

**ZELBORAF(R) F.C. Tablets (240 mg)**Version  
1.2Revision Date:  
07-20-2021Date of last issue: 02-11-2020  
Date of first issue: 06-10-2017**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 : 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.

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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the OSHA Hazard Communication Standard (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.

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attention.**Storage:**

P405 Store locked up.

**Disposal:**P501 Dispose of contents/ container to an approved waste  
disposal plant.**Other hazards**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

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

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**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.

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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.

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### 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:  
Gaseous hydrogen chloride (HCl).  
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.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid dust formation.

Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

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### 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

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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

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Vemurafenib	918504-65-1	IOEL	0.015 mg/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)
Silica	7631-86-9	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m <sup>3</sup> / %SiO <sub>2</sub> (Silica)	OSHA Z-3
		TWA	6 mg/m <sup>3</sup> (Silica)	NIOSH REL
		TWA (Respirable dust)	0.05 mg/m <sup>3</sup> (Silica)	NIOSH REL
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	10 mg/m <sup>3</sup>	OSHA P0
		TWA	10 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable)	10 mg/m <sup>3</sup>	ACGIH

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		particulate matter)		
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Vemurafenib	Surface waters	1.71 µg/l
	Remarks: Based on chronic data	

**Engineering measures** : No data available

### Personal protective equipment

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.

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

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## 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

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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

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### 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	:	No data available

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products

**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): &gt; 3,300 mg/kg

Acute inhalation toxicity : LC50 (Rat, male and female): > 5.01 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 436  
GLP: yes  
Assessment: The substance or mixture has no acute inhalation toxicityAcute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg  
Method: No information available.  
GLP: No information available.**Titanium oxide (TiO<sub>2</sub>):**Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401  
Remarks: No mortality observed at this dose.Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): &gt; 5,000 mg/kg

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

Acute oral toxicity : LD50 Oral (Rat): &gt; 2,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

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

**Silica:**

Species : Rabbit  
Exposure time : 4 h  
Method : OECD Test Guideline 404  
Result : No skin irritation  
GLP : No information available.

**Titanium oxide (TiO<sub>2</sub>):**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Vemurafenib:**

Remarks : This information is not available.

**Silica:**

Species : Rabbit  
Result : No eye irritation  
Exposure time : 24 h  
GLP : no

**Titanium oxide (TiO<sub>2</sub>):**

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

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Vemurafenib:**

Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : Not a skin sensitizer.



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GLP : yes

**Silica:**

Test Type : Maximization Test  
 Species : Guinea pig  
 Assessment : Does not cause skin sensitization.  
 Method : OECD Test Guideline 406  
 Result : Did not cause sensitization on laboratory animals.  
 GLP : yes

**Titanium oxide (TiO<sub>2</sub>):**

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

**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

**Silica:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
 Test system: Salmonella typhimurium  
 Metabolic activation: with and without metabolic activation  
 Method: OECD Test Guideline 471  
 Result: negative  
 GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)  
 Test system: Escherichia coli  
 Metabolic activation: with and without metabolic activation  
 Method: OECD Test Guideline 471  
 Result: negative  
 GLP: yes

Test Type: In vitro mammalian cell gene mutation test  
 Test system: mouse lymphoma cells  
 Metabolic activation: with and without metabolic activation  
 Method: OECD Test Guideline 490

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Result: negative  
GLP: yes

Genotoxicity in vivo : Species: Rat (male)  
Cell type: Bone marrow  
Application Route: Oral  
Exposure time: 6, 24, and 48 h  
Dose: 1.4, 14, 140, 500, 5000 mg/kg  
Method: OECD Test Guideline 475  
Result: negative  
GLP: no

**Carcinogenicity**

Suspected of causing cancer.

**IARC** Group 2B: Possibly carcinogenic to humans  
Titanium oxide (TiO<sub>2</sub>) 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**

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

**Silica:**

Effects on fertility : Species: Rat, male and female  
Application Route: Oral  
Dose: 100, 300, 1000 mg/kg bw/day  
General Toxicity Parent: NOAEL: >= 1,000 mg/kg body weight  
General Toxicity F1: NOAEL: >= 1,000 mg/kg body weight  
Method: OECD Test Guideline 416

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GLP: yes

Effects on fetal development : Species: Mouse, female  
Application Route: Oral  
Dose: 13.4, 62.3, 289, 1340 mg/kg bw/day  
Duration of Single Treatment: 6 - 15 d  
General Toxicity Maternal: LOAEL:  $\geq$  1,340 mg/kg bw/day  
Embryo-fetal toxicity.: NOAEL:  $\geq$  1,340  $\mu$ g/kg body weight  
Method: No information available.  
GLP: No information available.

**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:****Vemurafenib:**

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

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

**Aspiration toxicity**

Not classified based on available information.

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

No data available

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Remarks : Phototoxic (in vitro)

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**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

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  
Exposure 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

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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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0171 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
GLP: yes  
Remarks: average measured concentration

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

### Silica:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 5,000 mg/l  
End point: mortality  
Exposure time: 96 h  
Test Type: static test  
Analytical monitoring: no  
Method: OECD Test Guideline 203  
GLP: no

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 10,000 mg/l  
End point: Immobilization  
Exposure time: 24 h  
Test Type: static test  
Analytical monitoring: no  
Method: OECD Test Guideline 202  
GLP: yes

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 173.1 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 201  
GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 149.2 mg/l  
End point: mortality  
Exposure time: 21 d  
Test Type: semi-static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 211

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GLP: yes

Toxicity to microorganisms : NOEC (activated sludge): 1,000 mg/l  
 End point: Respiration inhibition  
 Exposure time: 3 h  
 Test Type: static test  
 Analytical monitoring: no  
 Method: OECD Test Guideline 209  
 GLP: yes

**Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

**Titanium oxide (TiO<sub>2</sub>):**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l  
 Exposure time: 96 h  
 Test Type: static test

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l  
 Exposure time: 96 h  
 Test Type: semi-static test  
 Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 1,000 mg/l  
 Exposure time: 48 h  
 Test Type: static test  
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
 Exposure time: 72 h  
 Test Type: static test  
 Method: OECD Test Guideline 201

EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l  
 Exposure time: 72 h  
 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

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- 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

**Silica:**

- Biodegradability : Remarks: Not applicable

**Titanium oxide (TiO<sub>2</sub>):**

- Biodegradability : Remarks: Not applicable

**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  
Method: OECD Test Guideline 117  
GLP: yes

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log Pow: 3.26  
pH: 9  
Method: OECD Test Guideline 117  
GLP: yes

**Silica:**

Partition coefficient: n-octanol/water : Remarks: Not applicable

**Titanium oxide (TiO2):**

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

**Mobility in soil**

**Components:**

**Vemurafenib:**

Distribution among environmental compartments : Koc method  
Medium: Soil  
Koc: 37000 - 55454  
Method: OECD Test Guideline 106  
Remarks: immobile

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.



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**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 : 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,

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N.O.S.  
(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  
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****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Carcinogenicity

**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).

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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
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**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**

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

**Washington Chemicals of High Concern**

Product does not contain any listed chemicals

**California Prop. 65**

WARNING: This product can expose you to chemicals including Titanium oxide (TiO<sub>2</sub>), which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California List of Hazardous Substances**

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

Silica	7631-86-9
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**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

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- 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

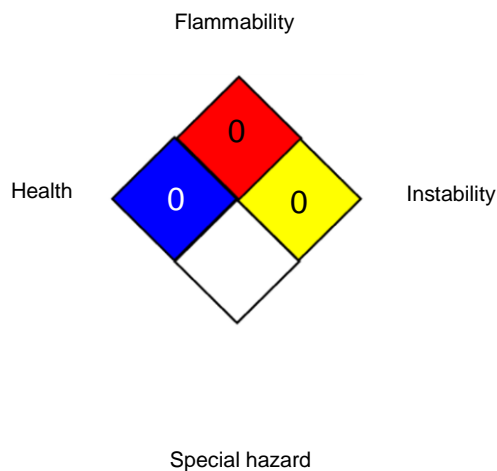
**TSCA list**

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 704:**



**HMIS® IV:**

<b>HEALTH</b>	*	<b>0</b>
<b>FLAMMABILITY</b>		<b>0</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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

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OSHA Z-1 / TWA : 8-hour time weighted average  
OSHA Z-3 / 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 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; 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 : 07-20-2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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