

## ERIVEDGE(R) Capsules (150 mg)

Version  
0.0

Revision Date:  
01-23-2020

Date of last issue: 06-10-2017  
Date of first issue: 12-04-2015

### SECTION 1. IDENTIFICATION

Product name : ERIVEDGE(R) Capsules (150 mg)

Product code : RO545-0815/F03

Common name(s), syno- : ERIVEDGE Capsules 150 mg  
nym(s) of the substance

#### 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

Emergency telephone num- : US Chemtrec phone (800)-424-9300  
ber

#### 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 29 CFR 1910.1200

Eye irritation : Category 2A

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1B

Specific target organ toxicity : Category 2  
- repeated exposure

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H319 Causes serious eye irritation.  
H350 May cause cancer.  
H360FD May damage fertility. May damage the unborn child.  
H373 May cause damage to organs through prolonged or re-

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peated exposure.

Precautionary Statements :

**Prevention:**

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P337 + P313 If eye irritation persists: 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)
Vismodegib	879085-55-9	35.29
Cellulose	9004-34-6	20.54
Gelatins	9000-70-8	17.51
Lactose-1-Hydrate	64044-51-5	16.82
Starch, carboxymethyl ether, sodium salt	9063-38-1	4.12
2-Pyrrolidinone, 1-ethenyl-, homo-polymer	9003-39-8	2.47
Sulfuric acid monododecyl ester sodium salt (1:1)	151-21-3	1.65
Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6	0.82
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.4
Titanium oxide (TiO <sub>2</sub> )	13463-67-7	0.35
Iron oxide (Fe <sub>3</sub> O <sub>4</sub> )	1317-61-9	0.02
Iron oxide (Fe <sub>2</sub> O <sub>3</sub> )	1309-37-1	0.01

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- General advice : Move out of dangerous area.  
Show this material safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If skin irritation persists, call a physician.  
If on skin, rinse well with water.  
If on clothes, remove clothes.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Take victim immediately to hospital.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.  
May cause cancer.  
May damage fertility. May damage the unborn child.  
May cause damage to organs through prolonged or repeated exposure.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:  
Gaseous hydrogen chloride (HCl).  
Sulfur oxides  
Nitrogen oxides (NOx)  
Carbon oxides

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- 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 : Prevent any exposure  
Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

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**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Containers which are opened must be carefully resealed and kept upright to prevent leakage.  
Electrical installations / working materials must comply with the technological safety standards.
- Storage temperature : 15 °C to 30 °C  
Protect against light.  
Protect from moisture.
- Further information on storage stability : No decomposition if stored and applied as directed.

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Packaging material : Suitable material: Plastic container of HDPE, Polyethylene bag in metal drum, Stainless steel

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Vismodegib	879085-55-9	IOEL	0.0003 mg/m <sup>3</sup>	Roche Industrial Hygiene Committee (RIHC)
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (Respirable fraction)	2 mg/m <sup>3</sup>	ACGIH
Octadecanoic acid, magnesium salt (2:1)	557-04-0	TWA (Inhalable fraction)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable fraction)	3 mg/m <sup>3</sup>	ACGIH
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 (Titanium dioxide)	10 mg/m <sup>3</sup>	ACGIH
Iron oxide (Fe <sub>2</sub> O <sub>3</sub> )	1309-37-1	TWA (Respirable fraction)	5 mg/m <sup>3</sup>	ACGIH
		TWA (Fumes)	10 mg/m <sup>3</sup>	OSHA Z-1
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1

# SAFETY DATA SHEET

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		TWA (Fumes)	10 mg/m3	OSHA P0
		TWA (dust and fume)	5 mg/m3 (Iron)	NIOSH REL

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Sulfuric acid monododecyl ester sodium salt (1:1)	Fresh water	0.176 mg/l
	Sea water	0.0176 mg/l
	Fresh water sediment	6.97 mg/kg
	Sea sediment	0.697 mg/kg
	Soil	1.29 mg/kg

**Engineering measures** : No data available

### Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
Effective dust mask

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.  
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles  
Wear face-shield and protective suit for abnormal processing problems.

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

Protective measures : Instruction of employees mandatory

Hygiene measures : When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and at the end of workday.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : capsules

Color : gray  
pink

Odor : Not applicable

Odor Threshold : Not applicable

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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

Viscosity

    Viscosity, dynamic : Not applicable

    Viscosity, kinematic : Not applicable

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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.

Incompatible materials : No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

**Product:**

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- Acute oral toxicity                      :    Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method
- Acute inhalation toxicity                :    Acute toxicity estimate: 63.49 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method
- Acute dermal toxicity                    :    Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

**Components:****Vismodegib:**

- Acute oral toxicity                      :    LD50 Oral (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
GLP: yes

**Cellulose:**

- Acute oral toxicity                      :    LD50 Oral (Rat): > 5,000 mg/kg
- Acute dermal toxicity                    :    LD50 Dermal (Rabbit): > 2,000 mg/kg

**Sulfuric acid monododecyl ester sodium salt (1:1):**

- Acute oral toxicity                      :    LD50 Oral (Rat): 1,200 mg/kg
- Acute inhalation toxicity                :    Assessment: The component/mixture is moderately toxic after  
short term inhalation.
- Acute dermal toxicity                    :    LD50 Dermal (Rat, male and female): > 2,000 mg/kg

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

- Acute oral toxicity                      :    LD50 Oral (Rat): > 2,000 mg/kg

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

- 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

**Iron oxide (Fe<sub>2</sub>O<sub>3</sub>):**

- Acute oral toxicity                      :    LD50 Oral (Rat): > 5,000 mg/kg
- Acute inhalation toxicity                :    Median lethal concentration (Rat): 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist
- LC50 (Rat): > 5 mg/l  
Exposure time: 4 h



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Test atmosphere: dust/mist

### **Skin corrosion/irritation**

Not classified based on available information.

#### **Product:**

Remarks : May cause skin irritation and/or dermatitis.

#### **Components:**

##### **Vismodegib:**

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

##### **Sulfuric acid monododecyl ester sodium salt (1:1):**

Result : Irritating to skin.

##### **Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

Remarks : This information is not available.

##### **Iron oxide (Fe<sub>2</sub>O<sub>3</sub>):**

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

### **Serious eye damage/eye irritation**

Causes serious eye irritation.

#### **Product:**

Remarks : May cause irreversible eye damage.

#### **Components:**

##### **Sulfuric acid monododecyl ester sodium salt (1:1):**

Result : Risk of serious damage to eyes.

##### **Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

Remarks : This information is not available.

##### **Iron oxide (Fe<sub>2</sub>O<sub>3</sub>):**

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

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**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Vismodegib:**

Genotoxicity in vitro : Test Type: Ames test  
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)  
Result: negative  
GLP: yes

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Rat  
Application Route: Oral  
Result: negative

**Carcinogenicity**

May cause cancer.

**Components:**

**Cellulose:**

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**Sulfuric acid monododecyl ester sodium salt (1:1):**

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**IARC** Group 2B: Possibly carcinogenic to humans  
Titanium oxide (TiO2) 13463-67-7

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** Known to be human carcinogen  
Talc (Mg3H2(SiO3)4) 14807-96-6  
(Silica, Crystalline (Respirable Size))

**Reproductive toxicity**

May damage fertility. May damage the unborn child.

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Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Embryo-fetal toxicity.: LOEL: 10 mg/kg/d  
Result: Teratogenicity and developmental toxicity  
GLP: yes

Reproductive toxicity - Assessment : Presumed human reproductive toxicant, May damage fertility.  
May damage the unborn child.

**STOT-single exposure**

Not classified based on available information.

**Components:****Sulfuric acid monododecyl ester sodium salt (1:1):**

Assessment : May cause respiratory irritation.

**Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

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**

May cause damage to organs through prolonged or repeated exposure.

**Components:****Vismodegib:**

Assessment : May cause damage to organs through prolonged or repeated exposure.

**Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

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:****Vismodegib:**

Species : Rat

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NOAEL	:	mg/kg/w, <5
Application Route	:	Oral
Exposure time	:	26 Weeks
Species	:	Mouse
NOAEL	:	mg/kg bw/day, 50
Application Route	:	Oral
Exposure time	:	84 d
Remarks	:	Subchronic toxicity

**Aspiration toxicity**

Not classified based on available information.

**Components:****Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

No data available

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

No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Vismodegib:**

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 1.5 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 GLP: yes
		NOEC (Danio rerio (zebra fish)): 1.5 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 Test Type: Immobilization Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: yes Remarks: nominal concentration
		NOEC (Daphnia magna (Water flea)): 0.85 mg/l Exposure time: 48 h Test Type: Immobilization Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: yes Remarks: average measured concentration

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- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (algae)): 0.118 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes
- EyC50 (Pseudokirchneriella subcapitata (algae)): 0.099 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes
- NOEC (Pseudokirchneriella subcapitata (algae)): 0.069 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration
- ErC50 (Desmodesmus subspicatus (green algae)): 0.95 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration
- EyC50 (Desmodesmus subspicatus (green algae)): 0.52 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration
- NOEC (Desmodesmus subspicatus (green algae)): 0.32 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
GLP: yes  
Remarks: nominal concentration
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1.5 mg/l  
Exposure time: 21 d  
Analytical monitoring: yes  
Method: OECD Test Guideline 211  
GLP: yes  
Remarks: nominal concentration
- Lowest Observed Effect Concentration (Daphnia magna (Water flea)): 1.5 mg/l  
Exposure time: 21 d  
Analytical monitoring: yes  
Method: OECD Test Guideline 211  
GLP: yes  
Remarks: nominal concentration
- Toxicity to microorganisms : (activated sludge): 54 mg/l  
Exposure time: 14 d  
Remarks: no adverse influence on substrate biodegradation  
nominal concentration

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Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

**Sulfuric acid monododecyl ester sodium salt (1:1):**

- Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): 29 mg/l  
LC50 (Lepomis macrochirus (Bluegill sunfish)): 4.1 mg/l  
Exposure time: 96 h  
LC50 (Oncorhynchus mykiss (rainbow trout)): 3.6 mg/l  
Exposure time: 96 h  
NOEC (Pimephales promelas (fathead minnow)): 1.36 mg/l  
Exposure time: 42 d
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 5.55 mg/l  
Exposure time: 48 h  
NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l  
Exposure time: 7 d
- Toxicity to microorganisms : LC50 (activated sludge): 135 mg/l  
Exposure time: 3 h  
Test Type: EC50  
Method: OECD Test Guideline 209

**Ecotoxicology Assessment**

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

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

Other organisms relevant to the environment : No data available

**Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

- Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100,000 mg/l  
Exposure time: 24 h

**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

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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

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

Toxicity to fish : LC<sub>0</sub> (Leuciscus idus (Golden orfe)): > 1,000 mg/l  
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates : EC<sub>0</sub> (Daphnia magna (Water flea)): 3 mg/l  
Exposure time: 720 h

**Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

**Iron oxide (Fe<sub>2</sub>O<sub>3</sub>):**

Toxicity to fish : LC<sub>0</sub> (Leuciscus idus (Golden orfe)): > 1,000 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC<sub>0</sub> (Daphnia magna (Water flea)): > 10,000 mg/l  
Exposure time: 48 h

**Persistence and degradability****Components:****Vismodegib:**

Biodegradability : aerobic  
Inoculum: activated sludge, non-adapted  
Theoretical oxygen demand  
Result: Not readily biodegradable.  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
GLP: yes

**Sulfuric acid monododecyl ester sodium salt (1:1):**

Biodegradability : Biodegradation: 90 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301  
Remarks: Readily biodegradable, according to appropriate OECD test.

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octanol/water : log Pow: 1.59  
Method: OECD Test Guideline 117  
GLP: yes**Cellulose:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Sulfuric acid monododecyl ester sodium salt (1:1):**Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): 3.9 - 5.3  
Exposure time: 3 dPartition coefficient: n-  
octanol/water : log Pow: -2.03 (20 °C / 20 °C)  
Method: OECD Test Guideline 107**Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**Partition coefficient: n-  
octanol/water : Remarks: No data available**Octadecanoic acid, magnesium salt (2:1):**Partition coefficient: n-  
octanol/water : log Pow: 0.8  
Method: OECD Test Guideline 107**Titanium oxide (TiO<sub>2</sub>):**Partition coefficient: n-  
octanol/water : Remarks: No data available**Iron oxide (Fe<sub>2</sub>O<sub>3</sub>):**Partition coefficient: n-  
octanol/water : Remarks: No data available**Mobility in soil****Components:****Vismodegib:**Distribution among environ-  
mental compartments : Koc method  
Medium: Soil  
Koc: 2129 - 5001 ml/g  
Method: OECD Test Guideline 106  
Remarks: Slightly mobile in soilsKoc method  
Medium: Sludge  
Koc: 684 - 895 ml/g



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Method: OECD Test Guideline 106

**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.  
Very toxic to aquatic life with long lasting effects.

**Components:****Sulfuric acid monododecyl ester sodium salt (1:1):**

- Additional ecological information : No data available

**Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>):**

- Adsorbed organic bound halogens (AOX) : Remarks: Not applicable
- Additional ecological information : No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS**
**Disposal methods**

- Waste from residues : The product should not be allowed to enter drains, water courses or the soil.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.
- Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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**SECTION 14. TRANSPORT INFORMATION**
**International Regulations****UNRTDG**

- UN number : UN 3077
- Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

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N.O.S.  
 (Vismodegib (35%) 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.  
 (Vismodegib (35%) mixture)

Class : 9  
 Packing group : III  
 Labels :  
 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.  
 (Vismodegib (35%) 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 for product as supplied.

**Domestic regulation**
**49 CFR**

UN/ID/NA number : UN 3077  
 Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
 (Vismodegib (35%) 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.

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**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.

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**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)
<b>SARA 311/312 Hazards</b>	: Serious eye damage or eye irritation Carcinogenicity Reproductive toxicity Specific target organ toxicity (single or repeated exposure)	

**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).

**Clean Water Act**

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

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

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

**US State Regulations**

**Massachusetts Right To Know**

Cellulose 9004-34-6

**Pennsylvania Right To Know**

Vismodegib 879085-55-9  
 Cellulose 9004-34-6  
 Gelatins 9000-70-8  
 Lactose-1-Hydrate 64044-51-5  
 Starch, carboxymethyl ether, sodium salt 9063-38-1

**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 (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**

2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose 9004-34-6

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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.  
  
Vismodegib
- 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

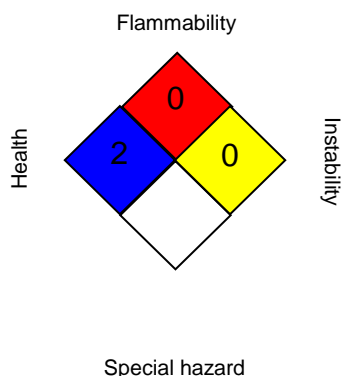
**TSCA list**

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:**



**HMIS® IV:**

<b>HEALTH</b>	*	<b>2</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 -

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	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 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

The GHS classification for skin irritation and/or sensitization of the pure ingredients causes a corresponding GHS classification for the whole formulation. In view of the nature of the formulated product (film-coated tablet, capsule, etc.) an over-interpretation of the potential hazard is possible.

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The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and re-

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lease 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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