

**GAVRETO(R) Capsules 100 mg**Version  
2.0Revision Date:  
04-08-2022Date of last issue: 04-20-2021  
Date of first issue: 11-30-2020**SECTION 1. IDENTIFICATION**

Product name : GAVRETO(R) Capsules 100 mg  
Product code : RO749-9790/F02  
Common name(s), syno- : GAVRETO Capsules (hard) 100 mg  
nym(s) of the substance

**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 :  
Emergency telephone num- : US Chemtrec phone (800)-424-9300  
ber

**Recommended use of the chemical and restrictions on use**


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

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

Carcinogenicity : Category 2  
Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 2 (Cardiovascular, Skeleton, hematopoietic system)  
- repeated exposure

**GHS label elements**

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H351 Suspected of causing cancer.  
H361d Suspected of damaging the unborn child.  
H373 May cause damage to organs (Cardiovascular, Skeleton, hematopoietic system) through prolonged or repeated exposure.

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Precautionary Statements : **Prevention:**  
 P201 Obtain special instructions before use.  
 P202 Do not handle until all safety precautions have been read and understood.  
 P260 Do not breathe dust.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
 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.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Pralsetinib	2097132-94-8	21.8
Cellulose, 2-hydroxypropyl methyl ether	9004-65-3	>= 20.0 - <= 25.0
Carbonic acid sodium salt (1:1)	144-55-8	>= 15.0 - <= 20.0
1,2,3-Propanetricarboxylic acid, 2-hydroxy-	77-92-9	>= 5.0 - < 10.0
Cellulose	9004-34-6	>= 5.0 - < 10.0
Starch	9005-25-8	>= 1.0 - < 5.0
Octadecanoic acid, magnesium salt (2:1)	557-04-0	< 1.0
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	< 0.5
non hazardous compounds	Not Assigned	> 20.0

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**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.

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- 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.  
 Take victim immediately to hospital.  
 Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Suspected of causing cancer.  
 Suspected of damaging the unborn child.  
 May cause damage to organs through prolonged or repeated exposure.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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**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:  
 Carbon monoxide  
 Hydrogen fluoride  
 Carbon oxides
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
 Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Avoid exposure  
 Use personal protective equipment.  
 Avoid dust formation.  
 Avoid breathing dust.

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- 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.
- Further information on storage conditions : See label, package insert or internal guidelines
- Storage temperature : Protected from heat and light  
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.
- Packaging material : Suitable material: Stainless steel, glass, Plastic container of HDPE

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Pralsetinib	2097132-94-8	IOEL	0.003 mg/m3	Roche Industrial Hygiene Com-

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				mittee (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
Starch	9005-25-8	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

**Predicted No Effect Concentration (PNEC):**

Substance name	Environmental Compartment	Value
Pralsetinib	Fresh water	0.011 mg/l
	Remarks: Based on chronic data	

**Engineering measures** : No data available

**Personal protective equipment**

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
Effective dust mask

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:

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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

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

Protective measures : Instruction of employees mandatory

Hygiene measures : When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and at the end of workday.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : capsules

Color : light blue

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

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

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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

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### 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

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Expert judgment
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

#### Components:

##### **Pralsetinib:**

Acute oral toxicity	:	LD50 Oral (Rat): > 300 mg/kg GLP: yes
		NOAEL (No observed adverse effect level) (Rat): 300 mg/kg GLP: yes

##### **Carbonic acid sodium salt (1:1):**

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- Acute oral toxicity : LD50 (Rat, male and female): > 4,000 mg/kg  
GLP: yes
- Acute inhalation toxicity : LC50 (Rat, male and female): > 4.74 mg/l  
Exposure time: 4.5 h  
Test atmosphere: dust/mist  
GLP: yes  
Assessment: The substance or mixture has no acute inhalation toxicity  
Remarks: No mortality observed at this dose.

**1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**

- Acute oral toxicity : LD50 Oral (Rat, male): 11,700 mg/kg  
Method: OECD Test Guideline 401
- Acute dermal toxicity : (Rat, male and female): > 2,000 mg/kg  
Method: OECD Test Guideline 402

**Cellulose:**

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

**Starch:**

- Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Expert judgment
- Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l  
Test atmosphere: dust/mist  
Method: Expert judgment
- Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Expert judgment

**Titanium oxide (TiO<sub>2</sub>):**

- 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

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Carbonic acid sodium salt (1:1):**

- Species : Rabbit  
Exposure time : 4 h  
Result : No skin irritation



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GLP : yes

**1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**Species : Rabbit  
Exposure time : 4 h  
Method : OECD Test Guideline 404  
Result : No skin irritation**Titanium oxide (TiO<sub>2</sub>):**Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Carbonic acid sodium salt (1:1):**Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
GLP : yes**1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**Species : Rabbit  
Result : Irritating to eyes.  
Method : OECD Test Guideline 405**Titanium oxide (TiO<sub>2</sub>):**Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Titanium oxide (TiO<sub>2</sub>):**Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Method : OECD Test Guideline 406**Germ cell mutagenicity**

Not classified based on available information.

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Genotoxicity in vitro : Test Type: Ames test  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Genotoxicity in vivo : Test Type: Micronucleus test  
Method: OECD Test Guideline 474  
Result: negative  
GLP: yes

**Carbonic acid sodium salt (1:1):**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Escherichia coli  
Metabolic activation: with and without metabolic activation  
Result: negative  
GLP: no

**1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Result: negative

Genotoxicity in vivo : Species: Rat (male)  
Cell type: Bone marrow  
Method: OECD Test Guideline 475  
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 (TiO<sub>2</sub>) 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**

Suspected of damaging the unborn child.

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Effects on fetal development : Test Type: reproductive and developmental toxicity study  
Species: Rat, male and female  
Application Route: Oral  
Target Organs: Kidney  
Result: Teratogenic potential.  
GLP: yes

Test Type: reproductive and developmental toxicity study  
Species: Rat, male and female  
Application Route: Oral  
Target Organs: Skeleton  
Result: Teratogenic potential.  
GLP: yes

Test Type: reproductive and developmental toxicity study  
Species: Rat, male and female  
Application Route: Oral  
Target Organs: Urinary tract  
Result: Teratogenic potential.  
GLP: yes

Test Type: reproductive and developmental toxicity study  
Species: Rat, male and female  
Application Route: Oral  
Target Organs: Testes  
Result: Teratogenic potential.  
GLP: yes

Reproductive toxicity - Assessment : Suspected human reproductive toxicant

Suspected of damaging the unborn child.

**Carbonic acid sodium salt (1:1):**

Effects on fetal development : Species: Rat, female  
Application Route: Oral  
Dose: 3.4, 15.8, 73.3, 340 mg/kg bw/day  
Duration of Single Treatment: 6 - 15 d  
Developmental Toxicity: NOAEL: > 340 mg/kg body weight  
Method: No information available.  
GLP: no

**STOT-single exposure**

Not classified based on available information.

**Components:****Starch:**

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

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### STOT-repeated exposure

May cause damage to organs (Cardiovascular, Skeleton, hematopoietic system) through prolonged or repeated exposure.

#### Components:

##### **Pralsetinib:**

Target Organs : Cardiovascular  
Assessment : May cause damage to organs through prolonged or repeated exposure.

Target Organs : Skeleton  
Assessment : May cause damage to organs through prolonged or repeated exposure.

Target Organs : hematopoietic system  
Assessment : May cause damage to organs through prolonged or repeated exposure.

##### **Starch:**

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

### Repeated dose toxicity

#### Components:

##### **Pralsetinib:**

Species : Rat  
: 20 mg/kg bw/day  
Application Route : Oral  
Exposure time : 13 Weeks  
GLP : yes

##### **1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**

NOAEL : 4,000 mg/kg  
Application Route : Oral  
Exposure time : 10 days

### Aspiration toxicity

Not classified based on available information.

#### Components:

##### **Starch:**

No data available

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- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Test Type: Immobilization  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: nominal concentration
- NOEC (Daphnia magna (Water flea)): 100 mg/l  
Exposure time: 48 h  
Test Type: Immobilization  
Method: OECD Test Guideline 202  
GLP: yes  
Remarks: nominal concentration
- Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration
- NOErC (Raphidocelis subcapitata (freshwater green alga)): 100 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration
- Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 0.110 mg/l  
Exposure time: 34 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)): 1.02 mg/l  
End point: Immobilization  
Test Type: semi-static test  
Method: OECD Test Guideline 211  
GLP: yes  
Remarks: average measured concentration
- Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
GLP: yes  
Remarks: nominal concentration

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

NOEC (activated sludge): 38.5 mg/l  
 Exposure time: 14 d  
 Method: OECD Test Guideline 301F  
 GLP: yes  
 Remarks: no adverse influence on substrate biodegradation

**Carbonic acid sodium salt (1:1):**

Toxicity to fish : LC50 (*Lepomis macrochirus* (Bluegill sunfish)): 7,100 mg/l  
 End point: mortality  
 Exposure time: 96 h  
 Test Type: flow-through test  
 Analytical monitoring: yes  
 GLP: yes

Toxicity to daphnia and other : EC50 (*Daphnia magna* (Water flea)): 4,100 mg/l  
 aquatic invertebrates : End point: Immobilization  
 Exposure time: 48 h  
 Test Type: flow-through test  
 Analytical monitoring: yes  
 GLP: yes

Toxicity to daphnia and other : NOEC (*Daphnia magna* (Water flea)): > 576 mg/l  
 aquatic invertebrates (Chronic toxicity) : End point: reproduction rate  
 Exposure time: 21 d  
 Test Type: semi-static test  
 Analytical monitoring: no  
 GLP: no

**Ecotoxicology Assessment**

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

Other organisms relevant to : No data available  
 the environment

**1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**

Toxicity to fish : LC50 (*Leuciscus idus* (Golden orfe)): 440 - 760 mg/l  
 Exposure time: 96 h

Toxicity to daphnia and other : EC50 (*Daphnia magna* (Water flea)): 120 mg/l  
 aquatic invertebrates : Exposure time: 72 h

Toxicity to algae/aquatic : EC0 (*Scenedesmus quadricauda* (Green algae)): 640 mg/l  
 plants

**Ecotoxicology Assessment**

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

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- 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

**Cellulose:****Ecotoxicology Assessment**

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

**Starch:**

- Toxicity to fish : LC50: > 100 mg/l  
Exposure time: 96 h

**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

**Titanium oxide (TiO<sub>2</sub>):**

- 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

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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**Persistence and degradability****Components:****Pralsetinib:**Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
GLP: yesPhysico-chemical removabil-  
ity : Method: OECD Test Guideline 301F  
Remarks: Not abiotically degradable**Carbonic acid sodium salt (1:1):**

Biodegradability : Remarks: Not applicable

**1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**Biodegradability : aerobic  
Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B**Titanium oxide (TiO<sub>2</sub>):**

Biodegradability : Remarks: Not applicable

**Bioaccumulative potential****Components:****Pralsetinib:**Partition coefficient: n-  
octanol/water : log Pow: 3.0 (68 °F / 20 °C)  
pH: 5  
Method: OECD Test Guideline 107  
GLP: yeslog Pow: 4.0 (68 °F / 20 °C)  
pH: 7  
Method: OECD Test Guideline 107



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GLP: yes

log Pow: 3.9 (68 °F / 20 °C)  
pH: 9  
Method: OECD Test Guideline 107  
GLP: yes**Carbonic acid sodium salt (1:1):**Partition coefficient: n-  
octanol/water : Remarks: No data available**1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow &lt;= 4).

Partition coefficient: n-  
octanol/water : log Pow: -1.72 (68 °F / 20 °C)**Cellulose:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Starch:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Titanium oxide (TiO<sub>2</sub>):**Partition coefficient: n-  
octanol/water : Remarks: No data available**Mobility in soil**

No data available

**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.  
Harmful to aquatic life with long lasting effects.

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### 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.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

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

Not applicable

#### Domestic regulation

##### 49 CFR

Not regulated as a dangerous good

#### Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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### 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

- : Carcinogenicity  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)

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**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 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

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

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
Starch	9005-25-8

**Pennsylvania Right To Know**

Cellulose, 2-hydroxypropyl methyl ether	9004-65-3
Pralsetinib	2097132-94-8
non hazardous compounds	Not Assigned
Carbonic acid sodium salt (1:1)	144-55-8
1,2,3-Propanetricarboxylic acid, 2-hydroxy-	77-92-9
Cellulose	9004-34-6
Starch	9005-25-8

**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 including Titanium oxide (TiO<sub>2</sub>), 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 Permissible Exposure Limits for Chemical Contaminants**

Cellulose	9004-34-6
Starch	9005-25-8

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

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- AIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
  
Pralsetinib  
  
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
- 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

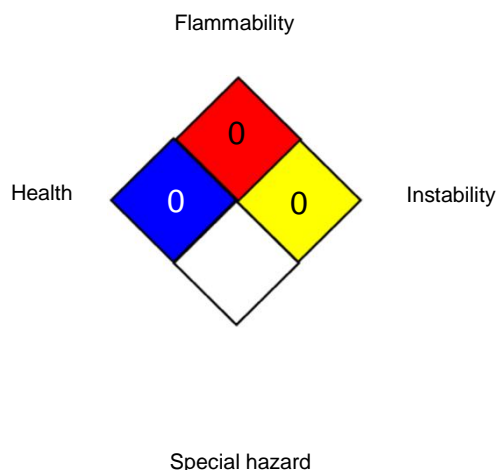
### TSCA list

No substances are subject to a Significant New Use Rule.

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

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## SECTION 16. OTHER INFORMATION

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<b>HEALTH</b>	*	<b>2</b>
<b>FLAMMABILITY</b>		<b>0</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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. 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 P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIC - 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; IECS - 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

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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

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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