

**ERIVEDGE(R) Capsules (150 mg)**Version  
1.4Revision Date:  
10-14-2021Date of last issue: 01-23-2020  
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),  
synonym(s) of the substance : ERIVEDGE Capsules 150 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)**

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.

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H373 May cause damage to organs through prolonged or repeated 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.  
 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-, homopolymer	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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**SECTION 4. FIRST AID MEASURES**

- General advice : Move out of dangerous area.  
Show this material safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If 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.

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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).  
Sulfur oxides

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Nitrogen oxides (NOx)  
Carbon oxides  
Sodium oxides

- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : 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.

**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.

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

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)	2 mg/m <sup>3</sup>	NIOSH REL
		TWA (Respirable particulate matter)	2 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

**Predicted No Effect Concentration (PNEC):**

Substance name	Environmental Compartment	Value
Vismodegib	Surface waters	6.9 µg/l

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	Remarks: Based on chronic data	
Sodium dodecylsulfate	Fresh water	0.176 mg/l

**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

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  
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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Not classified based on available information.

**Product:**Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation methodAcute inhalation toxicity : Acute toxicity estimate: 63.49 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation methodAcute 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): &gt; 5,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): &gt; 2,000 mg/kg

**Lactose-1-Hydrate:**

Acute oral toxicity : LD50 Oral (Rat): &gt; 10,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l  
Test atmosphere: dust/mist  
Method: Expert judgmentAcute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg  
Method: Expert judgment**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): &gt; 2,000 mg/kg

**Titanium oxide (TiO<sub>2</sub>):**Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 425



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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 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.

**Titanium oxide (TiO<sub>2</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.

**Titanium oxide (TiO<sub>2</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.

**Components:**

**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:**

**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.

**Lactose-1-Hydrate:**

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.

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<b>IARC</b>	Group 2B: Possibly carcinogenic to humans Titanium oxide (TiO <sub>2</sub> )	13463-67-7
<b>OSHA</b>	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.	
<b>NTP</b>	Known to be human carcinogen Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> ) (Silica, Crystalline (Respirable Size))	14807-96-6

**Reproductive toxicity**

May damage fertility. May damage the unborn child.

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

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Embryo-fetal toxicity.: LOEL: 10 mg/kg bw/day  
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:****Lactose-1-Hydrate:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

**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.

**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.

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Assessment : The substance or mixture is not classified as specific target organ toxicant, 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.

**Repeated dose toxicity****Components:****Vismodegib:**

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

**Aspiration toxicity**

Not classified based on available information.

**Components:****Lactose-1-Hydrate:**

No data available

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

No data available

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

Toxicity to fish	: LC <sub>50</sub> (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

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GLP: yes

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
aquatic invertebrates Exposure time: 48 hTest 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 concentrationToxicity to algae/aquatic : ErC50 (Pseudokirchneriella subcapitata (algae)): 0.118 mg/l  
plants Exposure time: 72 hMethod: 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 concentrationToxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 1.5 mg/l  
aquatic invertebrates Exposure time: 21 d  
(Chronic toxicity) Analytical monitoring: yes

Method: OECD Test Guideline 211

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Remarks: nominal concentrationLowest 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 concentrationToxicity to microorganisms : (activated sludge): 54 mg/l  
Exposure time: 14 d  
Remarks: no adverse influence on substrate biodegradation  
nominal concentration**Cellulose:****Ecotoxicology Assessment**

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

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

**Lactose-1-Hydrate:**Toxicity to fish : LC50: > 100 mg/l  
Exposure time: 96 hToxicity to fish (Chronic  
toxicity) : > 1 mg/l**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**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 hLC50 (Oncorhynchus mykiss (rainbow trout)): 3.6 mg/l  
Exposure time: 96 hNOEC (Pimephales promelas (fathead minnow)): 1.36 mg/l  
Exposure time: 42 d

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 5.55 mg/l

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aquatic invertebrates                                  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

**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

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Exposure time: 72 h  
Method: ISO 10253NOEC (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:****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.**Titanium oxide (TiO<sub>2</sub>):**

Biodegradability : Remarks: Not applicable

**Bioaccumulative potential****Components:****Vismodegib:**Partition coefficient: n-  
octanol/water : log Pow: 1.59  
Method: OECD Test Guideline 117  
GLP: yes**Cellulose:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Lactose-1-Hydrate:**



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10-14-2021Date of last issue: 01-23-2020  
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octanol/water : log Pow: -5.03**Sodium dodecylsulfate:**Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): 3.9 - 5.3  
Exposure time: 3 dPartition coefficient: n-  
octanol/water : log Pow: -2.03 (68 °F / 20 °C)  
Method: OECD Test Guideline 107**Talc:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Titanium dioxide:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Mobility in soil****Components:****Vismodegib:**Distribution among  
environmental 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  
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.

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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, 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 : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

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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  
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****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  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Serious eye damage or eye irritation

**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).

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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

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

**US State Regulations****Massachusetts Right To Know**

Cellulose	9004-34-6
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**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**

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**

2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8
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**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose	9004-34-6
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**California Regulated Carcinogens**

Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> )	14807-96-6
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**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.

Vismodegib

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- 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

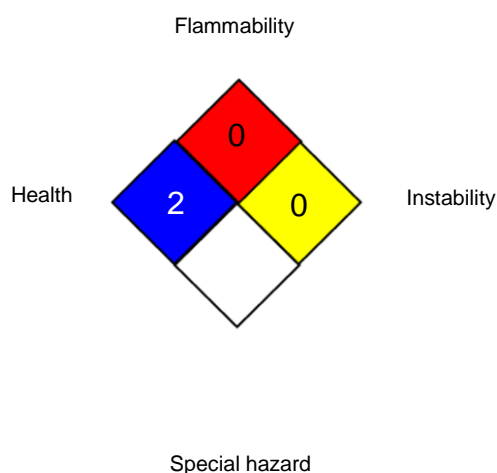
**TSCA list**

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**

**NFPA 704:**



**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 - 1910.1000
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1

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	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

AIIIC - 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; TECl - 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

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.

Revision Date : 10-14-2021

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

# SAFETY DATA SHEET

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specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2010