SECTION 1. IDENTIFICATION

Product name : ZELBORAF(R) F.C. Tablets (240 mg)
Product code : RO518-5426/F20
Common name(s), synonym(s) of the substance : BS11022 ZELBORAF F.C. Tablets ZELBORAF film-coated tablets 240 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 : 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
Carcinogenicity : Category 2

GHS label elements
Hazard pictograms :

Signal Word : Warning
Hazard Statements : H351 Suspected of causing cancer.
Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response: 
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage: 
P405 Store locked up.

Disposal: 
P501 Dispose of contents/ container to an approved waste dis- posal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vemurafenib</td>
<td>918504-65-1</td>
<td>27.6</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose acetate succinate</td>
<td>71138-97-1</td>
<td>64.4</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>3.4</td>
</tr>
<tr>
<td>Silica</td>
<td>7631-86-9</td>
<td>1.2</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>0.7</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>&lt; 0.7</td>
</tr>
<tr>
<td>Cellulose, 2-hydroxypropyl ether</td>
<td>9004-64-2</td>
<td>0.5</td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>&gt; 1.5</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice : 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.
**SAFETY DATA SHEET**

**ZELBORAF(R) F.C. Tablets (240 mg)**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>02-11-2020</td>
<td>06-10-2017</td>
<td>06-10-2017</td>
</tr>
</tbody>
</table>

If symptoms persist, call a physician.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed:

- Suspected of causing cancer.

Notes to physician:

- The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

**SECTION 5. FIRE-FIGHTING MEASURES**

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsuitable extinguishing media</td>
<td>High volume water jet</td>
</tr>
<tr>
<td>Specific hazards during fire fighting</td>
<td>Do not allow run-off from fire fighting to enter drains or water courses.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>In case of fire hazardous decomposition products may be produced such as: Gaseous hydrogen chloride (HCl), Hydrogen fluoride, Nitrogen oxides (NOx)</td>
</tr>
<tr>
<td>Further information</td>
<td>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.</td>
</tr>
<tr>
<td>Special protective equipment for fire-fighters</td>
<td>Wear self-contained breathing apparatus for firefighting if necessary.</td>
</tr>
</tbody>
</table>

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Avoid dust formation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental precautions</td>
<td>Prevent product from entering drains. Prevent further leakage or spillage if safe to do so.</td>
</tr>
<tr>
<td>Methods and materials for containment and cleaning up</td>
<td>Keep in suitable, closed containers for disposal.</td>
</tr>
</tbody>
</table>

**SECTION 7. HANDLING AND STORAGE**

| Advice on protection against fire and explosion | Provide appropriate exhaust ventilation at places where dust is formed. |
| Advice on safe handling | For personal protection see section 8. Smoking, eating and drinking should be prohibited in the |
application area. Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage: Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions: See label, package insert or internal guidelines

Storage temperature: Protected from heat and light Protect from moisture.

Further information on storage stability: No decomposition if stored and applied as directed.

Packaging material: Suitable material: Plastic container of HDPE

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>Vemurafenib</td>
<td>918504-65-1</td>
<td>IOEL</td>
<td>0.015 mg/m3</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
<tr>
<td>Silica</td>
<td>7631-86-9</td>
<td>TWA (Dust)</td>
<td>20 Million particles per cubic foot (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Dust)</td>
<td>80 mg/m3 / %SiO2 (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>6 mg/m3 (Silica)</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m3 (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

ZELBORAF(R) F.C. Tablets (240 mg)

Version 1.1  
Revision Date: 02-11-2020  
Date of last issue: 06-10-2017

Engineering measures: No data available

Personal protective equipment

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 imperious protective suit

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

Hygiene measures: Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: tablet

Color: light pink

Odor: Not applicable

Odor Threshold: Not applicable

pH: Not applicable

Melting point/range: No data available

Boiling point/boiling range: No data available

Evaporation rate: No data available

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
Explosive properties : No data available
Oxidizing properties : 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
Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

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

Components:
Vemurafenib:
Acute oral toxicity : No-observed-effect level (Rat): 1,000 mg/kg
   Assessment: The component/mixture is minimally toxic after single ingestion.

Silica:
Acute oral toxicity: LD50 Oral (Rat): > 3,300 mg/kg

Acute dermal toxicity: LD50 Dermal (Rabbit): > 5,000 mg/kg

**Titanium oxide (TiO2):**

Acute oral toxicity: LD50 (Rat): > 7,500 mg/kg

Acute inhalation toxicity:
- LC50 (Rat): > 6.82 mg/l
- Exposure time: 4 h
- Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 10,000 mg/kg

**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:**

**Vemurafenib:**
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
- GLP: yes

**Silica:**
- Result: No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Vemurafenib:**
- Remarks: This information is not available.

**Silica:**
- Result: No eye irritation

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

**Vemurafenib:**
**SAFETY DATA SHEET**

**ZELBORAF(R) F.C. Tablets (240 mg)**

<table>
<thead>
<tr>
<th>Version</th>
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<tr>
<td>1.1</td>
<td>02-11-2020</td>
<td>Date of first issue: 06-10-2017</td>
</tr>
</tbody>
</table>

**Species:**
- Guinea pig

**Result:**
- Not a skin sensitizer.

**GLP:**
- yes

**Silica:**
- Did not cause sensitization on laboratory animals.

**Germ cell mutagenicity**
- Not classified based on available information.

**Components:**

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

- Test Type: Chromosome aberration test in vitro
  - Result: negative

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

**Carcinogenicity**
- Suspected of causing cancer.

**IARC**
- Group 2B: Possibly carcinogenic to humans

**Titanium oxide (TiO2)**

**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**
- Not classified based on available information.

**Components:**

**Vemurafenib:**
- **Effects on fetal development**
  - Species: Rat
  - Application Route: Oral
  - Result: No teratogenic effects.

  - Species: Rabbit
  - Application Route: Oral
  - Teratogenicity: NOAEL: 450 mg/kg bw/day
  - Result: No teratogenic effects.
  - GLP: yes
Species: Rabbit, females  
Application Route: Oral  
Dose: 150 mg/kg bw/day  
Duration of Single Treatment: 14 d  
Teratogenicity: NOAEL: 150 mg/kg bw/day  
Result: No embryotoxic effects.  
GLP: no

**STOT-single exposure**
Not classified based on available information.

**Components:**

**Silica:**
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.

**STOT-repeated exposure**
Not classified based on available information.

**Components:**

**Silica:**
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.

**Repeated dose toxicity**

**Components:**

**Vemurafenib:**
Species : Rat  
NOAEL : mg/kg bw/day, 1000  
Application Route : Oral  
Exposure time : 28 Days  
Remarks : Subacute toxicity

Species : Rat  
NOAEL : mg/kg bw/day, 450  
Application Route : Oral  
Exposure time : 13 Weeks  
Remarks : Subchronic toxicity

**Aspiration toxicity**
Not classified based on available information.
Components:

Silica:
No data available

Octadecanoic acid, magnesium salt (2:1):
No data available

Further information

Components:

Vemurafenib:
Remarks : Phototoxic (in vitro)

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Vemurafenib:
Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
Remarks: nominal concentration

NOEC (Poecilia reticulata (guppy)): >= 0.27 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
GLP: yes
Remarks: nominal concentration

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 0.27 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)):
21.91 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes
Remarks: nominal concentration

ErC50 (Raphidocelis subcapitata (freshwater green alga)):
2.832 mg/l
### Exposition time: 72 h
**Method:** OECD Test Guideline 201
**GLP:** yes
**Remarks:** average measured concentration

**NOEC (Raphidocelis subcapitata (freshwater green alga)):** 0.156 mg/l
**Exposure time:** 72 h
**Method:** OECD Test Guideline 201
**GLP:** yes
**Remarks:** average measured concentration

#### Toxicity to fish (Chronic toxicity)
**NOEC (Danio rerio (zebra fish)):** 1.63 mg/l
**Exposure time:** 35 d
**Test Type:** Fish early-life stage (FELS) toxicity test (OECD 210)
**Analytical monitoring:** yes
**Method:** OECD Test Guideline 210
**GLP:** yes
**Remarks:** average measured concentration

**NOEC (Daphnia magna (Water flea)):** 0.0171 mg/l
**Exposure time:** 21 d
**Method:** OECD Test Guideline 211
**GLP:** yes
**Remarks:** average measured concentration

**NOEC (activated sludge):** 301 mg/l
**Test Type:** Respiration inhibition
**Method:** OECD Test Guideline 209

### Toxicity to algae/aquatic plants
**EC50 (Pseudokirchneriella subcapitata (green algae)):** 440 mg/l
**Exposure time:** 72 h
**NOEC (Pseudokirchneriella subcapitata (green algae)):** 60 mg/l
**Exposure time:** 72 h

### Ecotoxicology Assessment
**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:** LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
**Exposure time:** 48 h

**Toxicity to daphnia and other aquatic invertebrates:** EC0 (Daphnia magna (Water flea)): 3 mg/l
Ecotoxicology Assessment

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

Persistence and degradability

Components:

Vemurafenib:

Biodegradability:
Concentration: 31 mg/l
Result: Not inherently biodegradable.
Biodegradation: < 10 %
Exposure time: 28 d
Method: OECD Test Guideline 302C
GLP: yes

Result: very persistent
Method: OECD Test Guideline 308
GLP: yes

Bioaccumulative potential

Components:

Vemurafenib:

Bioaccumulation:
Species: Danio rerio (zebra fish)
Bioconcentration factor (BCF): 62.0 - 133.9
Exposure time: 28 d
Method: OECD Test Guideline 305
GLP: yes

Partition coefficient: n-octanol/water:
log Pow: 4.74
pH: 5
Method: OECD Test Guideline 117
GLP: yes

log Pow: 3.80
pH: 7
### Mobility in soil

#### Components:

**Vemurafenib:**

Distribution among environmental compartments:

<table>
<thead>
<tr>
<th>Koc method</th>
<th>Medium: Soil</th>
<th>Koc: 37000 - 55454</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 106</td>
<td>Remarks: immobile</td>
</tr>
</tbody>
</table>

Koc method

Medium: Sludge

Koc: 3739 - 53630

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.

Very toxic to aquatic life with long lasting effects.
Components:

Vemurafenib:
Results of PBT and vPvB assessment:
This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (vPvB).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues:
The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

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. (Vemurafenib 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. (Vemurafenib mixture)
Class: 9
Packing group: III
Labels: 956
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft):
Environmentally hazardous: yes

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

ZELBORAF® F.C. Tablets (240 mg)

(Vemurafenib 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. (Vemurafenib mixture)
Class : 9
Packing group : III
Labels : Class 9 - Miscellaneous dangerous substances and articles
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>
</table>

SARA 311/312 Hazards : Carcinogenicity

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
Silica 7631-86-9

Pennsylvania Right To Know
Hydroxypropyl methylcellulose acetate succinate 71138-97-1
Vemurafenib 918504-65-1
Croscarmellose sodium 74811-65-7
Silica 7631-86-9

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 List of Hazardous Substances
Silica 7631-86-9

California Permissible Exposure Limits for Chemical Contaminants
Silica 7631-86-9

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.
- Hydroxypropyl methylcellulose acetate succinate
- Vemurafenib
- 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: 0
  - Instability: 0

- **Special hazard:**
  - Instability

**HMIS® IV:**

- **HEALTH:**
  - *: Chronic hazard
  - 0: Absence of chronic hazard

- **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

**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...
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