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: DNA Way 1
94080 South San Francisco
CA
USA
Telephone: 001-(650) 225-1000
E-mail address: info.sds@roche.com
Emergency telephone number: US Chemtrec phone (800)-424-9300

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 29 CFR 1910.1200
Acute toxicity (Oral): Category 4
Reproductive toxicity: Category 1B

GHS label elements
Hazard pictograms:
Signal Word: Danger
Hazard Statements: H302 Harmful if swallowed.
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
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>43.8</td>
</tr>
<tr>
<td>Lactose-1-Hydrate</td>
<td>64044-51-5</td>
<td>29.2</td>
</tr>
<tr>
<td>Cobimetinib</td>
<td>1369665-02-0</td>
<td>17.8</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>3.9</td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>3.9</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>1.4</td>
</tr>
</tbody>
</table>

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.

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 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:
- In case of fire hazardous decomposition products may be produced such as:
  - Hydrogen fluoride
  - Nitrogen oxides (NOx)
  - 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.

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.
SAFETY DATA SHEET

COTELLIC(R) Tablets (20 mg)

Version 1.4
Revision Date: 01-22-2020
Date of last issue: 06-10-2017
Date of first issue: 12-07-2015

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (Respirable)</td>
<td>5 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (total)</td>
<td>10 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m3</td>
<td>OSHA P0</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

COTELLIC(R) Tablets (20 mg)

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobimetinib</td>
<td>Surface waters</td>
<td>8.98 µg/l</td>
<td>Based on chronic data</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC):

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobimetinib</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:

Material: Protective gloves

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
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: 560.04 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

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)

LD50 Oral (Dog): > 10 - < 30 mg/kg
The value is given in analogy to the following substances: Cobimetinib (free base)

Octadecanoic acid, magnesium salt (2:1):
Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Skin corrosion/irritation
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)

Serious eye damage/eye irritation
Not classified based on available information.
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

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
Not classified based on available information.

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 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.

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.

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.
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 based on available information.

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 : mg/kg bw/day, 1
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 : mg/kg bw/day, >3
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:

Octadecanoic acid, magnesium salt (2:1):
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.

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
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
## Safety Data Sheet

### COTELLIC(R) Tablets (20 mg)

| Remarks | average measured concentration
| Remarks | The value is given in analogy to the following substances:
| Remarks |

| Remarks | average measured concentration
| Remarks | The value is given in analogy to the following substances:
| Remarks |

| Remarks | average measured concentration
| Remarks | The value is given in analogy to the following substances:
| Remarks |

### Toxicity to Fish (Chronic Toxicity)

| Remarks | NOEC (Danio rerio (zebra fish)): >= 109 mg/l
| Remarks | Exposition time: 35 d
| Remarks | Method: OECD Test Guideline 210
| Remarks | GLP: yes
| Remarks | The value is given in analogy to the following substances:
| Remarks | Cobiimetinib (free base)

### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)

| Remarks | NOEC (Daphnia magna (Water flea)): 0.0898 mg/l
| Remarks | End point: Immobilization
| Remarks | Exposition time: 21 d
| Remarks | Method: OECD Test Guideline 211
| Remarks | GLP: yes
| Remarks | Remarks: average measured concentration
| Remarks | The value is given in analogy to the following substances:
| Remarks | Cobiimetinib (free base)

### Toxicity to Microorganisms

| Remarks | EC50 (activated sludge): > 1,000 mg/l
| Remarks | Exposition time: 3 h
| Remarks | Test Type: Respiration inhibition
| Remarks | Method: OECD Test Guideline 209
| Remarks | GLP: yes
| Remarks | Remarks: nominal concentration
| Remarks | 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)

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

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

Bioaccumulative potential

Components:

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

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

Octadecanoic acid, magnesium salt (2:1):
Partition coefficient: n- : log Pow: 0.8
SAFETY DATA SHEET

COTELLIC(R) Tablets (20 mg)

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

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.

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
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
SAFETY DATA SHEET

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Version 1.4  Revision Date: 01-22-2020  Date of last issue: 06-10-2017

Date of first issue: 12-07-2015

(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 : 9
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 : 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.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 311/312 Hazards</td>
<td></td>
<td>Acute toxicity (any route of exposure)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproductive toxicity</td>
</tr>
</tbody>
</table>

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

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
- non hazardous compounds Not Assigned

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Permissible Exposure Limit (PPM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>1</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>1</td>
</tr>
</tbody>
</table>

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

- DSL: This product contains the following components that are not on the Canadian DSL nor NDSL:
  - Cobimetinib
  - Croscarmellose sodium
non hazardous compounds

AICS : Not in compliance with the inventory
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 : Substance(s) not listed on TSCA 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:**

Flammability

Health

Instability

Special hazard

**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
- ACGIH / TWA : 8-hour, time-weighted average
SAFETY DATA SHEET

COTELLIC(R) Tablets (20 mg)

Version 1.4  
Revision Date: 01-22-2020  
Date of last issue: 06-10-2017  
Date of first issue: 12-07-2015

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

AICS - Australian Inventory of Chemical Substances; 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; 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; 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; RO - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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 : 01-22-2020

The information provided in this Material 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 / 1810