

Safety Data Sheet

ROZLYTREK™ Capsules (100 mg)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name ROZLYTREK™ Capsules (100 mg)
Product code RO710-2122-F09
Synonyms - Entrectinib Capsules (hard) 100 mg

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use - pharmaceutical active substance *1

1.3. Details of the supplier of the safety data sheet

Company information Enquiries: Local representation:
Genentech, Inc.
1 DNA Way
South San Francisco
USA-CA 94080
United States of America

Phone 001-(650) 225-1000
E-Mail info.sds@roche.com
US Chemtrec phone:
(800)-424-9300

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

*1 referring to: Entrectinib

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SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

3.3 Serious eye damage/eye irritation (Category 2A)
H319 Causes serious eye irritation.

Signalword: Warning

Label:



Precautionary statements:

- P280 Wear protective gloves/ protective clothing / eye protection / face protection.
- P312 Call a POISON CENTER/doctor if you feel unwell.
- P273 Avoid release to the environment.

Other hazards

Note

- no information available

SECTION 3: Composition/information on ingredients

Characterization

Entrectinib with other inactive ingredients

Ingredients

Concentration

GHS-Classification
(pure ingredient)

Entrectinib

1108743-60-7

35.1 %

- Serious eye damage/eye irritation (Category 2A), H319

Lactose anhydrous

63-42-3

22.8 %

Tartaric acid fine cryst.

87-69-4

10.4 %

- Serious eye damage/eye irritation (Category 2A), H319

Polyvinylpyrrolidone, cross-linked,

micronised

9003-39-8

4.2 %

2-Hydroxypropyl methyl ether

cellulose

9004-65-3

3.2 %

Microcrystalline cellulose

9004-34-6

2.4 %

For the full text of the 'Hazard statements' mentioned in this Section, see Section 16.

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SECTION 4: First aid measures

4.1. Description of first aid measures

- Eye contact - rinse with tap water for 20 minutes - open eyelids forcibly
- Skin contact - when in contact with the skin, clean with soap and water
- Inhalation - in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

- Note - no information available

4.3. Indication of any immediate medical attention and special treatment needed

- Note to physician - treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media - adapt extinguishing media to surrounding fire conditions, water spray jet, dry powder, foam, carbon dioxide
- Flash point (liquid) not applicable

5.2. Special hazards arising from the substance or mixture

- Specific hazards - substance is hazardous for water: contain fire-fighting wastewater

5.3. Advice for firefighters

- Protection of fire-fighters - precipitate gases/vapours/mists with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- Personal precautions - no special precautions required

6.2. Environmental precautions

- Environmental protection - the solvent should be held back due to environmental protection
- if the substance reaches waters or the sewer system, inform the competent authority

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6.3. Methods and material for containment and cleaning up

Methods for cleaning up - take up mechanically and dispose of

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - avoid dust formation
- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - room temperature
Validity - see expiry date on the label
Packaging materials - tightly closing

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.015 mg/m³ *1
PNEC - 0.3 µg/l, surface freshwaters, based on chronic data *1

8.2. Exposure controls

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- respiratory protection not necessary during normal operations
Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection - safety glasses

*1 referring to: Entrectinib

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color yellow
Form hard gelatin capsules

ROZLYTREK™ Capsules (100 mg)

Solubility ≥ 0.964 mg/l, water (20 °C, pH 7.3, OECD No. 105) *1
 ≤ 2.94 mg/l, water (20 °C, pH 8.7, OECD No. 105) *1

Partition coefficient log P_{ow} 2.7 (octanol/water 20 °C) pH 5.0 (Shake Flask Method, OECD No. 107) *1
log P_{ow} 4.3 (octanol/water 20 °C) pH 7.0 (Shake Flask Method, OECD No. 107) *1
log P_{ow} 5.1 (octanol/water 20 °C) pH 9.0 (Shake Flask Method, OECD No. 107) *1
log P_{ow} 4.43 (octanol/water 25 °C) pH 7.0 (OECD No. 123) *1

9.2. Other information

Note - no information available

*1 referring to: Entrectinib

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - LD₅₀ > 2'000 mg/kg (oral, rat) *1

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Local effects	<ul style="list-style-type: none"> - skin: non-irritant (rabbit) *1 - eye: slightly irritating (rabbit) *1 - phototoxic potential (In Vitro) *1
Sensitization	<ul style="list-style-type: none"> - no information available
Mutagenicity	<ul style="list-style-type: none"> - negative (various in vivo and in vitro test systems) *1
Carcinogenicity	<ul style="list-style-type: none"> - no information available
Reproductive toxicity	<ul style="list-style-type: none"> - may lead to malformations at dose levels that cause maternal toxicity (rat) *1
STOT-single exposure	<ul style="list-style-type: none"> - no information available
STOT-repeated exposure	<ul style="list-style-type: none"> - no information available
Aspiration hazard	<ul style="list-style-type: none"> - no information available
Potential Health Effects	<ul style="list-style-type: none"> - Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Entrectinib

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	<ul style="list-style-type: none"> - <i>Desmodesmus subspicatus</i> NOEC (72 h) 0.197 mg/l ErC₅₀ (72 h) > 100 mg/l (nominal concentration) EyC₅₀ (72 h) > 100 mg/l (nominal concentration) (OECD No. 201) *1 - <i>Daphnia magna</i> NOEC (48 h) 0.266 mg/l EC₅₀ (48 h) > 100 mg/l (nominal concentration) (OECD No. 202) *1 - <i>Daphnia magna</i> EC₁₀ (21 d) 0.0645 mg/l (average measured concentration) (OECD No. 211 (semi-static)) *1 - zebrafish EC₁₀ (35 d) 0.00311 mg/l (average measured concentration) (OECD No. 210) *1 - activated sludge NOEC (3 h) 1000 mg/l (nominal concentration) (OECD No. 209) *1 - no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 38.0 mg/l (Manometric Respirometry Test, OECD No. 301 F) *1
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12.2. Persistence and degradability

Ready biodegradability	- not readily biodegradable < 10 %, 28 d (Manometric Respirometry Test, OECD No. 301 F)	*1
Abiotic degradation	- not abiotically degradable (Manometric respirometry test, OECD no. 301 F, abiotic control)	*1

12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Entrectinib

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues

- return to supplier or hand over to authorized disposal company
- observe local/national regulations regarding waste disposal
- incinerate in qualified installation with flue gas scrubbing
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

SECTION 14: Transport information

IATA	Class	UN/ID	PG		PI	Label	Mark
	9	3077	III		956/956	9	EHS

ROZLYTREK™ Capsules (100 mg)

IMDG	Class	UN	PG	EmS	PI	Label	Mark	
	9	3077	III	F-A S-F	P002/IBC08	9	marine pollutant	
RID/ADR	Class	UN	PG	Haz.no	PI	Label	Mark	Classif. code
	9	3077	III	90	P002/IBC08	9	EHS	M7
DOT	Class	UN/ID	PG	PI	RQ	Label	Haz.no	
	9	3077	III			9		
Proper shipping name		ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.						
Technical name		Entrectinib						
SECTION 15: Regulatory information								
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture								
TSCA Status		- FDA Exemption - not on inventory						
Reporting Requirements		<ul style="list-style-type: none"> - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. - In New Jersey, report all releases which enter a waterway or into soil, or which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline and to local officials. - State and local regulations vary and may impose additional reporting requirements. 						
SECTION 16: Other information								
Safety-lab number		<ul style="list-style-type: none"> - BS11425 - BS11450 					*1 *1	
Full text of H-Statements referred to under section 3		H319 Causes serious eye irritation.						
Note		- none						
Edition documentation		- changes from previous version in sections 2, 3, 14						
*1 referring to:		Entrectinib						
The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.								