# ZELBORAF Tablets 240 mg

| Version | Revision Date: | Date of last issue: - |
|---|---|---|
| 1.0 | 06/14/2025 | Date of first issue: 06/14/2025 |

## SECTION 1. IDENTIFICATION

| | | |
|---|---|---|
| Product name | : | ZELBORAF Tablets 240 mg |
| Product code | : | RO518-5426/F20-00 |
| Common name(s), synonym(s) of the substance | : | BS11022<br>ZELBORAF F.C. Tablets<br>ZELBORAF film-coated tablets 240 mg |

**Manufacturer or supplier's details**

| | | |
|---|---|---|
| Company name of supplier | : | Genentech, Inc. |
| Address | : | 1 DNA Way<br>South San Francisco, CA 94080<br>USA |
| Telephone | : | 001-(650) 225-1000 |
| E-mail address | : | info.sds@roche.com |
| Emergency telephone<br>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)**

| | | |
|---|---|---|
| Carcinogenicity | : | Category 1A |

**GHS label elements**

Hazard pictograms :

| | | |
|---|---|---|
| Signal Word | : | Danger |
| Hazard Statements | : | H350 May cause cancer. |
| Precautionary Statements | : | **Prevention:**<br>P201 Obtain special instructions before use.<br>P202 Do not handle until all safety precautions have been read and understood.<br>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.<br>**Response:**<br>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) |
|---|---|---|
| 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 (TiO2) | 13463-67-7 | 0.7 |
| Cellulose, 2-hydroxypropyl ether | 9004-64-2 | 0.5 |
| non hazardous compounds | Not Assigned | 1.5 |

## 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 : 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.

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 | : | May cause cancer. |
| 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 | : | Gaseous hydrogen chloride (HCl).<br>Hydrogen fluoride<br>Nitrogen oxides (NOx) |
| Further information | : | Collect contaminated fire extinguishing water separately. This must not be discharged into drains.<br>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 | : | Use personal protective equipment.<br>Avoid dust formation.<br>Avoid breathing dust.<br>Refer to protective measures listed in sections 7 and 8. |
| Environmental precautions | : | Prevent product from entering drains.<br>Prevent further leakage or spillage if safe to do so.<br>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.<br>Provide appropriate exhaust ventilation at places where dust is formed. |
| Advice on safe handling | : | Avoid formation of respirable particles.<br>Do not breathe vapors/dust.<br>Avoid exposure - obtain special instructions before use.<br>Avoid contact with skin and eyes.<br>For personal protection see section 8.<br>Smoking, eating and drinking should be prohibited in the application area.<br>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.<br>Containers which are opened must be carefully resealed and kept upright to prevent leakage.<br>Electrical installations / working materials must comply with the technological safety standards. |
| Storage temperature | : | Protect from heat and light<br>Protect from moisture. |
| Further information on storage stability | : | No decomposition if stored and applied as directed. |
| Packaging material | : | Suitable material: Plastic container of HDPE, Stainless steel, glass |

## 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/m3 | Roche Industrial Hygiene Committee (RIHC) |
| Silica | 7631-86-9 | PEL (respirable) | 0.05 mg/m3 | OSHA CARC |
| | | TWA (Respirable dust) | 0.05 mg/m3 (Silica) | NIOSH REL |
| Titanium oxide (TiO2) | 13463-67-7 | TWA (total dust) | 15 mg/m3 | OSHA Z-1 |
| | | TWA (Total | 10 mg/m3 | OSHA P0 |

| | | | | |
|---|---|---|---|---|
| | | dust) | | |
| | | TWA (Respirable particulate matter) | 0.2 mg/m3 (Titanium dioxide) | ACGIH |
| | | TWA (Respirable particulate matter) | 2.5 mg/m3 (Titanium dioxide) | ACGIH |

| Substance name | Environmental Compartment | Value |
|---|---|---|
| Vemurafenib | Surface waters | 1.71 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 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.

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 | : | 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 |
| Flash point | : | Not applicable |
| 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<br>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 |
| | | No data available |
| Incompatible materials | : | No data available |
| | | Not applicable |
| Hazardous decomposition products | : | No data available |
| | | No hazardous decomposition products are known. |

## SECTION 11. TOXICOLOGICAL INFORMATION

**Acute toxicity**

Not classified due to lack of data.

**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 (Rat, male and female): > 5,000 mg/kg<br>GLP: yes |
| Acute inhalation toxicity | : | LC50 (Rat, male and female): > 5.01 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 436 |

GLP: yes
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg
Method: No information available.
GLP: No information available.

**Titanium oxide (TiO2):**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 425

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

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

**Skin corrosion/irritation**

Not classified due to lack of data.

**Components:**

**Vemurafenib:**

| | | |
|---|---|---|
| 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 (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:**

**Vemurafenib:**

| | | |
|---|---|---|
| Remarks | : | This information is not available. |

**Silica:**

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

**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.

**Respiratory sensitization**

Not classified due to lack of data.

**Components:**

**Vemurafenib:**

| | | |
|---|---|---|
| Species | : | Guinea pig |
| Method | : | OECD Test Guideline 406 |
| Result | : | Not a skin sensitizer. |
| 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 (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:**

**Vemurafenib:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Ames test<br>Method: OECD Test Guideline 471<br>Result: negative<br>GLP: yes<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Method: OECD Test Guideline 474<br>Result: negative<br>GLP: yes |

**Silica:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Microbial mutagenesis assay (Ames test)<br>Test system: Salmonella typhimurium<br>Metabolic activation: with and without metabolic activation<br>Method: OECD Test Guideline 471<br>Result: negative<br>GLP: yes<br><br>Test Type: Microbial mutagenesis assay (Ames test)<br>Test system: Escherichia coli<br>Metabolic activation: with and without metabolic activation<br>Method: OECD Test Guideline 471<br>Result: negative<br>GLP: yes<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Test system: mouse lymphoma cells<br>Metabolic activation: with and without metabolic activation<br>Method: OECD Test Guideline 490<br>Result: negative<br>GLP: yes |
| Genotoxicity in vivo | : | Species: Rat (male)<br>Cell type: Bone marrow<br>Application Route: Oral<br>Method: OECD Test Guideline 475<br>Result: negative |

GLP: no

**Carcinogenicity**

May cause cancer.

**Components:**

**Silica:**

| | | |
|---|---|---|
| Species | : | Rat, male and female |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| Method | : | No information available. |
| Result | : | negative |
| GLP | : | No information available. |

**Titanium oxide (TiO2):**

| | | |
|---|---|---|
| Carcinogenicity - Assessment | : | Limited evidence of a carcinogenic effect. |

| | | |
|---|---|---|
| **IARC** | Group 2B: Possibly carcinogenic to humans<br>Titanium oxide (TiO2) | 13463-67-7 |
| **OSHA** | OSHA specifically regulated carcinogen<br>Silica<br>(crystalline silica) | 7631-86-9 |
| **NTP** | Known to be human carcinogen<br>Silica<br>(Silica, Crystalline (Respirable Size)) | 7631-86-9 |

**Reproductive toxicity**

Not classified due to lack of data.

**Components:**

**Vemurafenib:**

| | | |
|---|---|---|
| Effects on fetal development | : | Species: Rat<br>Application Route: Oral<br>Result: No teratogenic effects.<br><br>Species: Rabbit<br>Application Route: Oral<br>Teratogenicity: NOAEL: 450 mg/kg bw/day<br>Result: No teratogenic effects.<br>GLP: yes<br><br>Species: Rabbit, females<br>Application Route: Oral<br>Dose: 150 mg/kg bw/day<br>Duration of Single Treatment: 14 d<br>Teratogenicity: NOAEL: 150 mg/kg bw/day |

Result: No embryotoxic effects.
GLP: no

**Silica:**

| | | |
|---|---|---|
| Effects on fertility | : | Species: Rat, male and female<br>Application Route: Oral<br>Dose: 100, 300, 1000 mg/kg bw/day<br>General Toxicity Parent: NOAEL: >= 1,000 mg/kg body weight<br>General Toxicity F1: NOAEL: >= 1,000 mg/kg body weight<br>Method: OECD Test Guideline 416<br>GLP: yes |
| Effects on fetal development | : | Species: Mouse, female<br>Application Route: Oral<br>Dose: 13.4, 62.3, 289, 1340 mg/kg bw/day<br>Duration of Single Treatment: 6 - 15 d<br>General Toxicity Maternal: LOAEL: >= 1,340 mg/kg bw/day<br>Embryo-fetal toxicity.: NOAEL: >= 1,340 µg/kg body weight<br>Method: No information available.<br>GLP: No information available. |

**STOT-single exposure**

Not classified due to lack of data.

**STOT-repeated exposure**

Not classified due to lack of data.

**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 |

**Silica:**

| | | |
|---|---|---|
| Species | : | Rat, male and female |
| NOEL | : | 4000 mg/kg |
| Application Route | : | Oral |

| | | |
|---|---|---|
| Exposure time | : | 13 Weeks |
| Method | : | OECD Test Guideline 408 |
| GLP | : | yes |

**Aspiration toxicity**

Not classified due to lack of data.

**Further information**

**Product:**

| | | |
|---|---|---|
| Remarks | : | No data available |

**Components:**

**Vemurafenib:**

| | | |
|---|---|---|
| Remarks | : | Phototoxic (in vitro) |

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Vemurafenib:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Poecilia reticulata (guppy)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>GLP: yes<br>Remarks: nominal concentration<br><br>NOEC (Poecilia reticulata (guppy)): >= 0.27 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>GLP: yes |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>GLP: yes<br>Remarks: nominal concentration<br><br>NOEC (Daphnia magna (Water flea)): 0.27 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>GLP: yes<br>Remarks: nominal concentration |
| Toxicity to algae/aquatic plants | : | ErC50 (Raphidocelis subcapitata (freshwater green alga)): 21.91 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>GLP: yes<br>Remarks: nominal concentration<br><br>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
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
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 (TiO2):**

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

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

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

**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 (TiO2):**

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

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

**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.

**Components:**

**Vemurafenib:**

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).
Substance is not very persistent and very bioaccumulative (vPvB).

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | The product should not be allowed to enter drains, water courses or the soil.<br>Do not contaminate ponds, waterways or ditches with chemical or used container.<br>Send to a licensed waste management company. |
| Contaminated packaging | : | Empty remaining contents.<br>Dispose of as unused product.<br>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.<br>(Vemurafenib) |
| 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.<br>(Vemurafenib) |
| 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.<br>(Vemurafenib) |
| 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) |
| 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.

## 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** : 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
This product does not contain any priority pollutants related to the U.S. Clean Water Act

**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**

| | |
|---|---|
| Silica | 7631-86-9 |

**Vermont Chemicals of High Concern**

**Washington Chemicals of High Concern**

**California Prop. 65**

WARNING: This product can expose you to chemicals including Silica, 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 Regulated Carcinogens**

| | |
|---|---|
| Silica | 7631-86-9 |

**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.<br><br>Hydroxypropyl methylcellulose acetate succinate<br><br>Vemurafenib<br><br>Croscarmellose sodium<br><br>non hazardous compounds |
| 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**

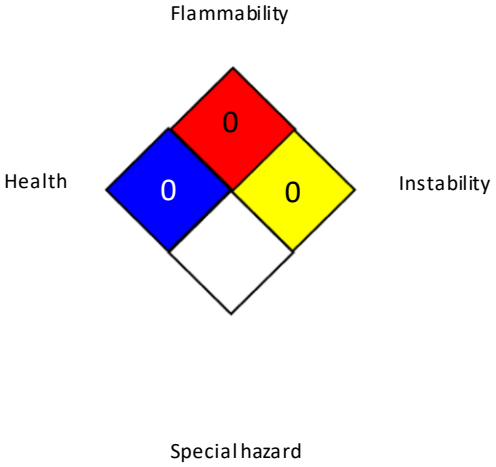
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

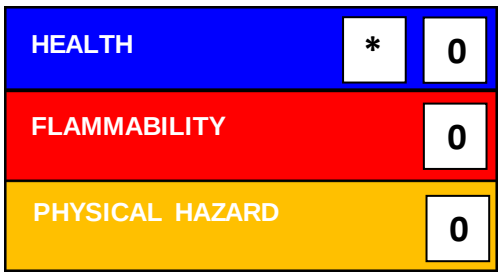
## SECTION 16. OTHER INFORMATION

**Further information**

**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 CARC | : | OSHA Specifically Regulated Chemicals/Carcinogens |
| 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 CARC / PEL | : | Permissible exposure limit (PEL) |
| 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 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 : 06/14/2025

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.

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