ROZLYTREK(TM) Capsules (100 mg)

Version	Revision Date:	Date of last issue: 01-24-2020
1.1	02-25-2020	Date of first issue: 01-24-2020

SECTION 1. IDENTIFICATION

Product name	:	ROZLYTREK(TM) Capsules (100 mg)
Product code	:	RO710-2122/F11

Manufacturer or supplier's details

Company name of supplier	:	Genentech, Inc.
Address	:	DNA Way 1 94080 South San Francisco CA USA
Telephone	:	001-(650) 225-1000
E-mail address	:	info.sds@roche.com
Emergency telephone		
Emergency telephone number	:	US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use	:	Formulated pharmaceutical active substance
Restrictions on use	:	For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Eye irritation	:	Category 2A
Carcinogenicity	:	Category 2

GHS label elements

Hazard pictograms :

Signal Word	:	Warning
Hazard Statements	:	H319 Causes serious eye irritation. H351 Suspected of causing cancer.
Precautionary Statements	:	**Prevention:** P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P264 Wash skin thoroughly after handling. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: 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	35.0
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
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.8
Silica	7631-86-9	0.2
Titanium oxide (TiO2)	13463-67-7	<= 0.4
non hazardous compounds	Not Assigned	21.0

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	Causes serious eye irritation. Suspected of causing cancer.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	In case of fire hazardous decomposition products may be produced such as: 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.
Environmental precautions	:	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so.

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.
Further information on storage conditions	:	See label, package insert or internal guidelines
Storage temperature	:	Store at room temperature.
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

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	10 mg/m3 (Titanium dioxide)	ACGIH
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable fraction)	10 mg/m3	ACGIH
		TWA (Respirable fraction)	3 mg/m3	ACGIH
Silica	7631-86-9	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 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	

Engineering measures : No data available

Personal protective equipment

Hand protection

Material : Protective gloves

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
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
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

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	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 100.97 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): > 7,500 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 6.82 mg/l Exposure time: 4 h Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

Octadecanoic acid, magnesium salt (2:1):

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

Silica:

Acute oral toxicity : LD50 Oral (Rat): > 3,300 mg/kg

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

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause skin irritation in susceptible persons.

Components:

Entrectinib:

Species : Rabbit
Result : No skin irritation

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

Remarks : Extremely corrosive and destructive to tissue.

Silica:

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks : May cause irreversible eye damage.

Components:

Entrectinib:

Species : Rabbit
Result : Mild eye irritation

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

Result : Irritating to eyes.
Remarks : May cause irreversible eye damage.

Silica:

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Silica:

Result : Did not cause sensitization on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:

Entrectinib:

Genotoxicity in vitro : Result: negative

Genotoxicity in vivo : Result: negative

Carcinogenicity

Suspected of causing 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.

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

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Entrectinib:

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

STOT-single exposure

Not classified based on available information.

Components:

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

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

Octadecanoic acid, magnesium salt (2:1):

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

Silica:

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

STOT-repeated exposure

Not classified based on available information.

Components:

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

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

Octadecanoic acid, magnesium salt (2:1):

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

Silica:

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

Aspiration toxicity

Not classified based on available information.

Components:

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

No data available

Octadecanoic acid, magnesium salt (2:1):

No data available

Silica:

No data available

Further information

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 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	:	LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l Exposure time: 48 h
Toxicity to daphnia and other aquatic invertebrates	:	EC0 (Daphnia magna (Water flea)): 3 mg/l Exposure time: 720 h

Ecotoxicology Assessment

Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

Octadecanoic acid, magnesium salt (2:1):

Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.
Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

Silica:

Toxicity to daphnia and other aquatic invertebrates	:	EC0 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 24 h
Toxicity to algae/aquatic plants	:	IC50 (Pseudokirchneriella subcapitata (green algae)): 440 mg/l Exposure time: 72 h NOEC (Pseudokirchneriella subcapitata (green algae)): 60 mg/l Exposure time: 72 h

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

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: < 1

Cellulose:

Partition coefficient: n-octanol/water : Remarks: No data available

Titanium oxide (TiO2):

Partition coefficient: n-octanol/water : Remarks: No data available

Octadecanoic acid, magnesium salt (2:1):

Partition coefficient: n-octanol/water : log Pow: 0.8
Method: OECD Test Guideline 107

Silica:

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

Components:

Entrectinib:

Distribution among environmental compartments : Medium: Soil
Koc: > 10000
Method: OECD Test Guideline 121

Stability in soil : Method: OECD Test Guideline 307
GLP: yes
Remarks: Primary biodegradation

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	:	This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (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. Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging	:	Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Entrectinib mixture)
Class	:	9
Packing group	:	III
Labels	:	9

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Entrectinib mixture)
Class	:	9
Packing group	:	III
Labels	:	
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 mixture)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable 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 mixture)
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

EPCRA - Emergency Planning and Community Right-to-Know

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 : Serious eye damage or eye irritation
Carcinogenicity

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

US State Regulations

Massachusetts Right To Know

Entrectinib	1108743-60-7
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

Entrectinib	1108743-60-7

Vermont Chemicals of High Concern

Entrectinib	1108743-60-7

Washington Chemicals of High Concern

Entrectinib	1108743-60-7

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), 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:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Entrectinib non hazardous compounds
AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Substance(s) not listed on TSCA inventory

TSCA list

No substances are subject to a Significant New Use Rule.

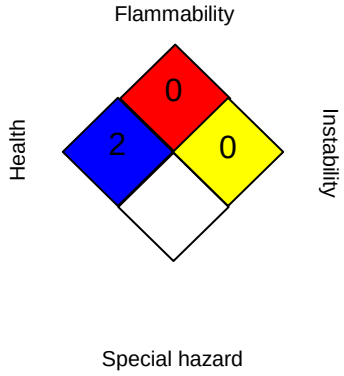
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

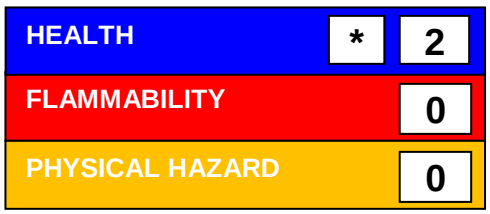
ROZLYTREK(TM) Capsules (100 mg)

Version	Revision Date:	Date of last issue: 01-24-2020
1.1	02-25-2020	Date of first issue: 01-24-2020

NFPA:



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 P0	:	USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
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 P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; 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; 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 Material 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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