

COTELLIC(R) Tablets (20 mg)

Version
1.5

Revision Date:
10-27-2021

Date of last issue: 01-22-2020
Date of first issue: 12-07-2015

SECTION 1. IDENTIFICATION

Product name : COTELLIC(R) Tablets (20 mg)
Product code : RO551-4041/F04
Common name(s),
synonym(s) of the substance : BS10010, BS10336, BS10337
Cobimetinib F.C. Tablets 20 mg
Cobimetinib Film Coated Tablets 20 mg
Cobimetinib Tablets 20 mg

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

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)

Acute toxicity (Oral) : Category 4
Carcinogenicity : Category 1A
Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
H350 May cause cancer.
H360D May damage the unborn child.

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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.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

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)
Cobimetinib	1369665-02-0	17.8
Cellulose	9004-34-6	43.9
Lactose-1-Hydrate	64044-51-5	29.2
Croscarmellose sodium	74811-65-7	3.9
Ethenol, homopolymer	9002-89-5	1.5
Octadecanoic acid, magnesium salt (2:1)	557-04-0	1.4
Titanium oxide (TiO ₂)	13463-67-7	< 1.0
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	25322-68-3	0.8
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	0.6

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

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- 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.
Take victim immediately to hospital.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
May cause cancer.
May damage the unborn child.
- 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 : Carbon oxides
In case of fire hazardous decomposition products may be produced such as:
Hydrogen fluoride
Nitrogen oxides (NOx)
- 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 : Avoid exposure
Use personal protective equipment.

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- emergency procedures : Avoid dust formation.
Avoid breathing dust.
- 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 : Store at room 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: glass, Stainless steel

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of	Control parameters /	Basis

SAFETY DATA SHEET

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		exposure)	Permissible concentration	
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Cobimetinib	1369665-02-0	IOEL	0.001 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
Titanium oxide (TiO ₂)	13463-67-7	TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (Total dust)	10 mg/m ³	OSHA P0
		TWA (Titanium dioxide)	10 mg/m ³	ACGIH
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable)	2 mg/m ³	NIOSH REL
		TWA (Respirable particulate matter)	2 mg/m ³	ACGIH

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Cobimetinib	Surface waters	8.98 µg/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

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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:
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 : Dust impervious protective suit
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 : tablet
Color : white
Odor : Not applicable
Odor Threshold : Not applicable
pH : No data available
Melting point/freezing point : No data available
Boiling point/boiling range : No data available
Evaporation rate : No data available
Self-ignition : No data available

SAFETY DATA SHEET

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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

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.

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 560.3 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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

Lactose-1-Hydrate:

- Acute oral toxicity : LD50 Oral (Rat): > 10,000 mg/kg
- Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment
- Acute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Cobimetinib:

- Acute oral toxicity : LD50 Oral (Rat): > 60 - < 75 mg/kg
GLP: yes
The value is given in analogy to the following substances:
Cobimetinib (free base)
- NOAEL (No observed adverse effect level) (Rat): 30 mg/kg
GLP: yes
The value is given in analogy to the following substances:
Cobimetinib (free base)

Ethenol, homopolymer:

- Acute oral toxicity : LD50 Oral (Rat): > 20,000 mg/kg
- Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment
- Acute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Octadecanoic acid, magnesium salt (2:1):

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

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

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Not classified based on available information.

Components:**Cobimetinib:**

Method : in silico model
Result : No skin irritation
The value is given in analogy to the following substances: Cobimetinib (free base)

Ethanol, homopolymer:

Remarks : This information is not available.

Titanium oxide (TiO₂):

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

Talc (Mg₃H₂(SiO₃)₄):

Remarks : This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Ethanol, homopolymer:**

Remarks : This information is not available.

Titanium oxide (TiO₂):

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Talc (Mg₃H₂(SiO₃)₄):

Remarks : This information is not available.

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

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Germ cell mutagenicity

Not classified based on available information.

Components:

Cobimetinib:

Genotoxicity in vitro : Result: negative
Remarks: In vitro tests did not show mutagenic effects
The value is given in analogy to the following substances:
Cobimetinib (free base)

Germ cell mutagenicity - Assessment : In vitro tests did not show mutagenic effects
The value is given in analogy to the following substances:
Cobimetinib (free base)

Carcinogenicity

May cause 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.

Lactose-1-Hydrate:

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 Known to be human carcinogen
Talc (Mg3H2(SiO3)4) 14807-96-6
(Silica, Crystalline (Respirable Size))

Reproductive toxicity

May damage the unborn child.

Components:

Cobimetinib:

Reproductive toxicity - Assessment : May damage the unborn child., Presumed human reproductive toxicant
The value is given in analogy to the following substances:
Cobimetinib (free base)

STOT-single exposure

Not classified based on available information.

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

Ethenol, homopolymer:

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.

Talc (Mg₃H₂(SiO₃)₄):

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:**Lactose-1-Hydrate:**

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

Ethenol, homopolymer:

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.

Talc (Mg₃H₂(SiO₃)₄):

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

Repeated dose toxicity**Components:****Cobimetinib:**Species : Rat
NOAEL : 1 mg/kg bw/day
Application Route : Oral
Exposure time : 28 Days
Test substance : yes
Remarks : Subacute toxicity

The value is given in analogy to the following substances: Cobimetinib (free base)

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Species : Rat
LOAEL : >3 mg/kg bw/day
Application Route : Oral
Exposure time : 13 Weeks
Test substance : yes
Remarks : Subchronic toxicity
The value is given in analogy to the following substances: Cobimetinib (free base)

Aspiration toxicity

Not classified based on available information.

Components:

Lactose-1-Hydrate:

No data available

Ethenol, homopolymer:

No data available

Octadecanoic acid, magnesium salt (2:1):

No data available

Talc (Mg₃H₂(SiO₃)₄):

No data available

Further information

Components:

Cobimetinib:

Remarks : Not phototoxic
The value is given in analogy to the following substances: Cobimetinib (free base)

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Ecotoxicology Assessment

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

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

Lactose-1-Hydrate:

Toxicity to fish : LC50: > 100 mg/l

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Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

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

Cobimetinib:Toxicity to fish : LC50 (Danio rerio (zebra fish)): 0.80 mg/l
End point: mortality
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
The value is given in analogy to the following substances:
Cobimetinib (free base)NOEC (Danio rerio (zebra fish)): 0.43 mg/l
End point: mortality
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
The value is given in analogy to the following substances:
Cobimetinib (free base)Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3.54 mg/l
End point: Immobilization
Exposure time: 48 h
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes
Remarks: average measured concentration
The value is given in analogy to the following substances:
Cobimetinib (free base)NOEC (Daphnia magna (Water flea)): 2.00 mg/l
End point: Immobilization
Exposure time: 48 h
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes
Remarks: average measured concentration
The value is given in analogy to the following substances:
Cobimetinib (free base)Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 11.8 mg/l
Exposure time: 72 h

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Analytical monitoring: yes
 Method: OECD Test Guideline 201
 GLP: yes
 Remarks: average measured concentration
 The value is given in analogy to the following substances:
 Cobimetinib (free base)

EyC50 (Desmodesmus subspicatus (green algae)): 2.25 mg/l
 Exposure time: 72 h
 Analytical monitoring: yes
 Method: OECD Test Guideline 201
 GLP: yes
 Remarks: average measured concentration
 The value is given in analogy to the following substances:
 Cobimetinib (free base)

NOErC (Desmodesmus subspicatus (green algae)): < 0.62 mg/l
 Exposure time: 72 h
 Analytical monitoring: yes
 Method: OECD Test Guideline 201
 GLP: yes
 Remarks: average measured concentration
 The value is given in analogy to the following substances:
 Cobimetinib (free base)

NOEyC (Desmodesmus subspicatus (green algae)): < 0.62 mg/l
 Exposure time: 72 h
 Analytical monitoring: yes
 Method: OECD Test Guideline 201
 GLP: yes
 Remarks: average measured concentration
 The value is given in analogy to the following substances:
 Cobimetinib (free base)

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): \geq 109 mg/l
 Exposure time: 35 d
 Method: OECD Test Guideline 210
 GLP: yes
 The value is given in analogy to the following substances:
 Cobimetinib (free base)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0898 mg/l
 End point: Immobilization
 Exposure time: 21 d
 Method: OECD Test Guideline 211
 GLP: yes
 Remarks: average measured concentration
 The value is given in analogy to the following substances:
 Cobimetinib (free base)

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

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GLP: yes
 Remarks: nominal concentration
 The value is given in analogy to the following substances:
 Cobimetinib (free base)

(activated sludge): 57.5 mg/l
 Exposure time: 28 d
 Method: OECD Test Guideline 301F
 Remarks: no adverse influence on substrate biodegradation
 measured initial concentration
 The value is given in analogy to the following substances:
 Cobimetinib (free base)

Ethenol, homopolymer:

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

Toxicity to fish (Chronic toxicity) : > 1 mg/l

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

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

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

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- Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 1,000 mg/l
 Exposure time: 48 h
 Test Type: static test
 Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
 Exposure time: 72 h
 Test Type: static test
 Method: OECD Test Guideline 201
- EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
 Exposure time: 72 h
 Method: ISO 10253
- NOEC (Skeletonema costatum (marine diatom)): 5,600 mg/l
 Exposure time: 72 h
 Method: ISO 10253

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Talc (Mg₃H₂(SiO₃)₄):

 Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100,000 mg/l
 Exposure time: 24 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

Persistence and degradability
Components:
Cobimetinib:

 Biodegradability : aerobic
 Inoculum: activated sludge
 Concentration: 60.8 mg/l
 Theoretical oxygen demand
 Result: Not readily biodegradable.
 Biodegradation: 0 %
 Exposure time: 28 Days
 Method: OECD Test Guideline 301F
 GLP: yes

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The value is given in analogy to the following substances:
Cobimetinib (free base)

Titanium oxide (TiO2):

Biodegradability : Remarks: Not applicable

Bioaccumulative potential

Components:

Cellulose:

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

Lactose-1-Hydrate:

Partition coefficient: n-octanol/water : log Pow: -5.03

Cobimetinib:

Partition coefficient: n-octanol/water : log Pow: 0.32

Polyvinyl alcohol:

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

Magnesium stearate:

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

Titanium dioxide:

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

Talc:

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

Mobility in soil

Components:

Cobimetinib:

Distribution among environmental compartments : Medium: Soil
Method: OECD Test Guideline 106
Remarks: immobile

Medium: Sludge
Method: OECD Test Guideline 106
Remarks: immobile

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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.
Toxic to aquatic life with long lasting effects.

Components:

Ethenol, homopolymer:

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

Additional ecological information : No data available

Talc (Mg₃H₂(SiO₃)₄):

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

Additional ecological information : No data available

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

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

Domestic regulation**49 CFR**

UN/ID/NA number : UN 3077
 Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
 (Cobimetinib, mixture)
 Class : 9
 Packing group : III
 Labels : CLASS 9
 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.

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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 : Acute toxicity (any route of exposure)
Carcinogenicity
Reproductive toxicity

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

Pennsylvania Right To Know

Cellulose 9004-34-6
Lactose-1-Hydrate 64044-51-5
Cobimetinib 1369665-02-0
Croscarmellose sodium 74811-65-7

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

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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
Octadecanoic acid, magnesium salt (2:1)	557-04-0

California Regulated Carcinogens

Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6
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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. Cobimetinib Croscarmellose sodium
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.

SECTION 16. OTHER INFORMATION

SAFETY DATA SHEET

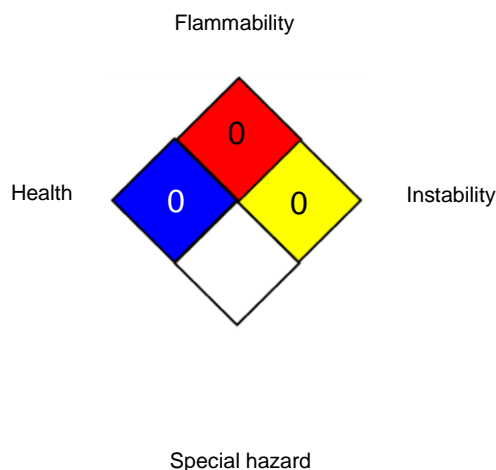
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NFPA 704:



HMIS® IV:

HEALTH	*	1
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. 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

AllC - 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; 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

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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.

US / Z8 / 2010