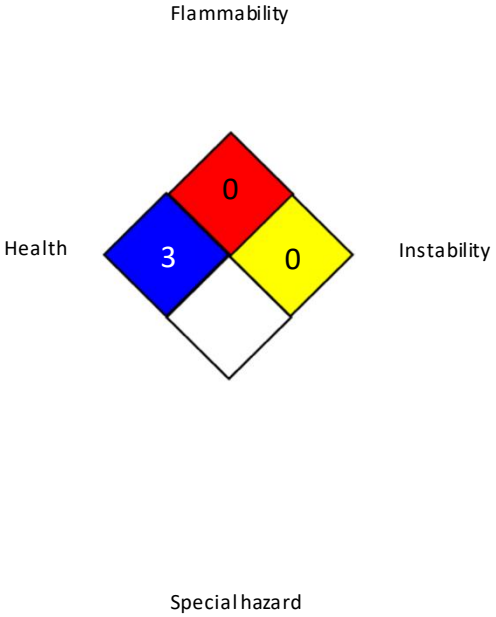
SECTION 16. OTHER INFORMATION

Further information

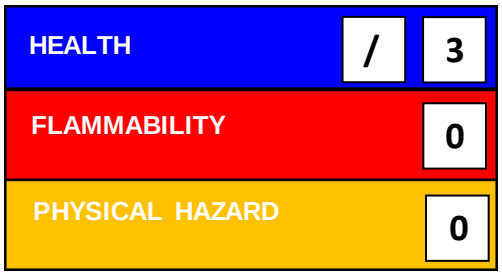
ROZLYTREK Capsules 100 mg

Version	Revision Date:	Date of last issue: 06/14/2025
2.0	09/03/2026	Date of first issue: 06/14/2025

NFPA 704:



HMIS® IV / CED:



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
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 Standardization; 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 Organization 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, Authorization 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 formulatedproduct (film-coated tablet, capsule, etc.), an over-interpretation of the potential hazard is possible.

Revision Date : 09/03/2026

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.