

COTELLIC Tablets 20 mg

Version 1.0 Revision Date: 06/13/2025 Date of last issue: - Date of first issue: 06/13/2025

SECTION 1. IDENTIFICATION

Product name : COTELLIC Tablets 20 mg
Product code : RO551-4041/F10-00
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 :
In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

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 2
Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms : 
Signal Word : Danger
Hazard Statements : H302 Harmful if swallowed.
H351 Suspected of causing cancer.
H360D May damage the unborn child.
Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read

COTELLIC Tablets 20 mg
Version
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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 (TiO2) | 13463-67-7 | 1 |
| Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy- | 25322-68-3 | 0.8 |
| Talc (Mg3H2(SiO3)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.

If inhaled : Do not leave the victim unattended.
 If unconscious, place in recovery position and seek medical advice.
 If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Induce vomiting immediately and call a physician.
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.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
Suspected of causing cancer.
May damage the unborn child.

Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing

Notes to physician : Treat symptomatically.

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
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, : Avoid exposure

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

| | |
|---|---|
| protective equipment and emergency procedures | Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Refer to protective measures listed in sections 7 and 8. |
| 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. |
| Storage temperature | : Store at room temperature. Protect 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 exposure) | Control parameters / Permissible concentration | Basis |
|------------|---------|----------------------------------|--|-------|
| | | | | |

SAFETY DATA SHEET

Genentech
A Member of the Roche Group

COTELLIC Tablets 20 mg

Version
1.0

Revision Date:
06/13/2025

Date of last issue: -
Date of first issue: 06/13/2025

| | | | | |
|---|--------------|-------------------------------------|--|---|
| 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 (Respirable particulate matter) | 0.2 mg/m ³ (Titanium dioxide) | ACGIH |
| | | TWA (Respirable particulate matter) | 2.5 mg/m ³ (Titanium dioxide) | ACGIH |
| Substance name | | Environmental Compartment | Value | |
| Cobimetinib | | Surface waters | 8.98 µg/l | |
| | | Remarks:Based on chronic data | | |

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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

Flash point : Not applicable

COTELLIC Tablets 20 mg

Version 1.0 Revision Date: 06/13/2025 Date of last issue: -
Date of first issue: 06/13/2025

Evaporation rate : No data available
Self-ignition : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : No data available
Solubility in other solvents : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, dynamic : Not applicable
Viscosity, kinematic : Not applicable
Explosive properties : No data available
Oxidizing properties : No data available
Particle characteristics
Particle Size Distribution : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : No decomposition if stored and applied as directed.
Conditions to avoid : No data available
Incompatible materials : No data available

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

Not applicable

Hazardous decomposition products : No data available
No hazardous decomposition products are known.

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

Components:**Cellulose:**

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
Test substance: anhydrous substance

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

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

Symptoms: muscle weakness

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 425Acute 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 due to lack of data.

Components:**Cobimetinib:**Method : in silico model
Result : No skin irritation

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

Titanium oxide (TiO₂):Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation**Serious eye damage/eye irritation**

Not classified due to lack of data.

Components:**Titanium oxide (TiO₂):**Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405**Respiratory or skin sensitization****Skin sensitization**

Not classified due to lack of data.

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**Respiratory sensitization**

Not classified due to lack of data.

Components:**Titanium oxide (TiO2):**

Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406

Germ cell mutagenicity

Not classified due to lack of data.

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

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.

Titanium oxide (TiO2):

Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

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

May damage the unborn child.

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**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 due to lack of data.

Components:**Octadecanoic acid, magnesium salt (2:1):**

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

STOT-repeated exposure

Not classified due to lack of data.

Components:**Octadecanoic acid, magnesium salt (2:1):**

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)

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 due to lack of data.

Components:**Ethenol, homopolymer:**

No data available

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**Octadecanoic acid, magnesium salt (2:1):**

No data available

Further information**Product:**

Remarks : No data available

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:**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

COTELLIC Tablets 20 mg

Version
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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

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

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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)): ≥ 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
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:**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

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**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 testLC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203Toxicity 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 202Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
Method: ISO 10253NOEC (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:****Lactose-1-Hydrate:**

Biodegradability : Remarks: No data available

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**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
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:

Bioaccumulation : Remarks: No data available
Partition coefficient: n-octanol/water : log Pow: -5.01
Remarks: anhydrous substance

Cobimetinib:

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

Ethenol, homopolymer:

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

Octadecanoic acid, magnesium salt (2:1):

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

Titanium oxide (TiO2):

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

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**Mobility in soil****Components:****Cobimetinib:**Distribution among
environmental compartments: Medium: Soil
Method: OECD Test Guideline 106
Remarks: immobileMedium: Sludge
Method: OECD Test Guideline 106
Remarks: immobile**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

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.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION**International Regulations**

COTELLIC Tablets 20 mg
Version
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**UNRTDG**

| | | |
|---------------------------|---|---|
| UN number | : | UN 3077 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Cobimetinib) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Environmentally hazardous | : | no |

IATA-DGR

| | | |
|--|---|---|
| UN/ID No. | : | UN 3077 |
| Proper shipping name | : | Environmentally hazardous substance, solid, n.o.s. (Cobimetinib) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | Class 9 - Miscellaneous dangerous substances and articles |
| 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) |
| 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) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | Class 9 - Miscellaneous dangerous substances and articles |
| ERG Code | : | 171 |
| Marine pollutant | : | no |

Special precautions for user

Remarks : No data available

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.

SAFETY DATA SHEET

Genentech
A Member of the Roche Group

COTELLIC Tablets 20 mg

Version
1.0

Revision Date:
06/13/2025

Date of last issue: -
Date of first issue: 06/13/2025

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

| Components | CAS-No. | Component TPQ (lbs) |
|-----------------------------|--|---------------------|
| SARA 311/312 Hazards | : Acute toxicity (any route of exposure) Carcinogenicity Reproductive toxicity | |

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

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

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

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

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

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 |
|-----------|-----------|

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

Octadecanoic acid, magnesium salt (2:1)

557-04-0

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

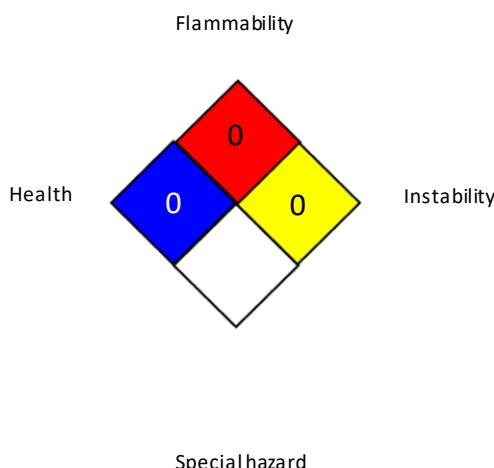
| | | |
|-------|---|---|
| AIIC | : | Not in compliance with the inventory |
| DSL | : | This product contains the following components that are not on the Canadian DSL nor NDSL. |
| | | Cobimetinib |
| | | Croscarmellose sodium |
| NZIoC | : | Not in compliance with the inventory |
| ENCS | : | Not 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**Further information**

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**NFPA 704:****HMIS® IV:**

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

| | | |
|-----------------|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| NIOSH REL | : | USA. NIOSH Recommended Exposure Limits |
| OSHA P0 | : | USA. 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 System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect

COTELLIC Tablets 20 mgVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025

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; 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

Revision Date : 06/13/2025

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 / EN / 2404