

GAVRETO(R) Capsules 100 mgVersion
2.1Revision Date:
08-19-2022Date of last issue: 04-08-2022
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.

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.

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 ₂)	13463-67-7	< 0.5
non hazardous compounds	Not Assigned	> 20.0

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.

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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.

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.

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 (TiO ₂)	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.

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

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: > 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 (TiO₂):

- Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 425
- Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
- Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

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 (TiO₂):**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 (TiO₂):**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 (TiO₂):**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 (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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): > 576 mg/l
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 the environment : No data available

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 aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 120 mg/l
Exposure time: 72 h

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

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 (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

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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 removability : 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 (TiO₂):**

Biodegradability : Remarks: Not applicable

Bioaccumulative potential**Components:****Pralsetinib:**Bioaccumulation : Species: Danio rerio (zebra fish)
Bioconcentration factor (BCF): 5.58
Exposure time: 13 d
Temperature: 72.5 °F / 22.5 °C
Concentration: 3,21 µg/l
Method: OECD Test Guideline 305
GLP: yes
Remarks: Does not bioaccumulate.

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Expert judgment

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
GLP: yeslog 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 <= 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 (TiO₂):Partition coefficient: n-
octanol/water

: Remarks: No data available

Mobility in soil**Components:**

Pralsetinib:

Distribution among environ-
mental compartments: Medium: Soil
Koc: 6247 - 37105 ml/g
Method: OECD Test Guideline 106
Remarks: immobileMedium: Sludge
Koc: 5960 - 8799 ml/g
Method: OECD Test Guideline 106

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Remarks: immobile

Stability in soil : Soil temperature: 68 °F / 20 °C
Dissipation time: 156 - 165 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: persistent
Fresh water sediment

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.

Components:**Pralsetinib:**

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.

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**

Not regulated as a dangerous good

IATA-DGR

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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

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)

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 I 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

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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 (TiO₂), which is/are known to the State of California to cause cancer. For more information go to 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:

- AIIC : 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

SAFETY DATA SHEET

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TSCA : Product contains substance(s) not listed on TSCA inventory.

TECI : Not in compliance with the inventory

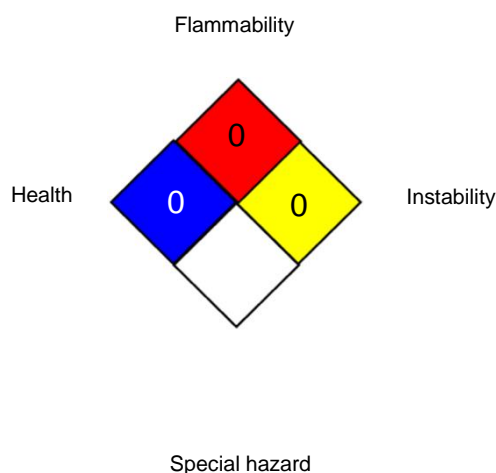
TSCA list

No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

NFPA 704:



HMIS® IV:

HEALTH	*	2
FLAMMABILITY		0
PHYSICAL HAZARD		0

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

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-

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tem; 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; TECL - 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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